ABRAXANE(GHP2027)

MEDICATION(S)
PACLITAXEL PROTEIN-BOUND PART

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ACTEMRA(GHP2027)

MEDICATION(S)
AVTOZMA 200 MG/10ML SOLUTION, AVTOZMA 400 MG/20ML SOLUTION, AVTOZMA 80 MG/4ML SOLUTION, TOFIDENCE, TYENNE 200 MG/10ML SOLUTION, TYENNE 400 MG/20ML SOLUTION, TYENNE 80 MG/4ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DX OF ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (JIA) AND PRESCRIPTION WRITTEN FOR IV FORMULATION. DX OF ACTIVE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS AND PRESCRIPTION WRITTEN FOR IV FORMULATION. DX OF CHIMERIC ANTIGEN RECEPTOR (CAR) T CELL-INDUCED SEVERE OR LIFE-THREATENING CYTOKINE RELEASE SYNDROME. DX OF GIANT CELL ARTERITIS AND PRESCRIPTION WRITTEN FOR IV FORMULATION.

Pending CMS Approval

AGE RESTRICTION
FOR JIA AND CRS: MUST BE 2 YEARS OF AGE OR OLDER. FOR RA AND GCA: MUST BE 18 YEARS OF AGE OR OLDER.

PRESCRIBER RESTRICTION
RHEUMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF

BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (FORMULARY ADALIMUMAB PRODUCT, ENBREL, RINVOQ, XELJANZ). FOR PJIA: FAILURE ON, CONTRAINDICATION TO OR INTOLERANCE TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT. FOR GCA: DOCUMENTATION OF USE IN COMBINATION WITH ORAL GLUCOCORTICOIDS. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ACTEMRA SUBQ(GHP2027)

MEDICATION(S)
AVTOZMA 162 MG/0.9ML SOLN A-INJ, AVTOZMA 162 MG/0.9ML SOLN PRSYR, TYENNE 162 MG/0.9ML SOLN A-INJ, TYENNE 162 MG/0.9ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DX OF GIANT CELL ARTERITIS. DX OF SYSTEMIC OR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS. DX OF SYSTEMIC SCLEROSIS ACCORDING TO THE AMERICAN COLLEGE OF RHEUMATOLOGY (ACR) AND EUROPEAN LEAGUE AGAINST RHEUMATISM (EULAR).

AGE RESTRICTION
FOR GIANT CELL ARTERITIS AND SSC-ILD: 18 YEARS OF AGE OR OLDER. FOR RA AND SJIA/PJIA: MUST BE 2 YEARS OF AGE OR OLDER.

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (FORMULARY ADALIMUMAB PRODUCT, ENBREL, RINVOQ, XELJANZ). FOR GIANT CELL ARTERITIS, DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH A TAPERING COURSE OF

Pending CMS Approval

ORAL GLUCOCORTICOIDS. FOR PJIA: FAILURE ON, CONTRAINDICATION TO OR INTOLERANCE TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ADAKVEO(GHP2027)

MEDICATION(S)
ADAKVEO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DIAGNOSIS OF SICKLE CELL DISEASE.

AGE RESTRICTION
MUST BE 16 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A HEMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF NUMBER OF VASOOCCLUSIVE CRISES IN THE PREVIOUS 12 MONTHS. DOCUMENTATION OF INTOLERANCE TO, CONTRAINDICATION OR THERAPEUTIC FAILURE ON 3 MONTH TRIAL OF HYDROXYUREA AND L-GLUTAMINE PACKETS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED OR SUSTAINED IMPROVEMENT IN THE ACUTE COMPLICATIONS OF SICKLE CELL DISEASE (I.E., DECREASE IN VASOOCCLUSIVE CRISES, HOSPITALIZATIONS, AND NUMBER OF ACUTE CHEST SYNDROME (ACS) OCCURRENCES).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

ADALIMUMAB(GHP2027)

MEDICATION(S)
AMJEVITA 10 MG/0.2ML SOLN PRSYR, AMJEVITA 20 MG/0.2ML SOLN PRSYR, AMJEVITA 40 MG/0.4ML SOLN A-INJ, AMJEVITA 40 MG/0.4ML SOLN PRSYR, AMJEVITA 80 MG/0.8ML SOLN A-INJ, AMJEVITA-PED 15KG TO <30KG 20 MG/0.2ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
ADULT RA - DX OF RA MADE IN ACCORDANCE WITH THE ACR CRITERIA. JIA - DX OF MODERATE TO SEVERE JIA. PSORIATIC ARTHRITIS - DX OF PSA AND ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. PLAQUE PSORIASIS - DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 3% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP OR GENITALS. CROHN'S - DX OF MODERATE TO SEVERE CROHNS DISEASE. ANKYLOSING SPONDYLITIS - DX OF A.S. AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 2 FORMULARY NSAIDS. ULCERATIVE COLITIS - DX OF MODERATE TO SEVERE UC. FOR HIDRADENITIS SUPPURATIVA (HS)-DX OF MODERATE TO SEVERE HS, DEFINED AS STAGE II OR III ON THE HURLEY STAGING SYSTEM AND DOCUMENTATION OF AT LEAST 3 ABSCESSES OR INFLAMMATORY NODULES. UVEITIS - DX OF NON-INFECTIOUS ITERMEDIATE, POSTERIOR OR PANUVEITIS.

Pending CMS Approval

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS FOR: PSORIASIS, PSA, RA, AND ANKYLOSING SPONDYLITIS.

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, GASTROENTEROLOGIST, DERMATOLOGIST OR OPHTHALMOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE DISEASE MODIFYING ANTI-RHEUMATIC DRUG (DMARD), SUCH AS BUT NOT LIMITED TO METHOTREXATE, LEFLUNOMIDE OR SULFASALAZINE. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE, CYCLOSPORINE OR PHOTOTHERAPY. FOR UVEITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE LOCAL OR SYSTEMIC CORTICOSTEROID AND ONE SYSTEMIC THERAPY, SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE. FOR UC: IF REQUEST IS FOR WEEKLY DOSING ONE OF THE FOLLOWING: INADEQUATE DRUG TROUGH LEVELS TO SUPPORT WEEKLY DOSING PER AGA GUIDELINES OR DOCUMENTATION THAT WEEKLY DOSING WAS INITIATED PRIOR TO THE MEMBER TURNING 18 YEARS AND THE MEMBER IS WELL-CONTROLLED ON THIS DOSE OR MEMBER IS LESS THAN 18 YEARS OF AGE AND RECEIVING AN APPROPRIATE DOSE BASED ON BODY WEIGHT. FOR CONTINUED THERAPY MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ADASUVE(GHP2027)

MEDICATION(S)
ADASUVE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF USE FOR THE ACUTE TREATMENT OF AGITATION ASSOCIATED WITH SCHIZOPHRENIA OR BIPOLAR I DISORDER. DOCUMENTATION THAT THERE IS NO CURRENT DIAGNOSIS OR HISTORY OF ASTHMA, COPD, OR OTHER LUNG DISEASE ASSOCIATED WITH BRONCHOSPASM.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE IMMEDIATE RELEASE FORMULARY ANTIPSYCHOTIC INCLUDING BUT NOT LIMITED TO ARIPIPRAZOLE, CHLORPROMAZINE, HALOPERIDOL, OLANZAPINE, QUETIAPINE, RISPERIDONE, OR ZIPRASIDONE. MUST BE ADMINISTERED IN AN ENROLLED HEALTHCARE FACILITY WITH IMMEDIATE, ON-SITE RESOURCES TO MANAGE BRONCHOSPASM AND/OR RESPIRATORY DISTRESS.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ADBRY(GHP2027)

MEDICATION(S)
ADBRY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
MEDICAL RECORD DOCUMENTATION OF FAILURE ON EITHER DAILY TREATMENT WITH AT LEAST MEDIUM POTENCY TOPICAL CORTICOSTEROID OR TOPICAL CALCINEURIN INHIBITOR (I.E. TACROLIMUS) IF TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ADCETRIS(GHP2027)

MEDICATION(S)
ADCETRIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CLASSICAL HODGKIN LYMPHOMA (CHL) AND DOCUMENTATION OF FAILURE OF AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANT OR FAILURE OF AT LEAST 2 MULTI-AGENT CHEMOTHERAPY REGIMENS IN THOSE WHO ARE NOT CANDIDATES FOR AUTO-HSCT OR DOCUMENTATATION OF USE AS CONSOLIDATION TREATMENT FOLLOWING AUTO-HSCT IN PATIENTS WITH HIGH RISK OR RELAPSE OR PROGRESSION POST-AUTO-HSCT. DX OF PREVIOUSLY UNTREATED, HIGH RISK CHL IN PEDIATRIC PATIENTS AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION W/ DOXORUBICIN, VINCRISTINE, ETOPOSIDE, PREDNISONE, AND CYCLOPHOSPHAMIDE. DX OF SYSTEMIC ANAPLASTIC LARGE CELL LYMPHOMA AND DOCUMENTATION OF FAILURE OF AT LEAST 1 PRIOR MULTI-AGENT CHEMOTHERAPY REGIMEN. DX OF PRIMARY CUTANEOUS ANAPLASTIC LARGE CELL LYMPHOMA OR CD30 EXPRESSING MYCOSIS FUNGOIDES AND DOCUMENTATION OF FAILURE OF PRIOR RADIATION OR SYSTEMIC THERAPY. DX OF PREVIOUSLY UNTREATED STAGE III OR IV CHL AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH CHEMOTHERAPY.

Pending CMS Approval

AGE RESTRICTION
PEDIATRIC CHL: MUST BE 2 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION

FOR STAGE III OR IV CHL: 6 MONTHS. FOR PEDIATRIC CHL: 15 WEEKS. ALL OTHER INDICATIONS: REMAINDER OF CONTRACT YEAR

OTHER CRITERIA

SUBSEQUENT APPROVAL WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. AUTHORIZATION BEYOND 6 MONTHS FOR STAGE III OR IV CHL WILL REQUIRE DOCUMENTATION OF WELL-CONTROLLED, PEER-REVIEWED LITERATURE WITH EVIDENCE TO SUPPORT TREATMENT BEYOND 6 MONTHS. AUTHORIZATION BEYOND 15 WEEKS FOR PEDIATRIC CHL WILL REQUIRE DOCUMENTATION OF WELL-CONTROLLED, PEER-REVIEWED LITERATURE WITH EVIDENCE TO SUPPORT TREATMENT BEYOND 15 WEEKS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ADCIRCA(GHP2027)

MEDICATION(S)
ALYQ, TADALAFIL (PAH)

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
RAYNAUDS PHENOMENON

EXCLUSION CRITERIA
CONCOMITANT USE OF ORGANIC NITRATES

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION. DIAGNOSIS OF SECONDARY RAYNAUDS PHENOMENON.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH: PULMONOLOGIST OR CARDIOLOGIST. RAYNAUDS: RHEUMATOLOGIST.

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR RAYNAUDS: THERAPEUTIC FAILURE ON ONE FORMULARY DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER OR DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH ONE FORMULARY DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ADEMPAS(GHP2027)

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
WHO FUNCTIONAL CLASS II, III, OR IV SYMPTOMS AND EITHER DOCUMENTATION OF WHO GROUP 1 PULMONARY ARTERIAL HYPERTENSION OR CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) (WHO GROUP 4) WHICH IS INOPERABLE OR PREVIOUSLY TREATED SURGICALLY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CARDIOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
CHRONIC-THROMBOEMBOLIC PULMONARY HYPERTENSION: DOCUMENTATION OF A BASELINE 6-MINUTE WALKING DISTANCE. 6 MONTH REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AN IMPROVEMENT IN 6-MINUTE WALKING DISTANCE FROM BASELINE OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS. PULMONARY ARTERIAL HYPERTENSION: DOCUMENTATION OF A BASELINE 6-MINUTE WALKING DISTANCE. FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BOSENTAN, OR DOCUMENTATION OF USE IN COMBINATION WITH BOSENTAN. 6 MONTH REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AN IMPROVEMENT IN 6-MINUTE WALKING DISTANCE FROM BASELINE

Pending CMS Approval

OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ADZYNMA(GHP2027)

MEDICATION(S)
ADZYNMA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of congenital thrombotic thrombocytopenia puppura (TTP).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

OTHER CRITERIA
Diagnosis confirmed by both of the following: (1) documentation of confirmed molecular genetic testing AND (2) documentation of ADATS13 activity less than 10% of normal activity as measured by the fluorescent resonance energy transfer-von Willebran factor 73 (FRETS-VWF73) assay. Documentation that member is currently receiving prophylactic therapy OR documentation of at least one thrombotic thrombocytopenia purpura (TTP) event. Reauthorizaton will require documentation of a positive clinical response as defined by one of the following: (1) documentation of a reduction in or improvement in actue and subacute thrombotic thrombocytopenia purpura (TTP) events OR (2) documentation of an improvement in clinical symptoms of congential thrombotic thrombocytopenia purpura (TTP) OR (3) if used for on-demand treatment, documentation of improved platelet level to greater than or equal to 150,000/uL or platelet count within 25% of baseline (prior to acute event).

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AFINITOR DISPERZ(GHP2027)

MEDICATION(S)
EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB SOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection OR adjunctive treatment of Tuberous Sclerosis Complex (TSC) associated partial-onset seizures

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ONCOLOGIST OR NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
For TSC associated partial onset seizures: documentation of a therapeutic failure on, intolerance to, or contraindication to 2 anti-epileptic drug (AED) regimens. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

AFINITOR(GHP2027)

MEDICATION(S)
EVEROLIMUS 10 MG TAB, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 5 MG TAB, EVEROLIMUS 7.5 MG TAB, TORPENZ, YULITHIRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, Nephrologist, Urologist, or Neurologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR BREAST CANCER: Documentation of HER2 Protein expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

AIMOVIG(GHP2027)

MEDICATION(S)
AIMOVIG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA AND ATTESTATION THAT MEMBER EXPERIENCES 4 OR MORE MIGRAINES PER MONTH.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH. ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE. REAUTHORIZATION WILL REQUIRE ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AKEEGA(GHP2027)

MEDICATION(S)
AKEEGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRCA pathogenic variant. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ALDURAZYME(GHP2027)

MEDICATION(S)
ALDURAZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HURLER FORM OF MPS I OR HURLER-SCHEIE FORM OF MPS I OR SCHEIE FORM OF MPS WITH MODERATE TO SEVERE SYMPTOMS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MUCOPOLYSACCHARIDOSIS

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ALECENSA(GHP2027)

MEDICATION(S)
ALECENSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ALK Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ALIQOPA(GHP2027)

MEDICATION(S)
ALIQOPA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ALTABAX(GHP2027)

MEDICATION(S)
ALTABAX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF IMPETIGO.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 DAYS

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MUPIROCIN OINTMENT AND ORAL ANTIBIOTIC THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ALUNBRIG(GHP2027)

MEDICATION(S)
ALUNBRIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ALK Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ALYFTREK(GHP2027)

MEDICATION(S)
ALYFTREK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CYSTIC FIBROSIS AND DOCUMENTATION OF ONE OF THE FOLLOWING: (1) AT LEAST ONE F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE AS DETERMINED BY AN FDA-CLEARED CYSTIC FIBROSIS MUTATION TEST OR (2) DOCUMENTATION OF A MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE AS DETERMINED BY AN FDA-CLEARED CYSTIC FIBROSIS MUTATION TEST THAT IS RESPONSIVE BASED ON IN VITRO DATA PER PRODUCT LABELING.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
By or in consultation with a pulmonologist or physician who specializes in the treatment of CF

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AMONDYS(GHP2027)

MEDICATION(S)
AMONDYS 45

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF DUCHENNE'S MUSCULAR DYSTROPHY CONFIRMED BY GENETIC TESTING WITH MUTATION OF THE DMD GENE THAT IS AMENABLE BY EXON 45 SKIPPING CONFIRMED BY A GENETIC COUNSELOR AND DOCUMENTATION THAT MEDICATION IS BEING GIVEN CONCURRENTLY WITH ORAL CORTICOSTEROIDS UNLESS CONTRAINDICATED OR INTOLERANT AND DOCUMENTATION THAT THE PATIENT IS AMBULATORY (ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND) AS PROVEN BY DOCUMENTATION OF A 6-MINUTE WALK TEST DISTANCE WITHIN THE PAST 3 MONTHS OF INITIATION OF AMONDYS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST OR GENETIC SPECIALIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION OF A DOSE CONSISTENT WITH THE FDA APPROVED LABELING. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED BENEFIT FROM TREATMENT, DOCUMENTATION OF CONTINUED CONCURRENT USE WITH ORAL CORTICOSTEROIDS, DOCUMENTATION OF A DOSE CONSISTENT WITH FDA APPROVED LABELING, AND DOCUMENTATION THAT THE PATIENT REMAINS AMBULATORY AS PROVEN

Pending CMS Approval

BY DOCUMENTATION OF A FOLLOW UP 6 MINUTE WALK TEST DISTANCE WITHIN THE PAST 6 MONTHS

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AMVUTTRA(GHP2027)

MEDICATION(S)
AMVUTTRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND documentation of either biopsy of tissue or organ to confirm amyloid presence OR a clinical manifestation typical of hATTR (such as neuropathy or CHF) without a better alternative explanation. Documentation of one of the following 1)medication being used to treat polyneuropathy AND documentation of familial amyloid polyneuropathy (FAP) stage 1-2 OR polyneuropathy disability score indicating the patient is not wheelchair bound or bedridden OR 2) documentation that medication is being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits. Diagnosis of wild-type transthyretin-mediated amyloidosis as confirmed by genetic testing AND documenation that medication is being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with neurologist, cardiologist or board certified medical geneticist, or specialist with experience treating hereditary or wild-type transthyretin-mediated amyloidosis

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

Documentation of a dose and duration of therapy that is consistent with FDA-approved labeling, nationally recognized compendia, or peer-reviewed medical leterature. Documentation that medication will not be used in combination with other RNA interference treatments. Reauthorization will require (1) documentation of medical necessity, (2) documentation of a dose and duration of therapy that is consistent with FDA-approved labeling, nationally recognized compendia, or peer-reviewed medical leterature, and (3) no documentation of FAP stage 3 OR polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ANKTIVA(GHP2027)

MEDICATION(S)
ANKTIVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

APTIOM(GHP2027)

MEDICATION(S)
ESLICARBAZEPINE ACETATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PARTIAL ONSET SEIZURES

AGE RESTRICTION
MUST BE 4 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ANTICONVULSANTS USED FOR THE REQUESTED DIAGNOSIS, ONE OF WHICH MUST BE OXCARBAZEPINE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

AQNEURSA(GHP2027)

MEDICATION(S)
AQNEURSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF NEIMANN-PICK DISEASE TYPE C (NPC)1 OR NPC2 CONFIRMED BY GENETIC TESTING DEMONSTRATING ONE OF THE FOLLOWING (1) MUTATIONS IN BOTH ALLELES OF NPC1 OR NPC2 OR (2) MUTATION IN ONE ALLELE AND EITHER A POSITIVE FILIPIN-STAINING OR ELEVATED CHOLESTANE TRIOL/OXYSTEROLS (GREATER THAN 2 TIMES THE UPPER LIMIT OF NORMAL) AND DOCUMENTATION OF AT LEAST ONE NEUROLOGICAL SIGN OF NPC (SUCH AS BUT NOT LIMITED TO LOSS OF FINE MOTOR SKILLS, SWALLOWING, SPEECH, AMBULATION).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A PHYSICIAN WHO SPECIALIZES IN TREATMENT OF NPC OR RELATED DISORDERS

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF WEIGHT GREATER THAN OR EQUAL TO 15 KG AND THAT DOSE IS WEIGHT APPROPRIATE. DOCUMENTATION THAT MEMBER HAS COMPLETED THE NPC CLINICAL SEVERITY SCALE (NPCCSS) ASSESSMENT TO DETERMINE BASELINE SCORE OF DISEASE SEVERITY. DOCUMENTATION THAT AQNEURSA WILL NOT BE USED IN

Pending CMS Approval

COMBINATION WITH MIPLYFFA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN NEUROLOGICAL SIGNS OF NPC (SUCH AS BUT NOT LIMITED TO STABLIZATION OR IMPROVEMENT IN NPCCSS SCORE, FINE MOTOR SKILLS, SWALLOWING, SPEECH, AND/OR AMBULATION) AND DOCUMENTATION THAT AQNEURSA CONTINUES TO BE PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN WHO SPECIALIZES IN THE TREATMENT OF NPC OR RELATED DISORDERS AND DOCUMENTATION THAT MEMBER IS NOT USING AQNEURSA IN COMBINATION WITH MIPLYFFA.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ARALAST(GHP2027)

MEDICATION(S)
ARALAST NP, PROLASTIN-C

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF PANACINAR EMPHYSEMA

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF A DECLINE IN FORCED EXPIRATORY VOLUME IN 1 SECOND (FEV1) DESPITE MEDICAL THERAPY WITH BRONCHODILATORS AND/OR CORTICOSTEROIDS AND DOCUMENTATION OF PHENOTYPE ASSOCIATED WITH CAUSING SERUM ALPHA 1-ANTITRYPSIN OF LESS THAN 80 MG/DL AND DOCUMENTATION OF AN ALPHA 1-ANTITRYPSIN SERUM LEVEL BELOW THE VALUE OF 35% OF NORMAL (LESS THAN 80 MG/DL).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ARANESP(GHP2027)

MEDICATION(S)
ARANESP (ALBUMIN FREE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
TX OF ANEMIA OF CHRONIC RENAL INSUFFICIENCY, CHRONIC RENAL FAILURE, INCLUDING ESRD and HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY FOR CKD NOT ON DIALYSIS, LESS THAN 11 GM/DL FOR CKD ON DIALYSIS, OR LESS THAN 12 GM/DL FOR PEDIATRIC CKD, OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED. TX OF ANEMIA IN NON-MYELOID MALIGNANCY - MUST BE ON ANEMIA CAUSING CHEMO AND THERE IS A MINIMUM OF TWO ADDITIONAL MONTHS OF PLANNED CHEMOTHERAPY and HGB MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY or DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED. FOR ALL INDICATIONS: DOCUMENTATION OF ADEQUATE IRON STORES W/ SERUM FERRITIN GREATER THAN 100 NG/ML OR TRANSFERRIN LEVEL SATURATION GREATER THAN 20% OR A HISTORY OF CHELATION THERAPY FOR IRON.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

REAUTHORIZATION WILL REQUIRE REPEAT HGB (WITHIN 3 MONTHS OF REAUTH) AND FERRITIN OR TSAT LEVELS (WITHIN 6 MONTHS OF REAUTH). THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ARCALYST(GHP2027)

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS), AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. DX OF DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) SUPPORTED BY DOCUMENTATION OF A HOMOZYGOUS OR COMPOUND HETEROZYGOUS MUTATION IN IL 1 RN (INTERLEUKIN 1 RECEPTRO ANTAGONIST GENE) AND DOCUMENTATION THAT MEDICATION IS BEING USED FOR MAINTENANCE OF REMISSION OF DIRA. DX OF RECUURENT PERICARDITIS (RP) AS EVIDENCED BY A RECURRENCE OF PERICARDITIS AFTER A SYMPTOM FREE INTERVAL OF 4 TO 6 WEEKS OR LONGER FOLLOWING A DOCUMENTED EPEISODE OF ACUTE PERICARDITIS.

Pending CMS Approval

AGE RESTRICTION
FOR RECURRENT PERICARDITIS: 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
IMMUNOLOGIST, RHEUMATOLOGIST, PEDIATRICIAN, ALLERGIST OR CARDIOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR CAPS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KINERET. REAUTHORIZATION WILL REQUIRE CONTINUED

IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF THE DISEASE. FOR DIRA: DOCUMENTATION OF A MEMBER WEIGHT GREATER THAN OR EQUAL TO 10 KG AND DOCUMENTATION OF REMISSION OF DIRA THAT WAS INDUCED BY ANAKINRA AND DOCUMENTATION OF THERAPEUTIC FAILURE, INTOLERANCE OR CONTRAINDICATION OF CONTINUING ANAKINRA. FOR RP: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO (1) COLCHICINE AND (2) A NONSTEROIDAL ANTI-INFLAMMATORY DRUG (NSAID) OR ASPIRIN. REAUTHORIZATION WILL REQUIRE MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ARIKAYCE(GHP2027)

MEDICATION(S)
ARIKAYCE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of refractory Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
Documentation that member has failed to achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen (such as, but not limited to, macrolide antibiotics, rifamycin antibiotics, and ethambutol). Documentation that medication will be used in conjunction with a multidrug background regimen (such as, but not limited to, macrolide antibiotics, rifamycin antibiotics, and ethambutol). Reauthorization will require documentation of continued use in conjunction with a multidrug background regimen AND one of the following: (1) documentation that member achieved a negative sputum culture for MAC in the last 6 months OR (2) documentation that member has not achieved a negative sputum culture for MAC AND documentation or attestation that the member has demonstrated clinical benefit while on medication.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ARISTADA(GHP2027)

MEDICATION(S)
ARISTADA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ARISTADA INITIO(GHP2027)

MEDICATION(S)
ARISTADA INITIO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of schizophrenia AND documentation that medication is being used for treatment initiation with transition to Aristada.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 MONTH

OTHER CRITERIA
Documentation that Aristada Initio will be given as a single dose in combination with one 30 mg dose of oral aripiprazole and the first month's dose of Aristada. (1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS).

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ARZERRA(GHP2027)

MEDICATION(S)
ARZERRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ASTAGRAF(GHP2027)

MEDICATION(S)
TACROLIMUS ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of kidney transplant.

AGE RESTRICTION
Must be 4 years of age or older

PRESCRIBER RESTRICTION
TRANSPLANT SPECIALIST OR PHYSICIAN EXPERIENCED IN IMMUNOSUPPRESSIVE THERAPY

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
If greater than 18 years of age: documentation of rationale for not using Envarsus XR if clinically appropriate.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ATTRUBY(GHP2027)

MEDICATION(S)
ATTRUBY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis OR hereditary transthyretin-mediated amyloidosis as confirmed by ONE of the following: 1) bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD or 2) biopsy of tissue of the affected organ to confirm amyloid presence and chemical typing to confirm presence of transthyretin (TTR) protein.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a cardiologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of NYHA Class I, II, or III heart failure. Documentation that medication will not be used in combination with another transthyretin (TTR) stabilizer (i.e. tafamidis). Reauthorizations will require prescriber attestation that the patient continues to benefit from therapy AND no documentation of NYHA class IV heart failure.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AUGTYRO(GHP2027)

MEDICATION(S)
AUGTYRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR NSCLC: Documentation of ROS-1 Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

AUSTEDO(GHP2027)

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION 12 & 18 & 24 & 30 MG TBER THPK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Huntingtons disease AND documentation of symptoms of chorea AND documentation of baseline total maximal chorea score prior to initiating therapy AND either evaluation by a psychiatrist if there is a history of prior suicide attempt, bipolar disorder, or major depressive disorder OR documentation of a mental health evaluation performed by the prescriber. Diagnosis of tardive dyskinesia as evidenced by either moderate to severe abnormal body movements (AIMS score 3 or 4) in at least 1 body area or mild abnormal body movements (AIMS score 1 or 2) in 2 or more body areas AND documentation of no other causes of involuntary movements AND documentation of baseline AIMS score prior to initiating therapy AND if TD is associated with the use of dopamine receptor–blocking agents, documentation of persistence of symptoms despite discontinuation or dosage reduction of dopamine receptor–blocking agent (or attestation by prescriber that discontinuation or dose reduction of the offending agent is not possible).

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH PSYCHIATRIST, NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

Reauthorization for Huntingtons will require documentation of stabilization or improvement in chorea as evidenced by a stabilization or reduction in the total maximal chorea score from baseline. Reauthorization for tardive dyskinesia will require documentation of an improvement in symptoms as evidenced by a reduction from baseline AIMS score.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AUVELITY(GHP2027)

MEDICATION(S)
AUVELITY, AUVELITY TITRATION PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON OR INTOLERANCE TO TWO ANTIDEPRESSANT CLASSES.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

AVEED(GHP2027)

MEDICATION(S)
AVEED

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: (1) Primary hypogonadism (congenital or acquired) OR (2) Hypogonadotropic hypogonadism (congenital or acquired).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to testosterone cypionate AND testosterone enanthate.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

AVLAYAH(GHP2027)

MEDICATION(S)
AVLAYAH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of mucopolysaccharidosis type II (MPS II), also knows as Hunter syndrome.

AGE RESTRICTION
MUST BE 17 YEARS OF AGE OR YOUNGER

PRESCRIBER RESTRICTION
By or in consultation with a physician who specializes in the treatment of metabolic disease or lysosomal storage disorders

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
Documentation that diagnosis is confirmed by one of the following: deficiency in IDS enzyme activity OR molecular genetic testing for deletion or mutations in the IDS gene. Documentation of a patient weight of at least 5 kg. Prescriber attestation of neurologic manifestations associated with MPS II, or the patient is presymptomatic and at risk for neurologic manifestations. Prescriber attestation that patient does not have advanced neurologic impairment. Documentation that medication will not be used in combination with another enzyme replacment therapy for mucopolysaccharidosis type II (MPS II). Documentation that dosing is consistent with FDA approved labeling and patient weight. Reauthorization will require prescriber attestation of continued disease improvement, stabilization, or lack of disease progression AND documentation that dosing is consistent with FDA approved labeling and patient weight

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AVMAPKI FAKZYNJA(GHP2027)

MEDICATION(S)
AVMAPKI FAKZYNJA CO-PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

AVSOLA(GHP2027)

MEDICATION(S)
AVSOLA, INFLECTRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CROHN'S DISEASE- DIAGNOSIS OF MODERATE TO SEVERE CROHN'S AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 12 WEEKS OF FORMULARY ADALIMUMAB PRODUCT THERAPY OR DIAGNOSIS OF CROHN'S WITH ACTIVE DRAINING FISTULAS. RA - DIAGNOSIS OF MODERATE TO SEVERE RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND BEING USED IN CONJUNCTION WITH METHOTREXATE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF CHRONIC, SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE PSA AND HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. ULCERATIVE COLITIS - DIAGNOSIS OF MODERATE TO SEVERE UC

Pending CMS Approval

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS OF AGE FOR THE FOLLOWING DIAGNOSES - RA, ,ANKYLOSING SPONDYLITIS, PLAQUE PSORIASIS, PSORIATIC ARTHRITIS. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS DISEASE AND ULCERATIVE COLITIS.

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, RINVOQ, XELJANZ). FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR UC (FORMULARY ADALIMUMAB PRODUCT, RINVOQ, SIMPONI, XELJANZ) OR DOCUMENTATION THAT AVOSLA IS BEING PRESCRIBED TO INDUCE DISEASE REMISSION. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR PSA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, RINVOQ, XELJANZ, COSENTYX). FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (COSENTYX, ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA). FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (ENBREL, COSENTYX, FORMULARY ADALIMUMAB PRODUCT, RINVOQ, XELJANZ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

AYVAKIT(GHP2027)

MEDICATION(S)
AYVAKIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, Allergist, or Immunologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of platelet count. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BACLOFEN(GHP2027)

MEDICATION(S)
BACLOFEN 10 MG/5ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of spasticity from multiple sclerosis OR spinal cord injuries and/or diseases.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of inability to tolerate or swallow tablets OR documentation of why a tablet formulation could not be used.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BALVERSA(GHP2027)

MEDICATION(S)
BALVERSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FGFR genomic alteration. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BANZEL(GHP2027)

MEDICATION(S)
RUFINAMIDE 200 MG TAB, RUFINAMIDE 400 MG TAB, RUFINAMIDE 40 MG/ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF LENNOX-GASTAUT SYNDROME or FOR USE IN REFRACTORY PARTIAL SEIZURES AS DEFINED AS FAILURE ON TWO FORMULARY SEIZURE MEDICATIONS

AGE RESTRICTION
MUST BE 1 YEAR OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BAVENCIO(GHP2027)

MEDICATION(S)
BAVENCIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BELEODAQ(GHP2027)

MEDICATION(S)
BELEODAQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BENLYSTA(GHP2027)

MEDICATION(S)
BENLYSTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF SYSTEMIC LUPUS ERYTHEMATOSUS AND DOCUMENTATION THAT PATIENT HAS ACTIVE DISEASE or RECURRENT FLARES or INABILITY TO WEAN STEROIDS IN SLE. DOCUMENTATION OF A POSITIVE ANA/ANTI-DSDNA ANTIBODY. DOCUMENTATION THAT MEDICATION IS BEING USED IN COMBINATION WITH, OR PATIENT HAS A CONTRAINDICATION OR INTOLERANCE TO, STANDARD THERAPY (SUCH AS BUT NOT LIMITED TO CORTICOSTEROIDS, NSAIDS ANTI-MALARIALS OR IMMUNOSUPPRESSANTS). DOCUMENTATION OF NO CNS INVOLVEMENT. DOCUMENTATION OF A DIAGNOSIS OF ACTIVE LUPUS NEPHRITIS, CLASS III, IV, V ALONE OR IN COMBINATION, CONFIRMED BY A KIDNEY BIOPSY.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR LUPUS NEPHRITIS: DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH STANDARD THERAPY (SUCH AS MYCOPHENOLATE MOFETIL (MMF), CORTICOSTEROIDS, CYCLOPHOSPHAMIDE, OR AZATHIOPRINE). REAUTHORIZTION FOR

LUPUS NEPHRITIS WILL REQUIRE DOCUMENTATION OF A POSITIVE CLINICAL RESPONSE TO THERAPY (SUCH AS IMPROVEMENT OR STABILIZATION IN UPCR, eGFR, OR RENAL RELATED EVENTS) and DOCUMENTATION OF CONTINUED USE IN COMBINATION WITH STANDARD THERAPY. REAUTHORIZATION FOR SLE WILL REQUIRE DOCUMENTATION SHOWING CLINICAL BENEIFT OF ONE OF THE FOLLOWING: IMPROVEMENT IN FUNCTIONAL IMPAIRMENT, DECREASE IN THE NUMBER OF EXACERBATIONS SINCE STARTING THERAPY, OR DECREASE IN THE DAILY REQUIRED DOSE OF ORAL CORTICOSTEROIDS

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

BERINERT(GHP2027)

MEDICATION(S)
BERINERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation that medication is being used for the treatment of an acute attack of abdominal, facial or laryngeal hereditary angioedema.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For members 18 years of age or older, documentation of failure on, intolerance to, or contraindication to icatibant.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BESPONSA(GHP2027)

MEDICATION(S)
BESPONSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BESREMI(GHP2027)

MEDICATION(S)
BESREMI, BESREMI PEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BEXAROTENE GEL(GHP2027)

MEDICATION(S)
BEXAROTENE 1 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BEYFORTUS(GHP2027)

MEDICATION(S)
BEYFORTUS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PROPHYAXIS OF SERIOUS LOWER RESPIRATORY TRACT DISEASE CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV) IN PEDIATRIC PATIENTS AT HIGH RISK, INCLUDING THOSE WITH BRONCHOPULMONARY DYSPLASIA OR COGENITAL HEART DISEASE, AND THOSE BORN PREMATURELY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS NOT RECEIVED ENFLONSIA DURING THE CURRENT RSV SEASON.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BIZENGRI(GHP2027)

MEDICATION(S)
BIZENGRI (750 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BLENREP(GHP2027)

MEDICATION(S)
BLENREP 70 MG RECON SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BLINCYTO(GHP2027)

MEDICATION(S)
BLINCYTO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BOSULIF(GHP2027)

MEDICATION(S)
BOSULIF, BOSUTINIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BOTULINUM TOXIN(GHP2027)

MEDICATION(S)
BOTOX, DYSPORT, MYOBLOC, XEOMIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR BOTOX: DX OF STRABISMUS OR ACHALASIA. DX OF CHRONIC MIGRAINE HEADACHE. DX OF PRIMARY AXILLARY HYPERHIDROSIS. DX OF URINARY INCONTINENCE DUE TO NEUROGENIC BLADDER. DX OF OVERACTIVE BLADDER (OAB). DX OF LOWER LIMB SPASTICITY AND DOC OF FAILURE ON CONVENTIONAL THERAPY (SUCH AS BUT NOT LIMITED TO PHYSICAL THERAPY, SPLINTING OR BRACING, OR SYSTEMIC ANTISPASTICITY MEDICATION). DX OF ANAL FISSURES. FOR XEOMIN AND BOTOX: DX OF BLEPHAROSPASM, CERVICAL DYSTONIA. DX OF CHRONIC SIALORRHEA RESULTING FROM PARKINSONS DISEASE, ATYPICAL PARKINSONISM, STROKE OR TRAUMATIC BRAIN INJURY. DX OF UPPER LIMB SPASTICITY. FOR MYOBLOC: DX OF CERVICAL DYSTONIA OR SIALORRHEA. FOR DYSPORT: DX OF CERVICAL DYSTONIA, UPPER LIMB SPASTICITY, LOWER LIMB SPASTICITY, ANAL FISSURES, OR SIALORRHEA.

Pending CMS Approval

AGE RESTRICTION
UPPER OR LOWER LIMB SPASTICITY: 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR MIGRAINE: (1) DOC OF HX OF 15 OR MORE MIGRAINE HEADACHE DAYS PER MONTH

THAT LAST 4 OR MORE HOURS PER DAY AND (2) FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AN ADEQUATE TRIAL OF AT LEAST 2 OF THE FOLLOWING: ONE BETA BLOCKER, TOPIRAMATE, DIVALPROEX OR SODIUM VALPROATE, AMITRIPTYLINE, OR VENLAFAXINE AND (3) ATTESTATION THAT BOTOX WILL NOT BE USED IN COMBINATION WITH A CGRP ANTAGONIST OR IF BEING USED IN COMBINATION, ATTESTATION OF THE FOLLOWING: FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. FOR AXILLARY HYPERHIDROSIS: DOC OF FAILURE OF A 6 MONTH TRIAL OF NON-SURGICAL TREATMENTS WITH TOPICAL DERMATOLOGICS (I.E., ALUMINUM CHLORIDE, TANNIC ACID, OR ANTICHOLINERGICS) AND ONE OF THE FOLLOWING: (1) DOC OF AN UNDERLYING CHRONIC MEDICAL CONDITION SUCH AS DERMATITIS, FUNGAL CONDITION, SKIN MACERATION, OR SECONDARY MICROBIAL CONDITION AS A RESULT OR HYPERHIDROSIS OR (2) DOC OF A DX OF SEVERE HYPERHIDROSIS (DEFINED AS INTOLERABLE SWEATING AND CAUSES FUNCTIONAL IMPAIRMENT THAT INTERFERES WITH MEMBER ABILITY TO PERFORM AGE-APPROPRIATE NORMAL DAILY ACTIVITIES. FOR NEUROGENIC BLADDER: FAILURE OF ANTICHOLINERGIC MEDICATION THERAPY. FOR OAB: (1) DOC OF SYMPTOMS OF URGE URINARY INCONTINENCE, URGENCY AND FREQUENCY AND (2) DOC OF AT LEAST 3 URINARY URGENCY INCONTINENCE EPISODES AND AT LEAST 24 MICTURITIONS IN 3 DAYS AND (3) FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 2 FORMULARY ORAL ANTICHOLINERGIC MEDICATIONS. REAUTHORIZATION FOR MIGRAINE WILL REQUIRE DOC OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HA FREQUENCY OR DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND ONE OF THE FOLLOWING: ATTESTATION THAT BOTOX WILL NOT BE USED IN COMBINATION WITH A CGRP ANTAGONIST OR IF BEING USED IN COMBINATION, ATTESTATION OF THE FOLLOWING: FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. ALL OTHER INDICATIONS: REAUTHORIZATION WILL REQUIRE DOC OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BRAFTOVI(GHP2027)

MEDICATION(S)
BRAFTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BRINSUPRI(GHP2027)

MEDICATION(S)
BRINSUPRI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
bronchiectasis due to Cystic Fibrosis

REQUIRED MEDICAL INFORMATION
Diagnosis of bronchiectasis confirmed by chest computed tomography (CT) scan.

AGE RESTRICTION
12 years of age or older

PRESCRIBER RESTRICTION
By or in consultation with a pulmonologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of a clinical history consistent with bronchiectasis (e.g., chronic cough, chronic sputum production and/or recurrent respiratory tract infections). Documentation of at least 2 pulmonary exacerbations for adults, or 1 pulmonary exacerbation for adolescents age 12-17 years, in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit or hospitalization. Reauthorization will require documentation or attestation of clinical benefit (such as a decrease in the frequency, severity or duration of pulmonary exacerbations) AND documentation of appropiate specialist clinical follow up.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

BRIUMVI(GHP2027)

MEDICATION(S)
BRIUMVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF A RELAPSING FORM OF MULTIPLE SCLEROSIS (MS), INCLUDING CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE AND DOCUMENTATION OF A HEPATITIS B SCREENING.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE FOR THE TREATMENT OF MULTIPLE SCLEROSIS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

BRIVIACT(GHP2027)

MEDICATION(S)
BRIVARACETAM 50 MG/5ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PARTIAL-ONSET SEIZURES AND DOCUMENTATION THAT BRIVIACT IS NOT BEING USED IN COMBINATION WITH LEVETIRACETAM

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 WEEK

OTHER CRITERIA
DOCUMENTATION OF INABILITY TO USE ORAL FORMULATION OF MEDICATION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BRONCHITOL(GHP2027)

MEDICATION(S)
BRONCHITOL, BRONCHITOL TOLERANCE TEST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of cystic fibrosis (CF) AND documentation of use as add-on maintenance therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
By or in consultation with a pulmonologist or CF specialist

COVERAGE DURATION
12 months

OTHER CRITERIA
Documentation of use in conjunction with standard CF therapies (such as, but not limited to: bronchodilators, antibiotics, or anti-inflammatory therapy). Documentation that patient has passed the bronchitol tolerance test. Reauthorization will require positive clinical response to therapy based on provider assessment.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BROVANA(GHP2027)

MEDICATION(S)
ARFORMOTEROL TARTRATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF COPD

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SEREVENT OR DOCUMENTATION OF INABILITY TO USE AN INHALER.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BRUKINSA(GHP2027)

MEDICATION(S)
BRUKINSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

BUDESONIDE ER(GHP2027)

MEDICATION(S)
BUDESONIDE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of ulcerative colitis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
8 WEEKS

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to sulfasalazine, balsalazide, or an oral mesalamine product

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

BYSANTI(GHP2027)

MEDICATION(S)
BYSANTI, BYSANTI TITRATION PACK A, BYSANTI TITRATION PACK B, BYSANTI TITRATION PACK C

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA OR DIAGNOSIS OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (ARIPIPRAZOLE, OLANZAPINE, QUETIAPINE, ZIPRASIDONE OR RISPERIDONE).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

CABLIVI(GHP2027)

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP). Documentation of (1) use in combination with daily plasma exchange and immunosuppressive therapy (such as glucocorticoids or rituximab) AND documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi OR (2) documentation that the member previously received daily plasma exchange, immunosuppressive therapy and Cablivi within the inpatient settings AND known date of the last plasma exchange AND documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi AND documentation of either the date of plasma exchange is within 30 days of the request date OR if the date of plasma exchange is greater than 30 days of the request date, documentation of persistent underlying disease (such as suppressed ADAMTS 13 activity levels remain present) and documentation of not exceeding the maximum treatment duration of Cablivi (30 days post plasma exchange and up to 28 days of extended treatment).

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
by or in consultation with a hematologist

COVERAGE DURATION
2 MONTHS INITIAL, 2 MONTHS REAUTH

OTHER CRITERIA
Reauthorization will be based on plasma exchange status and that member has not experienced more

than two recurrences of aTTP while on Cablivi. If currently receiving plasma exchange, documentation that medication is currently being used with plasma exchange and immunosuppressive therapy. If plasma exchange has been completed within 30 days, documentation of previously receiving daily plasma exchange and immunosuppressive therapy, the known date of the last plasma exchange, and that the date of plasma exchange is within 30 days of the request date. If plasma exchange has been completed for more than 30 days, documentation sign(s) of persistent underlying disease (such as suppressed ADAMTS13 activity levels remain present) AND date of last plasma exchange AND documentation of not exceeding the maximum treatment duration of Cablivi (30 days post plasma exchange and up to 28 days of extended treatment).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

CABOMETYX(GHP2027)

MEDICATION(S)
CABOMETYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CALQUENCE(GHP2027)

MEDICATION(S)
CALQUENCE 100 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CAPLYTA(GHP2027)

MEDICATION(S)
CAPLYTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA OR DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR DISORDER (BIPOLAR DEPRESSION). Diagnosis of Major Depressive Disorder.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR SCHIZOPHRENIA: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE) OR FOR BIPOLAR DEPRESSION: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO QUETIAPINE AND LURASIDONE. For MDD: Documentation that medication is being used as adjunctive therapy AND Documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of combination therapy with aripiprazole and and antidepressant.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

CARBAGLU(GHP2027)

MEDICATION(S)
CARGLUMIC ACID

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS). DIAGNOSIS OF PROPIONIC ACIDEMIA (PA) OR METHYLMALONIC ACIDEMIA (MMA).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC DISORDER SPECIALIST OR GENETICIST

COVERAGE DURATION
For MMA or PA: 7 days. NAGS: 6 MONTHS

OTHER CRITERIA
FOR ALL INDICATIONS: DOCUMENTATION THAT MEDICATION IS PRESCRIBED WITH A DOSE AND DURATION OF THERAPY THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. FOR MMA OR PA: (1)DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED AS ADJUNCTIVE TREATMENT TO STANDARD OF CARE (INCLUDING BUT NOT LIMITED TO INTRAVENOUS GLUCOSE, INSULIN, L-CARNITINE, PROTEIN RESTRICTION AND DIALYSIS), AND (2)DOCUMENTATION OF PLASMA AMMONIA LEVEL GREATER THAN OR EQUAL TO 50 MICROMOL/L. REAUTHORIZATIONS FOR NAGS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE

Pending CMS Approval

PROGRESSION

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

CARDAMYST(GHP2027)

MEDICATION(S)
CARDAMYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a history of sustained paroxysmal supraventricular tachycardia lasting greater than or equal to 20 minutes

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
Cardiologist

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CAYSTON(GHP2027)

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF CYSTIC FIBROSIS CONFIRMED BY APPROPRIATE DIAGNOSTIC OR GENETIC TESTING AND DOCUMENTATION THAT PSEUDOMONAS AERUGINOSA IS PRESENT IN THE CULTURES OF THE AIRWAY

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TOBRAMYCIN INHALATION SOLUTION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

CERDELGA(GHP2027)

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF GAUCHER DISEASE TYPE 1 (GD1) AND DOCUMENTATION THAT MEMBER IS A CYTOCHROME P450 (CYP)2D6 EXTENSIVE METABOLIZER (EM), INTERMEDIATE METABOLIZER (IM), OR POOR METABOLIZER (PM) AS DETECTED BY AN FDA-CLEARED TEST.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRADINDICATION TO MIGLUSTAT.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

CEREZYME(GHP2027)

MEDICATION(S)
CEREZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF TYPE 1 or TYPE 3 GAUCHER DISEASE ALONG WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS: ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST, GENETICIST, OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR TYPE 1 GAUCHER DISEASE: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO VPRIV. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

CIALIS(GHP2027)

MEDICATION(S)
CIALIS 5 MG TAB, TADALAFIL 2.5 MG TAB, TADALAFIL 5 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY 5-ALPHA REDUCTASE INHIBITOR (FINASTERIDE OR DUTASTERIDE) AND ONE FORMULARY ALPHA-1 ADRENERIGIC BLOCKER (ALFUZOSIN, TAMSULOSIN, DOXAZOSIN, TERAZOSIN)

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

CIBINQO(GHP2027)

MEDICATION(S)
CIBINQO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS.

AGE RESTRICTION
MUST BE 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH AN ALLERGIST, DERMATOLOGIST, OR IMMUNOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH ANOTHER JAK INHIBITORS, BIOLOGIC IMMUNOMODULATORS, OR OTHER IMMUNOSUPPRESSANTS. FOR AD: DOCUMENTATION OF: (1) THERAPEUTIC FAILURE ON DAILY TREATMENT WITH AT LEAST ONE MEDIUM (OR HIGHER) POTENCY TOPICAL CORTICOSTEROID (SUCH AS BUT NOT LIMITED TO TRIAMCINOLONE, BETAMETHASONE, OR CLOBETASOL) OR CALCINEURIN INHIBITOR (I.E. TACROLIMUS) IF TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE AND (2) DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE SYSTEMIC THERAPY FOR AD. REAUTHORIZATION WILL REQUIRE DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

CIMZIA(GHP2027)

MEDICATION(S)
CIMZIA, CIMZIA (1 SYRINGE), CIMZIA (2 SYRINGE), CIMZIA-STARTER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
ADULT RA - DIAGNOSIS OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. CROHN'S DISEASE - DIAGNOSIS OF CROHN'S DISEASE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PSORIATIC ARTHRITIS - DIAGNOSIS OF PSORIATIC ARTHRITIS AND DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY GREATER THAN OR EQUAL TO 3% OF BODY SURFACE AREA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP OR GENITALS. Diagnosis of non-radiographic axial spondylarthritis with documentation of either C-reactive protein (CRP) level above the upper limit of normal or Sacroiliitis on magnetic resonance imaging (MRI). DX OF ACTIVE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA).

Pending CMS Approval

AGE RESTRICTION
RA, CD, AS, PSA, PP, NR-axSpA: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, GASTROENTEROLOGIST OR DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB PRODUCT, RINVOQ, XELJANZ). FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, RINVOQ, XELJANZ, FORMULARY USTEKINUMAB PRODUCT). FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, FORMULARY USTEKINUMAB PRODUCT). FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (ENBREL, FORMULARY ADALIMUMAB PRODUCT, XELJANZ, RINVOQ). FOR CROHN'S: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE PREFERRED BIOLOGIC AGENT FOR CD (FORMULARY ADALIMUMAB PRODUCT, SKYRIZI, TREMFYA, FORMULARY USTEKINUMAB PRODUCT). FOR NR-AXSPA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR pJIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR pJIA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB PRODUCT, RINVOQ, XELJANZ) AND DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON PATIENT AGE AND WEIGHT. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

CINRYZE(GHP2027)

MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
MUST BE 6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
If being used for prophylaxis: documentation that medication is not being used in combination with another prophylactic human C1 esterase inhibitor (Haegarda), berotralstat (Orladeyo) or lanadelumab (Takhzyro) therapy for hereditary angioedema. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CINVANTI(GHP2027)

MEDICATION(S)
CINVANTI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOC THAT CINVANTI IS BEING USED FOR THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF HIGHLY EMETOGENIC CANCER CHEMOTHERAPY. DOC THAT CINVANTI IS BEING USED FOR THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF MODERATELY EMETOGENIC CANCER CHEMOTHERAPY AND THAT MEMBER HAS EXPERIENCED FAILURE ON OR CONTRAINDICATION TO ONDANSETRON OR GRANISETRON.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

CLOLAR(GHP2027)

MEDICATION(S)
CLOFARABINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

COBENFY(GHP2027)

MEDICATION(S)
COBENFY, COBENFY STARTER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE) AND DOCUMENTATION THAT MEMBER DOES NOT HAVE PRE-EXISTING URINARY RETENTION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

COLUMVI(GHP2027)

MEDICATION(S)
COLUMVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

COMETRIQ(GHP2027)

MEDICATION(S)
COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CONTRAVE(GHP2027)

MEDICATION(S)
CONTRAVE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ONE OF THE FOLLOWING: (1) BODY MASS INDEX (BMI) GREATER THAN OR EQUAL TO 30 KG/M2 OR (2) BMI GREATER THAN OR EQUAL TO 27 KG/M2 AND AT LEAST ONE WEIGHT-RELATED COMORBIDITY (E.G., HYPERTENSION, TYPE 2 DIABETES MELLITUS, OR DYSLIPIDEMIA). DOCUMENTATION OF USE AS ADJUNCT THERAPY TO REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY FOR CHRONIC WEIGHT MANAGEMENT.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS PARTICIPATED IN COMPREHENSIVE LIFESTYLE MODIFICATIONS INCLUDING REDUCED-CALORIE DIET, PHYSICAL ACTIVITY, AND BEHAVIORAL HEALTH FOR AT LEAST 3 MONTHS PRIOR TO BEGINNING CONTRAVE. FAILURE ON WEGOVY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER CONTINUES TO EXPERIENCE CLINICAL BENEFIT FROM CONTRAVE BASED ON THE PRESCRIBERS ASSESSMENT AND DOCUMENTATION THAT MEMBER HAS EXPERIENCED AT LEAST A 4 PERCENT REDUCTION IN WEIGHT FROM BASELINE.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

COPIKTRA(GHP2027)

MEDICATION(S)
COPIKTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CORLANOR(GHP2027)

MEDICATION(S)
IVABRADINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF STABLE, SYMPTOMATIC HEART FAILURE WITH A LEFT VENTRICULAR EJECTION FRACTION LESS THAN OR EQUAL TO 35% AND DOCUMENTATION OF BEING IN SINUS RHYTHM WITH RESTING HEART RATE GREATER THAN OR EQUAL TO 70 BEATS PER MINUTE. DOCUMENTATION OF STABLE, SYMPTOMATIC HEART FAILURE DUE TO DILATED CARDIOMYOPATHY and DOCUMENTATION OF CLASS II TO IV HEART FAILURE ACCORDING TO NYHA FUNCTIONAL CLASS OR ROSS CLASSIFICATIONS and DOCUMENTATION OF A LEFT VENTRICULAR EJECTION FRACTION LESS THAN OR EQUAL TO 45% and DOCUMENTATION OF BEING IN SINUS RHYTHM WITH RESTING HEART RATE GREATER THAN OR EQUAL TO THE LOWER LIMIT OF THE NORMAL RANGE BASED ON AGE

Pending CMS Approval

AGE RESTRICTION
HF with EF less than 35%: 18 years of age or older. HF due to cardiomyopathy: 6 months of age or older

PRESCRIBER RESTRICTION
CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THE MAXIMUM TOLERATED DOSES OF TWO FORMULARY BETA-BLOCKERS ONE OF WHICH MUST BE CARVEDILOL

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

COSELA(GHP2027)

MEDICATION(S)
COSELA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

COSENTYX(GHP2027)

MEDICATION(S)
COSENTYX 150 MG/ML SOLN PRSYR, COSENTYX 75 MG/0.5ML SOLN PRSYR, COSENTYX (300 MG DOSE), COSENTYX SENSOREADY (300 MG), COSENTYX SENSOREADY PEN, COSENTYX UNOREADY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF ANKYLOSING SPONDYLITIS. DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY BSA OF 3% OR GREATER INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, SCALP, OR GENITALS. DIAGNOSIS OF MODERATE TO SEVERE ACTIVE PSORIATIC ARTHRITIS WITH A HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS. DOCUMENTATION OF ONE OF THE FOLLOWING: C-REACTIVE PROTEIN (CRP) LEVEL ABOVE THE UPPER LIMIT OF NORMAL (10 MG/DL) OR SACROLIITIS ON MAGNETIC RESONANCE IMAGING (MRI). DIAGNOSIS OF ENTHESITIS-RELATED ARTHRITIS. DIAGNOSIS OF MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA (HS), DEFINED AS STAGE II OR III ON THE HURLEY STAGING SYSTEM.

Pending CMS Approval

AGE RESTRICTION
FOR HS: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (ENBREL, FORMULARY ADALIMUMAB PRODUCT, XELJANZ, RINVOQ). FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, FORMULARY USTEKINUMAB PRODUCT). FOR PSA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, RINVOQ, XELJANZ, FORMULARY USTEKINUMAB PRODUCT). FOR NR-AXSPA: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (CIMZIA, RINVOQ). FOR ENTHESITIS RELATED ARTHIRITIS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 1 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR PSORIASIS, PSORIATIC ARTHRITIS, AND ENTHESITIS RELATED ARTHRITIS: DOCUMENTATION THAT THE PRESCRIBED DOSE IS APPROPRIATE FOR PATIENTS WEIGHT. FOR HS: DOCUMENTATION OF AT LEAST 3 ABSECESSES OR INFLAMMATORY NODULES. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

COSENTYX IV(GHP2027)

MEDICATION(S)
COSENTYX 125 MG/5ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF ANKYLOSING SPONDYLITIS. DIAGNOSIS OF MODERATE TO SEVERE ACTIVE PERIPHERAL OR AXIAL PSORIATIC ARTHRITIS WITH A HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS. DOCUMENTATION OF ONE OF THE FOLLOWING: C-REACTIVE PROTEIN (CRP) LEVEL ABOVE THE UPPER LIMIT OF NORMAL (10 MG/DL) OR SACROLIITIS ON MAGNETIC RESONANCE IMAGING (MRI).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. DOCUMENTATION THAT THE PRESCRIBED DOSE IS APPROPRIATE FOR PATIENTS WEIGHT AND DOES NOT EXCEED 300MG PER INFUSION. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE

Pending CMS Approval

FORMULARY NSAID AND METHOTREXATE. FOR AXIAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR NR-AXSPA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

COTELLIC(GHP2027)

MEDICATION(S)
COTELLIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CRENESSITY(GHP2027)

MEDICATION(S)
CRENESSITY 100 MG CAP, CRENESSITY 50 MG CAP, CRENESSITY 50 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (20-OHD).

AGE RESTRICTION
Must be 4 years of age or older

PRESCRIBER RESTRICTION
By or in consultation with an endocrinologist or specialist experienced in CAH

COVERAGE DURATION
6 months initial, 12 months reauth

OTHER CRITERIA
Documentation that medication will be used as an adjunctive treatment to glucocorticoid replacement and documentation of receiving a stable regimen of glucocorticoid treatment for at least 4 weeks. Documentation of one of the following 1) member requires a supraphysiologic glucocorticoid dose to control their disease OR 2) androgen levels remain uncontrolled despite maximum tolerated glucocorticoid dosing. Documentation that member has not had a history of bilateral adrenalectomy, hypopituitarism, or other condition requiring chronic glucocorticoid therapy. Documentation of appropriate weight-based dosing. If the request is for oral solution in patients weighing 55 kg or greater OR in patients weighing 20 kg or greater and requiring a CYP3A4 dose adjustment: documentation that member is unable to swallow capsules or reason why a capsule formulation couldn't be used. Reauthorization will require documentation that a reduction in daily glucocorticoid dose was able to be achieved AND documentation that medication will continue to be used as an adjunctive treatement to

Pending CMS Approval

glucocorticoid replacement AND documentation of appropriate weight based dosing AND if the request is for oral solution in patients weighing 55 kg or greater OR in patients weighing 20 kg or greater and requiring a CYP3A4 dose adjustment: documentation that member is unable to swallow capsules or reason why a capsule formulation couldn't be used.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

CRESEMBA(GHP2027)

MEDICATION(S)
CRESEMBA 186 MG CAP, CRESEMBA 74.5 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS.

AGE RESTRICTION
MUST BE 6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH AN ONCOLOGIST, HEMATOLOGIST, INFECTIOUS DISEASE SPECIALIST, OR TRANSPLANT SERVICE PROVIDER

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT DOSING IS CONSISTENT WITH FDA APPROVED LABELING AND PATIENT WEIGHT. FOR PROPHYLAXIS OF INVASIVE ASPERGILLUS OR CANDIDA INFECTIONS, DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO POSACONAZOLE OR THAT MEMBER REQUIRES TREATMENT WITH AN ANTI-CANCER MEDICATION THAT INTERACTS WITH POSACONAZOLE. FOR PULMONARY COCCIDIOIODMYCOSIS, DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FLUCONAZOLE OR ITRACONZOLE. FOR CRYPTOCOCCAL MENINGITIS, DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FLUCONAZOLE. FOR OROPHARYNGEAL CANDIDIASIS, DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ORAL ANTIFUNGALS

Pending CMS Approval

(SUCH AS BUT NOT LIMITED TO POSACONAZOLE, ITRACONAZOLE, OR FLUCONAZOLE).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

CRIZOTINIB(GHP2027)

MEDICATION(S)
XALKORI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: ALK Gene rearrangement, ROS-1 Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

CRYSVITA(GHP2027)

MEDICATION(S)
CRYSVITA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF X-LINKED HYPOPHOSPHATEMIA AS EVIDENCED BY ONE OF THE FOLLOWING: REDUCED TMP/GFR RATIO WITH EITHER REDUCED PLASMA CONCENTRATION OF 1,25-DIHYDROXYCHOLECALCIFEROL (1,25-DHCC) OR 25-HYDROXYVITAMIN D (25(OH)D) OR GENETIC TESTING CONFIRMING A MUTATION IN THE PHEX (PHOSPHATE REGULATING ENDOPEPTIDASE ON THE X CHROMOSOME) GENE. DIAGNOSIS OF FGF23-RELATED HYPOPHOSPHATEMIA IN TUMOR-INDUCED OSTEOMALACIA (TIO) ASSOCIATED WITH PHOSPHATURIC MESENCHYMAL TUMORS AND DOCUMENTATION OF AN ELEVATED SERUM LEVEL OF FGF23 AND DOCUMENTATION THAT THE TUMOR CANNOT BE CURATIVELY RESECTED OR LOCALIZED.

Pending CMS Approval

AGE RESTRICTION
TIO:2 YEARS OR OLDER. X-LINKED:6 MONTHS OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, NEPHROLOGIST OR ONCOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
DOCUMENTATION THAT THE MEMBER IS NOT CURRENTLY USING ACTIVE VITAMIN D ANALOGS OR PHOSPHATE SUPPLEMENTS. SUBSEQUENT APPROVALS WILL REQUIRE

DOCUMENTATION OF CONTINUED FOLLOW UP AND DETERMINATION OF MEDICAL NECESSITY FROM AN ENDOCRINOLOGIST, NEPHROLOGIST OR ONCOLOGIST AND DOCUMENTATION OF IMPROVING PATIENT'S DISEASE AS EVIDENCED BY NORMALIZED OR IMPROVED SERUM PHOSPHORUS LEVELS AND DOCUMENTATION THAT PATIENT IS NOT USING ACTIVE VITAMIN D ANALOGS OR PHOSPHATE SUPPLEMENTS

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

CYRAMZA(GHP2027)

MEDICATION(S)
CYRAMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DANYELZA(GHP2027)

MEDICATION(S)
DANYELZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF RELAPSED OR REFRACTORY HIGH-RISK NEUROBLASTOMA IN THE BONE OR BONE MARROW WHO HAVE DEMONSTRATED A PARTIAL RESPONSE, MINOR RESPONSE OR STABLE DISEASE TO PRIOR THERAPY AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH GRANULOCYTE-MACROPHAGE COLONY STIMULATING FACTOR (GM-CSF).

AGE RESTRICTION
MUST BE 1 YEAR OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

DARAPRIM(GHP2027)

MEDICATION(S)
PYRIMETHAMINE 25 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of toxoplasmosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
3 MONTHS INITIAL, 6 MONTHS CONTINUATION

OTHER CRITERIA
Documentation of use in combination with leucovorin and a sulfonamide OR therapeutic failure on, intolerance to or contraindication to a sulfonamide. Reauthorization will require documentation of clinical syndrome (such as headache or other neurological symptom) OR documentation of persistent radiographic disease.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

DARZALEX FASPRO(GHP2027)

MEDICATION(S)
DARZALEX FASPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DARZALEX(GHP2027)

MEDICATION(S)
DARZALEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DATROWAY(GHP2027)

MEDICATION(S)
DATROWAY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DAURISMO(GHP2027)

MEDICATION(S)
DAURISMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DAXXIFY(GHP2027)

MEDICATION(S)
DAXXIFY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CERVICAL DYSTONIA.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DAYBUE(GHP2027)

MEDICATION(S)
DAYBUE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CLASSIC, OR TYPICAL, RETT SYNDROME AND DOCUMENTATION OF MECP2 GENE MUTATION.

AGE RESTRICTION
2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF PATIENT BASELINE SYMPTOMS USING AS APPROPRIATE RATING SCALE (E.G., RETT SYNDROME BEHAVIORAL QUESTIONNAIRE, SIMPLIFIED SEVERITY SCORE, CLINICAL GLOBAL IMPRESSION-IMPROVEMENT ASSESSMENT) AND DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT IN RETT SYNDROME SYMPTOMS AS MEASURED BY AN APPROPRIATE RATING SCALE (COMPARED TO PREVIOUS MEASUREMENT)

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

DEMSER(GHP2027)

MEDICATION(S)
METYROSINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
TREATMENT OF PHEOCHROMOCYTOMA PREOPERATIVELY. TREATMENT OF PHEOCHROMOCYTOMA IN MANAGEMENT OF PATIENTS WHEN SURGERY IS CONTRAINDICATED. CHRONIC TREATMENT OF MALIGNANT PHEOCHROMOCYTOMA.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DIACOMIT(GHP2027)

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Dravet syndrome AND documentation that medication is to be used in combination with clobazam AND documentation of weight greater than or equal to 7 kg.

AGE RESTRICTION
MUST BE 6 MONTHS OF AGE OR OLDER

PRESCRIBER RESTRICTION
by or in consultation with a neurologist

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DIFICID(GHP2027)

MEDICATION(S)
DIFICID 40 MG/ML RECON SUSP, FIDAXOMICIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTED DIAGNOSIS OF C. DIFFICILE INFECTION (CDI).

AGE RESTRICTION
6 MONTHS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
10 DAYS

OTHER CRITERIA
DOCUMENTATION OF AN APPROPIATE DOSE AND DURATION OF THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

DOPTELET(GHP2027)

MEDICATION(S)
DOPTELET 20MG TAB, DOPTELET TAB 40MG DAILY DOSE PACK, DOPTELET TAB 60MG DAILY DOSE PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC LIVER DISEASE AND DOCUMENTATION OF A PLATELET COUNT LESS THAN 50 X 1000000000 (10 TO THE 9TH POWER)/L MEASURED WITHIN THE PAST 30 DAYS. DOCUMENTATION OF A PLANNED INVASIVE PROCEDURE TO BE PERFORMED 10 TO 13 DAYS AFTER INITIATION OF TREATMENT. DIAGNOSIS OF CHRONIC IMMUNE THROMBOCYTOPENIA AND DOCUMENTATION OF A PLATELET COUNT LESS THAN 30,000/MICROL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, endocrinologist, or surgeon

COVERAGE DURATION
pre-procedure:30 DAYS. Chronic ITP 3 months initial, 12 months reauth

OTHER CRITERIA
Documentation that the member is not receiving other TPO-Ras (i.e. romiplostin, eltrombopag). For pre-procedure of thrombocytopenia with chronic liver disease: Documentation that the correct dose of medication is being used based on the platelet count (platelet count 40-50 x 1000000000 (10 TO THE 9TH POWER)/L: 40 mg once daily for 5 consecutive days, platelet count less than 40 x 1000000000

Pending CMS Approval

(10 TO THE 9TH POWER)/L,000: 60 mg once daily for 5 consecutive days). For chronic ITP: documentation of a therapeutic failure on one previous treatment, including, but not limited to: corticosteroids, IVIG, Rhogam (if RhD-positive and spleen intact), Rituximab, splenectomy, eltrombopag or romiplostim. Subsequent approval after 3 months will require documentation of medical necessity such as a platelet count necessary to reduce the risk for bleeding OR a hematological response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

DRIZALMA(GHP2027)

MEDICATION(S)
DRIZALMA SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF ONE OF THE FOLLOWING: MAJOR DEPRESSIVE DISORDER, DIABETIC PERIPHERAL NEUROPATHIC PAIN, CHRONIC MUSCULOSKELETAL PAIN, FIBROMYALGIA, OR GENERALIZED ANXIETY DISORDER

AGE RESTRICTION
For GAD: 7 years of age or older. All others: 18 years or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF DIFFICULTY SWALLOWING OR DOCUMENTATION OF ADMINISTRATION OF MEDICATION THROUGH A NASOGASTRIC TUBE OR DOCUMENTATION OF WHY DULOXETINE CAPSULES COULD NOT BE USED.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

DRONABINOL(GHP2027)

MEDICATION(S)
DRONABINOL 10 MG CAP, DRONABINOL 2.5 MG CAP, DRONABINOL 5 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING or DIAGNOSIS OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

Pending CMS Approval

OTHER CRITERIA
FOR CHEMOTHERAPY INDUCED NAUSEA AND VOMITING: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO ANTIEMETIC THERAPIES, ONE OF WHICH MUST BE A 5HT3 ANTAGONIST. FOR ANOREXIA: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MEGESTEROL ACETATE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

DUPIXENT(GHP2027)

MEDICATION(S)
DUPIXENT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate to severe atopic dermatitis. Documentation of either oral corticosteroid dependent asthma OR moderate to severe eosinophilic asthma with a blood eosinophilic count greater than or equal to 150 cells/microL. For asthma, documentation that medication will be used as an add-on maintenance treatment. Diagnosis of add-on maintenance treatment of inadequately controlled chronic rhino-sinusitis with nasal polyps (CRwNP). Diagnosis of eosinophilic esophagitis. Diagnosis of prurigo nodularis. DIAGNOSIS OF INADEQUATELY CONTROLLED COPD WITH AN EOSINOPHILIC PHENOTYPE AND DOCUMENTATION OF USE AS ADD-ON MAINTENANCE TREATMENT AND DOCUMENTATION OF A BLOOD EOSINOPHIL COUNT OF 300 CELLS/MCL OR GREATER DURING THE 12 MONTH PERIOD BEFORE SCREENING OR 150 CELLS/MCL OR GREATER WITHIN 3 MONTHS OF THE START OF THERAPY. Diagnosis of Bullous Pemphigoid. Diagnosis of moderate to severe chronic spontaneous urticaria. Diagnosis of allergic fungal rhinosinusitis (AFRS) and documentation that member has a history of sino-nasal surgery.

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AGE RESTRICTION
AD: 6 MONTHS OR OLDER. ASTHMA and AFRS: 6 YRS OR OLDER. CRwNP and URTICARIA: 12 YRS OR OLDER. EoE: 1 YR OR OLDER. PN, COPD AND BULLOUS PEMPHIGOID: 18 YRS OR OLDER

PRESCRIBER RESTRICTION
MUST BE PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST, DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST, GASTROENTEROLOGIST OR OTOLARYNGOLOGIST (ENT provider)

COVERAGE DURATION

6 MONTHS INITIAL, 12 MONTHS RENEWAL

OTHER CRITERIA

FOR AD: FAILURE ON EITHER DAILY TREATMENT WITH AT LEAST MEDIUM POTENCY TOPICAL CORTICOSTEROID OR TOPICAL CALCINEURIN INHIBITOR (I.E. TACROLIMUS) IF TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE. FOR ASTHMA, DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBO WITH BENRALIZUMAB, MEPOLIZUMAB, OMALIZUMAB, RESLIZUMAB, DEPEMOKIMAB, OR TEZEPELUMAB AND ONE OF THE FOLLOWING: CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST 3-MONTH TRIAL OF MAXIMALLY TOLERATED INHALED CORTICOSTEROIDS OR ORAL SYSTEMIC CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST OR DOCUMENTATION OF ONE EXACERBATION IN THE PREVIOUS 12 MONTHS REQUIRING ADDITIONAL MEDICAL TREATMENT DESPITE CURRENT THERAPY OR INTOLERANCE TO INHALED CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST. FOR CRWNP: CHRONIC RHINOSINUSITIS IS DEFINED AS NASAL MUCOSAL INFLAMMATION WHICH PERSISTS FOR 12 WEEKS OR LONGER. THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO INTRANASAL CORTICOSTEROIDS. DOCUMENTATION THAT MEDICATION WILL BE USED AS ADD ON THERAPY (I.E. WITH INTRANASAL CORTICOSTEROIDS OR OTHER THERAPY). FOR EoE: DOCUMENTATION OF 15 OR MORE INTRAEPITHELIAL EOSINOPHILS PER HIGH POWER FIELD (eos/hpf). CONTRAINDICATION TO, INTOLERANCE TO, THERAPEUTIC FAILURE ON A PROTON PUMP INHIBITOR OR A REASON WHY A PROTON PUMP INHIBITOR COULD NOT BE TRIED. DOCUMENTATION THAT MEMBER IS EXPERIENCING CHRONIC SYMPTOMS OF ESOPHAGEAL DYSFUNCTION (such as but not limited to, i.e., dysphagia, food impaction, abdominal pain, heartburn). FOR COPD: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 1) SPIRIVA or INCRUSE ELLIPTA AND 2) ONE LONG-ACTING BETA AGONISTS. For Bullous Pemphigoid: Failure on, intolerance to, or contraindication to 1) an oral tetracycline OR an oral corticosteroid therapy AND 2) a corticosteroid sparing therapy (e.g. such as but not limited to azathioprine, methotrexate or mycophenolate). Documentation that medication is being prescribed with a tapering course of oral corticosteroids during the initial treatment phase, unless documentation indicates corticosteroid intolerance or contraindication. Documentation that medication will not be used in combination with other biologic immunomodulators or JAK inhibitors. For Urticaria: 1)documentation of at least 6 week history of symptoms (e.g., hives associated with itching or angioedema), 2) documentation of a dose consistent with FDA approved labeling, 3) therapeutic failure on, intolerance to, or contraindication to a four week trial of maximal dose of one antihistamine, and 4) documentation that medication will not be used in combination with benralizumab, omalizumab, mepolizumab, tezepelumab or reslizumab. FOR AFRS: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO

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INTRANASAL CORTICOSTEROIDS. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND (FOR CRWNP), DOCUMENTATION THAT MEDICATION CONTINUES TO BE USED AS ADD ON THERAPY.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

EBGLYSS(GHP2027)

MEDICATION(S)
EBGLYSS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate to severe atopic dermatitis.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that the member weighs greater than 40 kg. Documentation of contraindication to, intolerance to, or failure to one systemic therapy (e.g., phototherapy, immunotherapy, or other systemic agents). Documentation of failure on, intolerance to, or contraindication to Dupixent. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EKTERLY(GHP2027)

MEDICATION(S)
EKTERLY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
MUST BE AT LEAST 12 YEARS OF AGE

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
DOCUMENTATION THAT SEBETRALSTAT IS BEING USED FOR TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACK. DOCUMENTATION THAT SEBETRALSTAT IS NOT BEING USED IN COMBINATION WITH OTHER APPROVED TREATMENTS FOR ACUTE HAE ATTACKS. Reauthorization will require documentation of continued follow up or assessment by provider since last authorization and documentation that SEBETRALSTAT is not being used in combination with other approved treatments for acute HAE attacks.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

ELAHERE(GHP2027)

MEDICATION(S)
ELAHERE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, Nephrologist, Urologist, or Neurologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ELAPRASE(GHP2027)

MEDICATION(S)
ELAPRASE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HUNTER'S SYNDROME (MPS II)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MPS II

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ELELYSO(GHP2027)

MEDICATION(S)
ELELYSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF TYPE 1 GAUCHER DISEASE WITH AT LEAST ONE OF THE FOLLOWING - ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST, GENETICIST OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ELETRIPTAN (GHP2027)

MEDICATION(S)
ELETRIPTAN HYDROBROMIDE 40 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to treatment with two formulary triptan agents (almotriptan, naratriptan, rizatriptan, sumatriptan, or zolmitriptan).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ELFABRIO(GHP2027)

MEDICATION(S)
ELFABRIO 20 MG/10ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF FABRY DISEASE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST WITH EXPERIENCE TREATING FABRY DISEASE

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ELIDEL(GHP2027)

MEDICATION(S)
PIMECROLIMUS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF ATOPIC DERMATITIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TACROLIMUS OINTMENT AND ONE FORMULARY TOPICAL CORTICOSTEROID UNLESS INADVISABLE DUE TO RISKS (SUCH AS USE ON SENSITIVE SKIN AREAS (FACE, AXILLAE, GROIN))

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ELITEK(GHP2027)

MEDICATION(S)
ELITEK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HYPERURICEMIA IN PATIENTS WITH LEUKEMIA, LYMPHOMA, AND SOLID TUMOR MALIGNANCIES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
1 COURSE OF THERAPY (5 DAYS)

OTHER CRITERIA
DOCUMENTATION OF A HIGH RISK OF TUMOR LYSIS SYNDROME CHARACTERIZED BY ELEVATED SERUM CREATININE OR LEUKEMIAS WITH VERY HIGH WHITE BLOOD CELL COUNTS OF GREATER THAN OR EQUAL TO 25,000 / MM(3) OR BURKITT'S LYMPHOMA OR T-CELL NON-HODGKIN'S LYMPHOMA OR SERUM URIC ACID LEVEL GREATER THAN OR EQUAL TO 8 MG/DL AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ORAL OR INJECTABLE ALLOPURINOL

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ELREXFIO(GHP2027)

MEDICATION(S)
ELREXFIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

EMFLAZA(GHP2027)

MEDICATION(S)
DEFLAZACORT 18 MG TAB, DEFLAZACORT 30 MG TAB, DEFLAZACORT 36 MG TAB, DEFLAZACORT 6 MG TAB, JAYTHARI 18 MG TAB, JAYTHARI 30 MG TAB, JAYTHARI 36 MG TAB, JAYTHARI 6 MG TAB, KYMBEE 18 MG TAB, KYMBEE 30 MG TAB, KYMBEE 36 MG TAB, KYMBEE 6 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF DUCHENNE MUSCULAR DYSTROPHY CONFIRMED BY GENETIC TESTING

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST OR PEDIATRIC NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PREDNISONE

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EMGALITY(GHP2027)

MEDICATION(S)
EMGALITY, EMGALITY (300 MG DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA AND ATTESTATION THAT MEMBER EXPERIENCES 4 OR MORE MIGRAINES PER MONTH. DIAGNOSIS OF EPISODIC CLUSTER HEADACHE AND NUMBER OF BASELINE CLUSTER HEADACHE ATTACK FREQUENCY AND ATTESTATION THAT MEMBER IS CURRENTLY EXPERIENCING A CLUSTER HEADACHE PERIOD (PERIOD OF RECURRENT ATTACKS).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MIGRAINE: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION. CLUSTER HA: 6 MONTHS.

OTHER CRITERIA
MIGRAINE: NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH. ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE. REAUTHORIZATION WILL REQUIRE ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE

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PREVENTATIVE TREATMENT OF MIGRAINE. CLUSTER HA: REAUTHORIZATION WILL REQUIRE A DIAGNOSIS OF EPISODIC CLUSTER HEADACHE AND ATTESTATION THAT MEMBER IS CURRENTLY EXPERIENCING A CLUSTER HEADACHE PERIOD (PERIOD OF RECURRENT ATTACKS) AND ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN CLUSTER HEADACHE ATTACK FREQUENCY.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EMPAVELI(GHP2027)

MEDICATION(S)
EMPAVELI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH). DIAGNOSIS OF COMPLEMENT 3 GLOMERULOPATHY (C3G) or PRIMARY IMMUNE-COMPLEX MEMBRANOPROLIFERATIVE GLOMERULONEPHRITIS (IC-MPGN) AND DOCUMENTATION THAT MEDICATION IS BEING USED TO REDUCE PROTEINURIA.

AGE RESTRICTION
FOR C3G AND IC-MPGN: 12 YEARS OF AGE OR OLDER.

PRESCRIBER RESTRICTION
HEMATOLOGIST or NEPHROLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS RECEIVED VACCINATIONS AGAINST ENCAPSULATED BACTERIA, INCLUDING STREPTOCOCCUS PNEUMONIAE, NEISSERIA MENINGITIDIS, AND HAEMOPHILUS INFLUENZA TYPE B. FOR PHN: DOCUMENTATION OF DIAGNOSIS CONFIRMED BY FLOW CYTOMETRY. DOCUMENTATION OF ONE OF THE FOLLOWING:1)MEMBER IS TRANSFUSION-DEPENDENT PRIOR TO STARTING THERAPY (I.E., HAS AT LEAST 1 TRANSFUSION IN THE 24 MONTHS PRIOR TO INITIATION OF MEDICATION DUE TO HEMOGLOBIN LESS THAN 7 G/DL IN PERSONS WITHOUT ANEMIC SYMPTOMS OR LESS THAN 9 G/DL IN PERSONS WITH SYMPTOMS FROM ANEMIA) OR 2) THERE IS SIGNIFICANT ADVERSE

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IMPACT ON MEMBERS HEALTH SUCH AS END ORGAN DAMAGE OR THROMBOSIS WITHOUT OTHER CAUSE. FOR C3G AND IC-MPGN: (1) DOCUMENTATION OF EGFR GREATER THAN OR EQUAL TO 30 ML/MIN/1.73 M2, PROTEINURIA GREATER THAN OR EQUAL TO 1 G/DAY, AND URINE PROTEIN TO CREATININE RATIO (UPCR) GREATER THAN OR EQUAL TO 1 G/G AND (2) DOCUMENTATION OF OPTIMIZED DOSES OF ANGIOTENSIN-CONVERTING ENZYME INHIBITORS, ANGIOTENSIN RECEPTOR BLOCKERS AND/OR SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS OR IMMUNOSUPPRESANT MEDICATIONS. REAUTHORIZATION FOR PHN WILL REQUIRE DOCUMENTATION OF HEMOLYSIS CONTROL MEASURED BY LACTIC ACID DEHYDROGENASE (LDH) LEVEL LESS THAN 1.5 TIMES THE UPPER LIMIT OF NORMAL AND REDUCED NEED OR ELIMINATION OF TRANSFUSION REQUIREMENTS OR STABILIZATION OF HEMOGLOBIN LEVELS. REAUTHORIZATION FOR C3G PR OR IC-MPGN WILL REQUIRE PROVIDER ASSESSMENT OF RESPONSE TO THERAPY OR DOCUMENTATION OF A DECREASE OR MAINTENANCE IN PROTEINURIA COMPARED TO BASELINE

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EMPLICITI(GHP2027)

MEDICATION(S)
EMPLICITI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

EMRELIS(GHP2027)

MEDICATION(S)
EMRELIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ENBREL(GHP2027)

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
ADULT RA - DIAGNOSIS OF RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. PJIA - DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATE TO SEVERE PSA AND DOCUMENTATION OF ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF MODERATE TO SEVERE ADULT OR PEDIATRIC PLAQUE PSORIASIS WITH GREATER THAN OR EQUAL TO 3% OF BSA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, SCALP, OR GENITALS. DIAGNOSIS OF MODERATE TO SEVERE JUVENILE PSORIATIC ARTHRITIS (JPsA).

Pending CMS Approval

AGE RESTRICTION
JIA AND JPsA: MUST BE AT LEAST 2 YEARS OF AGE, PP: MUST BE AT LEAST 4 YEARS OF AGE, ALL OTHERS: MUST BE AT LEAST 18 YEARS OF AGE

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF

BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE DISEASE MODIFYING ANTI-RHEUMATIC DRUG (DMARD), SUCH AS BUT NOT LIMITED TO METHOTREXATE, LEFLUNOMIDE OR SULFASALAZINE. FOR JPSA: DOCUMENTATION THAT PRESCRIBED DOSE IS APPROPRIATE FOR PATIENT'S WEIGHT. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 1 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE OR PHOTOTHERAPY. FOR PEDIATRIC PLAQUE PSORIASIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY TOPICAL CORTICOSTEROIDS. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ENDARI(GHP2027)

MEDICATION(S)
L-GLUTAMINE 5 GM PACKET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of sickle cell disease AND documentation of being used to reduce the acute complications of sickle cell disease.

AGE RESTRICTION
MUST BE 5 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
WRITTEN BY OR IN CONSULTATION WITH A HEMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of a therapeutic failure on, intolerance to, or contraindication to hydroxyurea. Reauthorization will require documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e. number of sickle cell crises, hospitalizations or number of acute chest syndrome occurrences)

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ENHERTU(GHP2027)

MEDICATION(S)
ENHERTU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ENSACOVE(GHP2027)

MEDICATION(S)
ENSACOVE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ALK Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ENSPRYNG(GHP2027)

MEDICATION(S)
ENSPRYNG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of Neuromyelitis Optica Spectrum Disorder (NMOSD) AND documentation that member is anti-aquaporin-4 (AQP4) antibody positive.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a neurologist or ophthalmologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ENTYVIO(GHP2027)

MEDICATION(S)
ENTYVIO, ENTYVIO PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate to severe active Crohns disease. Diagnosis of moderate to severe ulcerative colitis.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For CD: Failure on, intolerance to, or contraindication to two preferred agents Crohn’s disease (formulary adalimumab product, Cimzia, Skyrizi, infliximab). For UC: documentation of failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g., 6-mercaptopurine or azathioprine). Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

YES

Pending CMS Approval

EPCLUSA(GHP2027)

MEDICATION(S)
SOFOSBUVIR-VELPATASVIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF HEPATITIS C INFECTION WITH IDENTIFICATION OF GENOTYPE AND SUBTYPE. DOCUMENTATION OF METAVIR LIVER FIBROSIS OR CIRRHOSIS ASSESSMENT BY A NON-INVASIVE TEST. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 6 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT, BASIC METABOLIC PANEL. DOCUMENTATION OF A BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Pending CMS Approval

AGE RESTRICTION
MUST BE 3 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BOARD CERTIFIED GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

COVERAGE DURATION
PER AASLD/IDSA GUIDELINES

OTHER CRITERIA
Documentation of any potential drug interactions that may impact drug therapy addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or

counseling of the risks associated with the use of both medications when they interact) per AASLD/IDSA guidance (e.g., HIV medications, PPIs, antacids). Documentation of either 1) completed hepatitis B series OR 2) Hepatitis B screening (sAb/sAg and cAb/cAg) and quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg AND either documentation of treatment for Hepatitis B if there is detectable hepatitis B virus OR documentation of being vaccinated against Hepatitis B if negative for hepatitis B sAb. Documentation of intolerance to, contraindication to, or therapeutic failure of Mavyret, if appropriate.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

EPIDIOLEX(GHP2027)

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or seizures associated with tuberous sclerosis complex.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For Lennox-Gastaut Syndrome: documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary anticonvulsants used for the requested diagnosis.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EPKINLY(GHP2027)

MEDICATION(S)
EPKINLY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

EPOETIN(GHP2027)

MEDICATION(S)
EPOGEN, PROCRIT, RETACRIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
TX OF ANEMIA OF CHRONIC KIDNEY DISEASE. TX OF ANEMIA IN NON-MYELOID MALIGNANCY - MUST BE ON ANEMIA CAUSING CHEMO AND THERE IS A MINIMUM OF TWO ADDITIONAL MONTHS OF PLANNED CHEMO. TX OF ANEMIA IN ZIDOVUDINE TREATED HIV INFECTED INDIVIDUAL AND ENDOGENOUS EPO LEVELS OF 500 MU/ML OR LESS and ZIDOVUDINE DOSES OF 4200 MG OR LESS PER WEEK. REDUCTION OF ALLOGENEIC BLOOD TRANSFUSION IN ANEMIC INDIVIDUAL UNDERGOING ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY IN WHICH ANTICIPATED BLOOD LOSS IS GREATER THAN 2 UNITS AND THE NEED FOR ALLOGENEIC BLOOD TRANSFUSION IS ANTICIPATED. FOR CRF NOT ON DIALYSIS AND CANCER: HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED FOR CKD ON DIALYSIS HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 11 GM/DL FOR CONTINUATION OF THERAPY OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED FOR SURGERY INDICATION: PERIOPERATIVE HGB MUST BE MORE THAN 10 G/DL AND LESS THAN OR EQUAL TO 13 G/DL. FOR ALL OTHER INDICATIONS: HGB MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 12 GM/DL FOR CONTINUATION OF THERAPY. FOR ALL INDICATIONS: DOCUMENTATION OF ADEQUATE IRON STORES W/ SERUM FERRITIN GREATER THAN 100 NG/ML OR TRANSFERRIN LEVEL SATURATION GREATER THAN 20% OR A HISTORY OF CHELATION THERAPY FOR IRON.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

FOR SURGICAL INDICATION: 3 MONTHS. ALL OTHER INDICATIONS 12 MONTHS

OTHER CRITERIA

NON MYELOID MALIGNANCIES INCLUDE ALL TYPES OF CARCINOMA, SARCOMA, MELANOMA, MULTIPLE MYELOMA, LYMPHOMA, AND LYMPHOCYTIC LEUKEMIA. REAUTHORIZATION WILL REQUIRE REPEAT HGB (WITHIN 3 MONTHS OF REAUTH) AND FERRITIN OR TSAT LEVELS (WITHIN 6 MONTHS OF REAUTH). THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EPRONTIA(GHP2027)

MEDICATION(S)
TOPIRAMATE 25 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PARTIAL ONSET SEIZURES, PRIMARY GENERALIZED TONIC-CLONIC SEIZURES, OR LENNOX GASTUAT SYNDROME. DOCUMENTATION OF A DIAGNOSIS OF USE FOR MIGRAINE PROPHYLAXIS.

AGE RESTRICTION
SEIZURES: 2 YRS OF AGE OR OLDER. MIGRAINES: 12 YRS OR AGE OR OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES USED FOR THE TREATMENT OF ASSOCIATED DIAGNOSIS OR DOCUMENTATION OF DIFFICULTY SWALLOWING TABLETS AND THERAPEUTIC FAILURE ON OR INTOLERANCE TO TWO FORMULARY ALTERNATIVES USED FOR THE TREATMENT OF ASSOCIATED DIAGNOSIS

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ERIVEDGE(GHP2027)

MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ERLEADA(GHP2027)

MEDICATION(S)
ERLEADA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ERZOFRI(GHP2027)

MEDICATION(S)
ERZOFRI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA. DIAGNOSIS OF SCHIZOAFFECTIVE DISORDERS AS MONOTHERAPY OR AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ESBRIET(GHP2027)

MEDICATION(S)
PIRFENIDONE 267 MG CAP, PIRFENIDONE 801 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF IDIOPATHIC PULMONARY FIBROSIS (IPF) CONFIRMED BY EITHER A USUAL INTERSTITIAL PNEUMONIA PATTERN ON HIGH RESOLUTION CT SCAN OR BOTH HRCT AND SURGICAL LUNG BIOPSY PATTERN SUGGESTIVE OF IPF OR PROBABLE IPF MADE BY AN INTERDISCIPLINARY TEAM INCLUDING, BUT NOT LIMITED TO SPECIALISTS FROM PULMONARY MEDICINE, RADIOLOGY, THORACIC SURGERY, PATHOLOGY OR RHEUMATOLOGY AND DOCUMENTATION THAT THERE ARE NO OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE SUCH AS DOMESTIC AND OCCUPATIONAL ENVIRONMENTAL EXPOSURES, CONNECTIVE TISSUE DISEASE OR DRUG TOXICITY.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
PULMONOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ESZOPICLONE(GHP2027)

MEDICATION(S)
ESZOPICLONE 1 MG TAB, ESZOPICLONE 2 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DOCUMENTATION OF FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO RAMELTEON (GENERIC ROZEREM) AND DOXEPIN (GENERIC SILENOR).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EUCRISA(GHP2027)

MEDICATION(S)
EUCRISA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of mild to moderate atopic dermatitis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MUST BE PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment for members 2 years of age and older. Documentation of contraindication to, intolerance to, or therapeutic failure on at least one formulary topical corticosteroid unless deemed inadvisable due to potential risks such as use on sensitive skin areas (face, axillae, or groin).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EVKEEZA(GHP2027)

MEDICATION(S)
EVKEEZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AND DOCUMENATION OF USE AS ADJUNCTIVE THERAPY WITH OTHER LOW-DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C) LOWERING THERAPIES. DOCUMENTATION OF EITHER (1) GENETIC TESTING TO CONFIRM DIAGNOSIS SHOWING A MUTATION IN THE LOW-DENSITY LIPOPROTEIN (LDL) RECEPTOR (LDLR) GENE, APOLIPOPROTEIN B (APOB) GENE, PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 (PCSK9) GENE OR LDL PROTEIN RECEPTOR 1 ADAPTOR 1 (LDLRAP1) GENE OR (2) DIAGNOSIS MADE BASED ON HISTORY OF AN UNTREATED LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) GREATER THAN 500 MG/DL AND EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) IN BOTH PARENTS.

Pending CMS Approval

AGE RESTRICTION
MUST BE AT LEAST 1 YEAR OF AGE

PRESCRIBER RESTRICTION
LIDIPOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF FAILURE TO ADEQUATELTY CONTROL LDL LEVELS WITH A MAXIMUM TOLERATED STATIN THERAPY (IF STATIN TOLERANT) TO LESS THAN 130 MG/DL IN

PEDIATRIC PATIENTS 1 TO 18 YEARS OF AGE OR LESS THAN 100 MG/DL IN ADULTS WITHOUT CVD OR LESS THAN 70 MG/DL IN ADULTS WITH ESTABLISHED CVD. FOR PATIENTS 10 YEARS AND OLDER: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO EVOLOCUMAB (REPATHA). FOR PATIENTS 18 YEARS AND OLDER: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO EVOLOCUMAB (REPATHA) OR ALIROCUMAB (PRAULENT). FOR REQUESTS FOR USE IN COMBINATION WITH JUXTAPID: DOCUMENTATION OF FAILURE TO ADEQUATELY CONTROL LDL LEVELS WITH A MINIMUM 6-MONTH TRIAL OF MAXIMUM TOLERATED JUXTAPID DOSE WITHOUT CONCOMIITANT USE OF EVKEEZA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY AND THAT THERAPY WITH EVKEEZA IS EFFECTIVE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

EVRYSDI(GHP2027)

MEDICATION(S)
EVRYSDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of 5q Spinal Muscular Atrophy (SMA) confirmed by genetic testing with either one of the following: 1)Homozygous exon 7 gene deletion, 2) Homozygous exon 7 conversion mutation OR 3) compound heterozygous exon 7 mutation OR documentation of diagnostic testing confirming zero SMN1 copies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST OR PEDIATRIC NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that patient has not received prior treatment with gene therapy (such as, but not limited to Zolgensma) AND documentation that member will not receive routine concomitant SMN modifying therapy (such as, but not limited to Spinraza). Reauthorization will require documentation of medical necessity AND documentation that member has not received prior treatment with gene therapy AND documentation that member will not receive routine concomitant SMN modifying therapy.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EXDENSUR(GHP2027)

MEDICATION(S)
EXDENSUR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of severe eosinophilic asthma AND documentation that medication is being used as add-on maintenance treatment. Documentation of a blood eosinophil count of 150 cell/mcL or greater within 3 months of starting therapy or documentation of a blood eosinophil count of 300 cells/mcL or greater during the 12-month period before screening

AGE RESTRICTION
MUST BE 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, OR PULMONOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH ANOTHER BIOLOGIC MEDICATION INDICATED FOR ASTHMA TREATMENT (e.g., DUPILUMAB, OMALIZUMAB, MEPOLIZUMAB, TEZEPELUMAB, RESLIZUMAB OR BENRALIZUMAB). DOCUMENTATION OF CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST A 3-MONTH TRIAL OF HIGH-DOSE INHALED CORTICOSTEROIDS AND/OR ORAL SYSTEMIC CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST OR ONE EXACERBATION IN THE PREVIOUS 12 MONTHS REQUIRING ADDITIONAL MEDICAL TREATMENT (ORAL CORTICOSTEROIDS, EMERGENCY DEPARTMENT

Pending CMS Approval

OR URGENT CARE VISTIS, OR HOSPITALIZATION) DESPITE CURRENT THERAPY OR INTOLERANCE TO INHALED CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

EXJADE(GHP2027)

MEDICATION(S)
DEFERASIROX 125 MG TAB SOL, DEFERASIROX 250 MG TAB SOL, DEFERASIROX 500 MG TAB SOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) OR diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia

AGE RESTRICTION
for transfusional hemosiderosis: must be 2 years of age or older. For non-transfusional dependent thalassemia: must be 10 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
For transfusional hemosiderosis: documentation of a serum ferritin level greater than 1000 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 500 MCG/L, but decreased from baseline. For non-transfusion dependent thalassemia: documentation of LIC (liver iron concentration) greater than 5 milligrams of iron per gram of dry liver tissue weight (FE/Gdw) AND serum ferritin greater than 300 MCG/L. Continuation of coverage requires documentation of a serum ferritin level greater than 300 MCG/L, but decreased from baseline.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EXONDYS(GHP2027)

MEDICATION(S)
EXONDYS 51

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF DUCHENNE'S MUSCULAR DYSTROPHY CONFIRMED BY GENETIC TESTING WITH MUTATION OF THE DMD GENE THAT IS AMENABLE BY EXON 51 SKIPPING AND DOCUMENTATION THAT MEDICATION IS BEING GIVEN CONCURRENTLY WITH ORAL CORTICOSTEROIDS AND DOCUMENTATION THAT THE PATIENT IS AMBULATORY (ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND) AS PROVEN BY DOCUMENTATION OF A 6-MINUTE WALK TEST DISTANCE WITHIN THE PAST 3 MONTHS OF INITIATION OF EXONDYS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST OR GENETIC SPECIALIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE CONTINUED CONCURRENT USE WITH ORAL CORTICOSTEROIDS AND DOCUMENTATION THAT THE PATIENT REMAINS AMBULATORY AS PROVEN BY DOCUMENTATION OF A FOLLOW UP 6 MINUTE WALK TEST DISTANCE WITHIN THE PAST 6 MONTHS

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

EXXUA(GHP2027)

MEDICATION(S)
EXXUA, EXXUA TITRATION PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS OF AGE

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FABHALTA(GHP2027)

MEDICATION(S)
FABHALTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Paroxysmal Nocturnal Hemoglobin (PNH). Diagnosis of primary Immunoglobulin A Nephropathy (IgAN) AND documentation that Fabhalta will be used for reduction of proteinuria in those at risk of rapid disease progression (such as but not limited to a urine protein to creatinine ratio (UPCR) of greater than or equal to 1.5 g/g or proteinuria greater than or equal to 1 g/day).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For IgAN: Documentation of a therapeutic failure on, intolerance to, or contraindication to Filspari. Reauthorizations will require documentation or provider attestation of continued disease improvement.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FABIOR(GHP2027)

MEDICATION(S)
FABIOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acne, acne vulgaris, or adult onset acne.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to two formulary topical retinoids, including but not limited to adapalene and tretinoin.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FABRAZYME(GHP2027)

MEDICATION(S)
FABRAZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF FABRY DISEASE

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST WITH EXPERIENCE TREATING FABRY DISEASE

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FARYDAK(GHP2027)

MEDICATION(S)
FARYDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FASENRA(GHP2027)

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of severe eosinophilic asthma AND documentation that medication is being used as add-on maintenance treatment. Documentation of a blood eosinophil count of 150 cell/mcL or greater within 3 months of starting therapy. DIAGNOSIS OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA) CONFIRMED BY BIOPSY EVIDENCE OF VASCULITIS AND 4 OR MORE OF THE FOLLOWING CRITERIA: ASTHMA, EOSINOPHILIA, MONONEUROPATHY OR POLYNEUROPATHY, MIGRATORY OR TRANSIENT PULMONARY OPACITIES DETECTED RADIOGRAPHICALLY, PARANASAL SINUS ABNORMALITY OR BIOPSY CONTAINING A BLOOD VESSEL SHOWING THE ACCUMULATION OF EOSINOPHILS IN EXTRAVASCULAR AREAS.

Pending CMS Approval

AGE RESTRICTION
ASTHMA: 6 years of age or older, EGPA: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR ASTHMA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST. FOR EGPA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST, OR RHEUMATOLOGIST.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT FASENRA IS NOT BEING USED IN COMBINATION WITH DUPILUMAB, OMALIZUMAB, MEPOLIZUMAB, TEZEPELUMAB, DEPEMOKIMAB, OR RESLIZUMAB. FOR ASTHMA: DOCUMENTATION OF CONTRAINDICATION, INTOLERANCE TO, OR POORLY

CONTROLLED SYMPTOMS DESPITE AT LEAST A 3-MONTH TRIAL OF MAXIMALLY TOLERATED INHALED CORTICOSTEROIDS AND/OR ORAL SYSTEMIC CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST OR ONE EXACERBATION IN THE PREVIOUS 12 MONTHS REQUIRING ADDITIONAL MEDICAL TREATMENT (ORAL CORTICOSTEROIDS, EMERGENCY DEPARTMENT OR URGENT CARE VISTIS, OR HOSPITALIZATION) DESPITE CURRENT THERAPY OR INTOLERANCE TO INHALED CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST. FOR EGPA: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO SYSTEMIC GLUCOCORTICOID THERAPY. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FENSOLVI(GHP2027)

MEDICATION(S)
FENSOLVI (6 MONTH)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CENTRAL PRECOCIOUS PUBERTY (CPP).

AGE RESTRICTION
2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LUPRON DEPOT-PED (1 MONTH) AND TRIPTODUR.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FERRIPROX(GHP2027)

MEDICATION(S)
DEFERIPRONE, FERRIPROX 100 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF TRANSFUSIONAL IRON OVERLOAD DUE TO ONE OF THE FOLLOWING: 1)THALASSEMIA SYNDROMES or 2) SICKLE CELL DISEASE OR OTHER ANEMIAS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO EXJADE. DOCUMENTATION OF ANC GREATER THAN 1.5 X 1000000000 (10 TO THE 9TH POWER)/L. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF SERUM FERRITIN LEVEL GREATER THAN 300 MCG/L.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FETROJA(GHP2027)

MEDICATION(S)
FETROJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF COMPLICATED URINARY TRACT INFECTION, INCLUDING PYELONEPHRITIS CAUSED BY THE FOLLOWING SUCEPTIBLE GRAM NEGATIVE MICROORGANISMS: ESCHERICHIA COLI, KLEBSIELLA PENUMONIAE, PROTEUS MIRABILIS, PSEUDOMONAS AERUGINOSA, OR ENTEROBACTER CLOACAE COMPLEX. DOCUMENTATION OF HOSPITAL ACQUIRED BACTERIAL PNEUMONIA (HABP) OR VENTILATOR ASSOCIATED BACTERIAL PNEUMONIA (VABP) CAUSED BY THE FOLLOWING SUSCEPTIBLE GRAM NEGATIVE MICROORGANISMS: ACINETOBACTER BAUMANNII COMPLEX, ESCHERICHIA COLI, KLEBSIELLA PENUMONIAE, PSEUDOMONAS AERUGINOSA, SERRATIA MARCESCENS , OR ENTEROBACTER CLOACAE COMPLEX.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

COVERAGE DURATION
2 WEEKS

OTHER CRITERIA
DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO PREFERRED ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO

OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

FETZIMA(GHP2027)

MEDICATION(S)
FETZIMA, FETZIMA TITRATION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FILSPARI(GHP2027)

MEDICATION(S)
FILSPARI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF PRIMARY IMMUNOGLOBULIN 1 NEPHROPATHY (IgAN) VERIFIED BY BIOPSY.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEPHROLOGIST

COVERAGE DURATION
9 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT MEMBER IS AT HIGH RISK OF DISEASE PROGRESSION AND DOCUMENTATION THAT MEMBER HAS RECEIVED A STABLE DOSE OF A RAS INHIBITOR AT A MAXIMALLY TOLERATED DOSE FOR AT LEAST 90 DAYS AND DOCUMENTATION THAT RAS INHIBITORS WILL BE DISCONTINUED PRIOR TO INITIATION OF TREATMENT WITH FILSPARI AND DOCUMENTATION THAT FILSPARI WILL NOT BE USED IN COMBINATION WITH ANY RAS INHIBITORS, ENDOTHELIN RECEPTOR ANTAGONISTS, OR ALISKIREN. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION ACCORDING TO PRESCRIBER (I.E., DECREASED LEVELS OF PROTEINURIA FROM BASELINE OR DECREASED UPCR FROM BASELINE) AND DOCUMENTATION THAT FILSPARI WILL NOT BE USED IN COMBINATION WITH ANY RAS

Pending CMS Approval

INHIBITORS, ENDOTHELIN RECEPTOR ANTAGONISTS, OR ALISKIREN.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

FINTEPLA(GHP2027)

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF DRAVET SYNDROME OR A DIAGNOSIS OF LENNOX-GASTAUT SYNDROME

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR DRAVET SYNDROME: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES USED FOR THE TREATMENT OF DRAVET SYNDROME, INCLUDING BUT NOT LIMITED TO CANNABIDIOL, CLOBAZAM, VALPROATE, AND TOPIRAMATE. FOR LENNOX-GASTAUT SYNDROME: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES USED FOR THE TREATMENT OF LENNOX-GASTAUT SYNDROME, INCLUDING BUT NOT LIMITED TO CANNABIDIOL, CLOBAZAM, LAMOTRIGINE, FELBAMATE, CLONAZEPAM, RUFINIMIDE AND TOPIRAMATE.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

FIRAZYR(GHP2027)

MEDICATION(S)
ICATIBANT ACETATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS OF AGE

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
DOCUMENTATION THAT ICATIBANT IS BEING USED FOR TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACK. DOCUMENTATION THAT ICATIBANT IS NOT BEING USED IN COMBINATION WITH OTHER APPROVED TREATMENTS FOR ACUTE HAE ATTACKS. Reauthorization will require documentation of continued follow up or assessment by provider since last authorization and documentation that icatibant is not being used in combination with other approved treatments for acute HAE attacks.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

FIRDAPSE(GHP2027)

MEDICATION(S)
FIRDAPSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Lambert-Eaton Myasthenic Syndrome confirmed by one of the following: post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value OR high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent OR positive anti-P/Q type voltage-gated calcium channel antibody test.

AGE RESTRICTION
MUST BE 6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION or PRESCRIBER ATTESTATION OF MEDICAL NECESSITY AND THAT THE MEMBER WILL BENEFIT FROM CONTINUED THERAPY.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

FLECTOR(GHP2027)

MEDICATION(S)
DICLOFENAC EPOLAMINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF USE FOR THE TREATMENT OF ACUTE PAIN DUE TO MINOR STRAINS, SPRAINS, CONTUSIONS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 WEEKS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FORTEO(GHP2027)

MEDICATION(S)
TERIPARATIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PRIMARY, HYPOGONADAL, OR GLUCOCORTICOID INDUCED OSTEOPOROSIS IN MALES or POSTMENOPAUSAL or GLUCOCORTICOID INDUCED OSTEOPOROSIS IN FEMALES. DOCUMENTATION THAT MEMBER HAS NOT PREVIOUSLY BEEN ON A PARATHYROID HORMONE ANALOG FOR GREATER THAN 2 YEARS or DOCUMENTATION THAT MEMBER REMAINS AT OR RETURNS TO HAVING A HIGH RISK FOR FRACTURE

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
24 MONTHS

OTHER CRITERIA
DOCUMENTATION OF AN ATTEMPT OF THERAPY WITH OR CONTRAINDICATION TO BISPHOSPHONATES or EITHER A PREVIOUS OSTEOPOROTIC FRACTURE OR HIGH RISK OF FRACTURE (T-SCORE LESS THAN -2.5 WITH DOCUMENTED RISK FACTORS). Duration of teriparatide therapy should not exceed 2 years, if requesting use beyond 2 years of therapy: documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

FOTIVDA(GHP2027)

MEDICATION(S)
FOTIVDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FROVATRIPTAN(GHP2027)

MEDICATION(S)
FROVATRIPTAN SUCCINATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to treatment with two formulary triptan agents (almotriptan, naratriptan, rizatriptan, sumatriptan, or zolmitriptan).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

FRUZAQLA(GHP2027)

MEDICATION(S)
FRUZAQLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FYARRO(GHP2027)

MEDICATION(S)
FYARRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

FYCOMPA(GHP2027)

MEDICATION(S)
PERAMPANEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PARTIAL ONSET SEIZURES OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: carbamazepine, divalproex, valproic acid, felbamate, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, tiagabine, topiramate, zonisamide, pregabalin, vigabatrin, Aptiom, lacosamide

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

GAMIFANT(GHP2027)

MEDICATION(S)
GAMIFANT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PRIMARY HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH) BASED ON ONE OF THE FOLLOWING: 1) A MOLECULAR DIAGNOSIS (HLH GENE MUTATIONS) OR 2) A FAMILY HISTORY CONSISTENT WITH PRIMARY HLH (X-LINKED LYMPHOPROLIFERATIVE SYNDROME) OR 3) FULLFILLMENT OF AT LEAT 5 OF THE FOLLOWING CRITERIA: FEVER GREATER THAN 38.5C, SPLENOMEGALY (CYTOPENIAS AFFECTING 2 OF 3 LINEAGES IN THE PERIPHERAL BLOOD (HEMOGLOBIN LESS THAN 9 G/DL (OR LESS THAN 10 G/DL FOR INFANTS AGED LESS THAN 4 WEEKS OLD), PLATELETS LESS THAN 100X10 TO THE 9TH/L, NEUTROPHILS LESS THAN 1X10 TO THE 9TH/L)), HYPERTRIGLYCERIDEMIA (FASTING TRIGLYCERIDES GREATER THAN 3 MMOL/L OR GREATER THAN 265 MG/DL AND/OR HYPERFIBRINOGENEMIA (LESS THAN OR EQUAL TO 1.5 G/DL)), HEMOPHAGOCYTOSIS IN BONE MARROW, SPLEEN, OR LYMPH NODES WITH NO EVIDENCE OF MALIGNANCY, LOW OR ABSENT NK-CELL ACTIVITY, FERRITIN GREATER THAN OR EQUAL TO 500 MCG/L, SOLUBLE CD25 LEVEL (I.E. SOLUBLE IL-2 RECEPTOR) OR GREATER THAN OR EQUAL TO 2400 U/ML.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
UNCONFIRMED MOLECULAR DX: 4 WEEKS. CONFIRMED DX: 6 MONTHS. 6 MONTH REAUTH

OTHER CRITERIA

DOCUMENTATION OF REFRACTORY, RECURRENT OR PRORESSIVE DISEASE OR INTOLERANCE WITH CONVENTIONAL HLH THERAPY (SUCH AS, BUT NOT LIMITED TO ETOPOSIDE, DEXAMETHASONE, CYCLOSPORINE A, INTRATHECAL METHOTREXATE). REAUTHORIZATION WITHOUT A CONFIRMED MOLECULAR DIAGNOSIS WILL REQUIRE DOCUMENTATION OF PRIMARY HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS BASED ON MOLECULAR DIAGNOSIS (HLH MUTATION) AND DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION FOLLOWING A CONFIRMED MOLECULAR DIAGNOSIS WILL REQUIE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

GATTEX(GHP2027)

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SHORT BOWEL SYNDROME

AGE RESTRICTION
MUST BE AT LEAST 1 YEAR OF AGE

PRESCRIBER RESTRICTION
GASTROENTEROLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT THE MEMBER IS DEPENDENT ON PARENTERAL NUTRITION/INTRAVENOUS SUPPORT. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT SUCH BUT NOT LIMITED TO A DECREASE OF PARENTERAL NUTRITION/INTRAVENOUS SUPPORT, ENTERAL AUTONOMY, OR REDUCTION IN PARENTERAL SUPPORT INFUSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

GAVRETO(GHP2027)

MEDICATION(S)
GAVRETO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of RET Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

GAZYVA(GHP2027)

MEDICATION(S)
GAZYVA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist. Lupus nephritis: rheumatologist or nephrologist

COVERAGE DURATION
Oncology Dx: 6 MONTHS, Lupus nephritis: 12 MONTHS.

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements. For lupus nephritis: 1) diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy and 2) Documentation that medication will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, or azathioprine). Reauthorization for Lupus nephritis will require documentation or attestation of a positive clinical response to therapy (e.g., improvement or stabilization in UPCR, eGFR, or renal-related events) AND documentation that medication will continue to be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, or azathioprine).

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

GCSF(GHP2027)

MEDICATION(S)
NEUPOGEN, NIVESTYM, RELEUKO 300 MCG/0.5ML SOLN PRSYR, RELEUKO 480 MCG/0.8ML SOLN PRSYR, ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE

REQUIRED MEDICAL INFORMATION
PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME. FOR STEM CELL TRANSPLANTATION WHEN ONE OF THE FOLLOWING IS MET: DOCUMENTATION OF NON-MYELOID MALIGNANCY UNDERGOING MYELOABLATIVE CHEMOTHERAPY FOLLOWED BY AUTOLOGOUS OR ALLOGENIC BONE MARROW TRANSPLANTATION or USED FOR MOBILIZATION OF AUTOLOGOUS HEMATOPOIETIC PROGENITOR CELLS INTO THE PERIPHERAL BLOOD FOR COLLECTION BY LEUKAPHARESIS. AML RECEIVING INDUCTION OR CONSOLIDATION THERAPY. FOR SEVERE CHRONIC NEUTROPENIA WHEN THE FOLLOWING ARE MET: DX OF CONGENITAL, CYCLIC OR IDIOPATHIC NEUTROPENIA and ABSOLUTE NEUTROPHIL COUNT IS LESS THAN 500 CELLS/MM3 ON THREE SEPARATE OCCASIONS DURING A 6 MONTH PERIOD OR FIVE CONSECUTIVE DAYS OF ANC LESS THAN 500 CELLS/MM3 PER CYCLE and DOCUMENTATION OF INFECTION, FEVER OR OROPHARYNGEAL ULCER DURING THE PAST 12 MONTHS.

AGE RESTRICTION
N/A

Pending CMS Approval

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

GCSF LA(GHP2027)

MEDICATION(S)
FULPHILA, FYLNETRA, NEULASTA 6 MG/0.6ML SOLN PRSYR, NYVEPRIA, STIMUFEND, UDENYCA, UDENYCA ONBODY, ZIEXTENZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE

REQUIRED MEDICAL INFORMATION
PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME. Documentation of Hematopoietic syndrome of Acute Radiation Syndrome (HSARS) with documentation of an acute exposure to myelosuppressive doses of radiation.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
HSARS: 14 days. All others: 6 months.

OTHER CRITERIA
ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE,

BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CRCL LESS THAN 50 ML/MIN).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

GENOTROPIN(GHP2027)

MEDICATION(S)
GENOTROPIN, GENOTROPIN MINIQUICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

GILOTRIF(GHP2027)

MEDICATION(S)
GILOTRIF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

GIVLAARI(GHP2027)

MEDICATION(S)
GIVLAARI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ACUTE HEPATIC PORPHYRIA (AHP), INCLUDING ACUTE INTERMITTENT PORPHYRIA (AIP), HEREDITARY COPROPORPHYRIA (HCP), VARIEGATE PORPHYRIA (VP), AND AMINOLEVULINIC ACID DEHYDRATASE (ALAD) PORPHYRIA (ADP) CONFIRMED MY AT LEAST ONE OF THE FOLLOWING: 1)ELEVATED URINARY OR PLASMA AMINOLEVULINIC ACID (ALA) OR 2)ELEVATED URINARY OR PLASMA PORPHOBILINOGEN (PBG) OR 3) GENETIC TESTING CONFIRMING A MUTATION ASSOCIATED WITH ACUTE HEPATIC PORPHYRIA (AHP).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
SPECIALIST WITH EXPERIENCE MANAGING PORPHYRIAS (I.E., HEMATOLOGIST, HEPATOLOGIST OR GASTROENTEROLOGIST)

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
DOCUMENTATION OF THE BASELINE NUMBER OF PORPHYRIA ATTACKS REQUIRING HOSPITALIZATION, URGENT HEALTHCARE VISIT, OR IV HEMIN TREATMENT WITHIN THE PREVIOUS 6 MONTHS AND DOCUMENTATION OF ACTIVE DISEASE WITH AT LEAST TWO DOCUMENTED PORPHYRIA ATTACKS WITH THE PREVIOUS 6 MONTHS. REUATHORIZATION WILL REQUIRE DOCUMENTATION OF A CLINICALLY SIGNIFICANT RESPONSE TO TREATMENT

Pending CMS Approval

AS EVIDENCED BY: 1) A REDUCTION IN THE NUMBER OF PORPHYRIA ATTACKS REQUIRING HOSPITALIZATION, URGENT HEALTHCARE VISIT, OR IV HEMIN TREATMENT WITHIN THE PREVIOUS 6 MONTHS FROM BASELINE OR 2) DECREASED SEVERITY IN THE SYMPTOMS OF ACUTE HEPATIC PORPHYRIA, OR 3) A REDUCTION IN THE LEVELS OF URINARY OR PLASMA AMINOLEVULINIC ACID (ALA) OR URINARY OR PLASMA PORPHOBILINOGEN (PBG).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

GOMEKLI(GHP2027)

MEDICATION(S)
GOMEKLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of Neurofibromatosis type 1 as defined by having either (1) two of the following, or (2) a parent with neurofibromatosis type 1 with one of the following: 1) Six or more café-au-lait macules (more than 5 mm diameter in prepubertal individuals and more than 15 mm in post-pubertal individuals), 2) Freckling in axillary or inguinal regions, 3) two or more neurofibromas of any type or one plexiform neurofibroma, 4) optic pathway glioma, 5) two or more Lisch nodules (iris hamartomas) or two or more choroidal abnormalities, 6) a distinctive bony lesion (i.e., sphenoid dysplasia) anterolateral bowing of the tibia, or long bone pseudoarthritis, or 7) a heterozygous pathogenic NF1 variant allele fraction of 50% in apparently normal tissue. Documentation of symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

Pending CMS Approval

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
WRITTEN BY OR IN CONSULTATION WITH AN ONCOLOGIST, NEUROLOGIST OR GENETICIST

COVERAGE DURATION
6 Months

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

GRAFAPEX(GHP2027)

MEDICATION(S)
GRAFAPEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) AND documentation that medication will be used in combination with fludarabine as a preparative regimen for allogeneic stem cell transplantation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
1 MONTH

OTHER CRITERIA
Documentation that member has not received a prior allogeneic hematopoietic stem cell transplantation.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

GROWTH HORMONE(GHP2027)

MEDICATION(S)
NORDITROPIN FLEXPRO 30 MG/3ML SOLN PEN, NUTROPIN AQ NUSPIN 10, NUTROPIN AQ NUSPIN 20, NUTROPIN AQ NUSPIN 5

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

HAEGARDA(GHP2027)

MEDICATION(S)
HAEGARDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
MUST BE 6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
If being used for prophylaxis: documentation that medication is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze), berotralstat (Orladeyo) or lanadelumab (Takhzyro) therapy for hereditary angioedema. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

HALAVEN(GHP2027)

MEDICATION(S)
ERIBULIN MESYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

HERNEXEOS(GHP2027)

MEDICATION(S)
HERNEXEOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of HER2 (ERBB2) tyrosine kinase activating mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

HETLIOZ(GHP2027)

MEDICATION(S)
TASIMELTEON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF NON-24-HOUR SLEEP-WAKE DISORDER (FREE-RUNNING DISORDER) AND DOCUMENTATION THAT THE MEMBER IS TOTALLY BLIND WITH NO PERCEPTION OF LIGHT. DOCUMENTATION OF A DIAGNOSIS OF NIGHTTIME SLEEP DISTURBANCES IN SMITH-MAGENIS SYNDROME (SMS).

AGE RESTRICTION
SLEEP WAKE DISORDER:18 YRS OF AGE OR OLDER. SMS: 16 YRS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATION FOR NON-24-HOUR SLEEP WAKE DISORDER WILL REQUIRE DOCUMENTATION OF PROVER ASSESSED INCREASE IN NIGHTTIME SLEEP OR A DECREASE IN DAYTIME SLEEP. REAUTHORIZATION FOR SMS WILL REQUIRE DOCUMENTATION OF PROVIDER ASSESSED INCREASE IN NIGHTTIME SLEEP OR A DECREASE IN NIGHTTIME SLEEP DISTURBANCES.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

HUMATROPE(GHP2027)

MEDICATION(S)
HUMATROPE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

HYRNUO(GHP2027)

MEDICATION(S)
HYRNUO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IBRANCE(GHP2027)

MEDICATION(S)
IBRANCE 100 MG TAB, IBRANCE 125 MG CAP, IBRANCE 125 MG TAB, IBRANCE 75 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, hormone receptor expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IBTROZI(GHP2027)

MEDICATION(S)
IBTROZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 Months

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ICLUSIG(GHP2027)

MEDICATION(S)
ICLUSIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
For CML and Ph+ ALL: Documentation of T315I mutation expression (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ICOTYDE(GHP2027)

MEDICATION(S)
ICOTYDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 3% OR GREATER INVOLVEMENT OF BODY SURFACE AREA OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, SCALP, OR GENITALS.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF A MEMBER WEIGHT OF AT LEAST 40 KG. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY (SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE) OR PHOTOTHERAPY. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

IDHIFA(GHP2027)

MEDICATION(S)
IDHIFA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of IDH2 mutation expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ILARIS(GHP2027)

MEDICATION(S)
ILARIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DIAGNOSIS OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS) AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. DIAGNOSIS OF SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) AND MEDICAL RECORD DOCUMENTATION OF ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) DIAGNOSED PRIOR TO AGE 16 YEARS, CHARACTERIZED BY GREATER OR EQUAL TO 2 JOINTS WITH ACTIVE ARTHRITIS AND SPIKING, INTERMITTENT FEVER (GREATER THAN 38 DEGREES C) WITHOUT INFECTIOUS CAUSE AND CRP GREATER THAN 30 MG/DL). DIAGNOSIS OF TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME (TRAPS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE TNFRSF1A GENE MUTATION. DIAGNOSIS OF HYPERIMMUNOGLOBULIN D SYNDROME (HIDS) OR MEVALONATE KINASE DEFICIENCY (MKD) WITH DOCUMENTATION OF ELEVATED IGG D LEVEL OR GENETIC TESTING TO IDENTIFY THE MVK GENE MUTATION. DIAGNOSIS OF FAMILIAL MEDITERRANEAN FEVER (FMF) AS CONFIRMED BY GENETIC TESTING TO IDENTIFY THE MEFV GENE MUTATION. DIAGNOSIS OF ADULT ONSET STILL'S DISEASE DIAGNOSED AFTER AGE 16 YEARS WITH ACTIVE DISEASE CHARACTERIZED BY DISEASE ACTIVITY BASED ON DISEASE ACTIVITY SCORE 28 (DAS28) OF 3.2 OR GREATER AND DOCUMENTATION OF AT LEAST 4 PAINFUL AND 4 SWOLLEN JOINTS AT SCREENING AND BASELINE. DIAGNOSIS OF ACUTE GOUT FLARE.

AGE RESTRICTION
CAPS: 4 YEARS OF AGE OR OLDER. SJIA: 2 YEARS OF AGE OR OLDER. GOUT: 18 YEARS OF AGE OR OLDER.

Pending CMS Approval

PRESCRIBER RESTRICTION

FOR CAPS, TRAPS, HIDS,MKD OR FMF: PRESCRIBED BY AN IMMUNOLOGIST, RHEUMATOLOGIST, DERMATOLOGIST OR ALLERGIST. FOR SJIA, STILLS, OR GOUT: PRESCRIBED BY A RHEUMATOLOGIST.

COVERAGE DURATION

FOR CAPS: 12 WEEKS THEN 1 YEAR. FOR GOUT: 3 MONTHS. FOR ALL OTHER INDICATIONS: 6 MONTHS THEN 1 YEAR.

OTHER CRITERIA

FOR SJIA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ACTEMRA. FOR FMF: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO COLCHICINE. FOR CAPS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO KINERET. FOR GOUT: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BOTH OF THE FOLLOWING: (1) 1 FORMULARY NSAID OR COLCHICINE AND (2) 1 FORMULARY CORTICOSTEROID. REAUTHORIZATION WITH REQUIRE CONTINUED IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF THE DISEASE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

IMBRUVICA(GHP2027)

MEDICATION(S)
IMBRUVICA 140 MG CAP, IMBRUVICA 140 MG TAB, IMBRUVICA 280 MG TAB, IMBRUVICA 420 MG TAB, IMBRUVICA 70 MG CAP, IMBRUVICA 70 MG/ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Transplant Specialist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR CLL/SLL: Documentation of 17p chromosome expression (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IMDELLTRA(GHP2027)

MEDICATION(S)
IMDELLTRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IMFINZI(GHP2027)

MEDICATION(S)
IMFINZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IMJUDO(GHP2027)

MEDICATION(S)
IMJUDO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IMKELDI(GHP2027)

MEDICATION(S)
IMKELDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, Dermatologist, or Allergist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IMPAVIDO(GHP2027)

MEDICATION(S)
IMPAVIDO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of one of the following: 1) Visceral leishmaniasis due to Leishmania donovani, 2) Cutaneous leishmaniasis due to Leishmania brazilienis, Leishmania guyanensis, or Leishmani panamensis, 3) Mucosal leishmaniasis due to Leishmania brazilienis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
By or in consultation with an infectious disease specialist

COVERAGE DURATION
28 days

OTHER CRITERIA
For visceral leishmaniasis: documentation of a therapeutic failure on, intolerance to, or contraindication to liposomal amphotericin B.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

INFLIXIMAB(GHP2027)

MEDICATION(S)
RENFLEXIS, ZYMFENTRA (1 PEN), ZYMFENTRA (2 PEN), ZYMFENTRA (2 SYRINGE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CROHN'S DISEASE- DIAGNOSIS OF MODERATE TO SEVERE CROHN'S OR CROHN'S WITH ACTIVE DRAINING FISTULAS AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTRA. RA - DIAGNOSIS OF MODERATE TO SEVERE RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND BEING USED IN CONJUNCTION WITH METHOTREXATE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF CHRONIC, SEVERE PLAQUE PSORIASIS WITH AT LEAST 3% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP, OR GENITALS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE PSA AND HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. ULCERATIVE COLITIS - DIAGNOSIS OF MODERATE TO SEVERE UC

Pending CMS Approval

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS OF AGE FOR THE FOLLOWING DIAGNOSES - RA, ANKYLOSING SPONDYLITIS, PLAQUE PSORIASIS, PSORIATIC ARTHRITIS. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS DISEASE AND ULCERATIVE COLITIS.

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTA. FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTRA. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 12 WEEK TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR DOCUMENTATION THAT INFLIXIMAB IS BEING PRESCRIBED TO INDUCE DISEASE REMISSION. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTA. FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTA. FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) or INFLECTA. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

INGREZZA(GHP2027)

MEDICATION(S)
INGREZZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of tardive dyskinesia as evidenced by either moderate to severe abnormal body movements (AIMS score 3 or 4) in at least 1 body area or mild abnormal body movements (AIMS score 1 or 2) in 2 or more body areas AND documentation of no other causes of involuntary movements AND documentation of baseline AIMS score prior to initiating therapy AND if TD is associated with the use of dopamine receptor–blocking agents, documentation of persistence of symptoms despite discontinuation or dosage reduction of dopamine receptor–blocking agent (or attestation by prescriber that discontinuation or dose reduction of the offending agent is not possible). DIAGNOSIS OF HUNTINGTON'S DISEASE AND DOCUMENTATION OF SYMPTOMS OF CHOREA AND DOCUMENTATION OF PATIENT'S BASELINE TOTAL MAXIMAL CHOREA SCORE PRIOR TO INITIATING THERAPY AND ONE OF THE FOLLOWING: (1) DOCUMENTATOIN THAT PATIENT WAS EVALUATED AND TREATED BY PSYCHIATRIST IF THERE IS HISTORY OF PRIOR SUICIDE ATTEMPT, BIPOLAR DISORDER, OR MDD OR (2) DOCUMENTATION OF MENTAL HEALTH EVALUATION PERFORMED BY PRESCRIBER.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH PSYCHIATRIST OR NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

FOR HD: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TETRABENAZINE. Reauthorization FOR TD will require documentation of improvement in condition as evidenced by a reduction from baseline AIMS score. REAUTHORIZATION FOR HD WILL REQUIRE AN IMPROVEMENT IN CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE AS EVIDENCED BY A REDUCTION IN THE TOTAL MAXIMAL CHOREA SCORE FROM BASELINE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

INJECTABLE ANTIPSYCHOTICS(GHP2027)

MEDICATION(S)
ZYPREXA RELPREVV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR ABILIFY MAINTENA - DIAGNOSIS OF SCHIZOPHRENIA or BIPOLAR I DISORDER AS MONOTHERAPY. FOR ARISTADA AND INVEGA TRINZA- DIAGNOSIS OF SCHIZOPHRENIA. FOR INVEGA SUSTENNA - DIAGNOSIS OF SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDERS AS MONOTHERAPY OR AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS. FOR RISPERIDONE ER INJECTION - SCHIZOPHRENIA OR BIPOLAR I DISORDER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS). FOR INVEGA TRINZA - DOCUMENTATION THAT THE PATIENT HAS BEEN ADEQUATELY TREATED WITH INVEGA SUSTENNA FOR AT LEAST 4 MONTHS.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

INLURIYO(GHP2027)

MEDICATION(S)
INLURIYO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR BREAST CANCER: Documentation of HER2 Protein expression and Hormone receptor expression or mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

INLYTA(GHP2027)

MEDICATION(S)
INLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

INQOVI(GHP2027)

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

INREBIC(GHP2027)

MEDICATION(S)
INREBIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentaion of platelet count. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

INSULIN CONCENTRATE(GHP2027)

MEDICATION(S)
HUMULIN R U-500 KWIKPEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF TYPE 1 OR TYPE 2 DIABETES MELLITUS. DOCUMENTATION THAT MEMBER REQUIRES MORE THAN 200 UNITS OF INSULIN PER DAY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS BEEN INSTRUCTED ON THE APPROPRIATE DOSING OF THE MEDICATION, INCLUDING THE DIFFERENCES BETWEEN U-500 AND U-100 INSULIN.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

INVEGA(GHP2027)

MEDICATION(S)
INVEGA SUSTENNA, INVEGA TRINZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR INVEGA TRINZA- DIAGNOSIS OF SCHIZOPHRENIA. FOR INVEGA SUSTENNA - DIAGNOSIS OF SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDERS AS MONOTHERAPY OR AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS). FOR INVEGA TRINZA - DOCUMENTATION THAT THE PATIENT HAS BEEN ADEQUATELY TREATED WITH INVEGA SUSTENNA FOR AT LEAST 4 MONTHS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

INVEGA HAFYERA(GHP2027)

MEDICATION(S)
INVEGA HAFYERA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT FORM OF MEDICATION. DOCUMENTATION THAT THE PATIENT HAS BEEN ADEQUATELY TREATED WITH INVEGA SUSTENNA FOR AT LEAST 4 MONTHS OR WITH INVEGA TRINZA FOR AT LEAST 3 MONTHS.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

IRESSA(GHP2027)

MEDICATION(S)
GEFITINIB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ISTODAX(GHP2027)

MEDICATION(S)
ROMIDEPSIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ISTURISA(GHP2027)

MEDICATION(S)
ISTURISA 1 MG TAB, ISTURISA 5 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Cushing's disease.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that pituitary surgery is not an option or has not been curative. Documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: ketoconazole, metopirone, Signifor, or Signifor LAR. Reauthorization will require documentation of continued disease improvement (such as and improvement in urinary free cortisol levels compared to baseline) or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ITOVEBI(GHP2027)

MEDICATION(S)
ITOVEBI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 protein expression, Hormone Receptor expression, PIK3CA gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ITRACONAZOLE(GHP2027)

MEDICATION(S)
ITRACONAZOLE 100 MG CAP, ITRACONAZOLE 10 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
POSITIVE CULTURE SUBSTANTIATING DIAGNOSIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR ONYCHOMYCOSIS: FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO TERBINAFINE

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

IVERMECTIN(GHP2027)

MEDICATION(S)
IVERMECTIN 3 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
TREATMENT OR PREVENTION OF COVID-19 INFECTION

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DIAGNOSIS OF STRONGYLOIDIASIS OF THE INTESTINAL TRACT (NON-DISSEMINATED), ONCHOCERCIASIS, OR USE FOR A MEDICALLY ACCEPTED INDICATION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IVIG(GHP2027)

MEDICATION(S)

ALYGLO, ASCENIV, BIVIGAM, CUTAQUIG, CUVITRU, FLEBOGAMMA DIF, GAMMAGARD, GAMMAGARD ERC, GAMMAGARD S/D LESS IGA, GAMMAKED, GAMMAPLEX, GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PANZYGA, PRIVIGEN, XEMBIFY

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

USE OF IVIG FOR THE FOLLOWING INDICATIONS IS CONSIDERED INVESTIGATIONAL AND WILL NOT BE COVERED: ALZHEIMER'S DISEASE, AMYOTROPHIC LATERAL SCLEROSIS, ATOPIC DERMATITIS, AUTISM, CHRONIC FATIGUE SYNDROME, CHRONIC MUCOCUTANEOUS CANDIDIASIS, COMPLEX REGIONAL PAIN SYNDROME, EPILEPSY, INCLUSION BODY MYOSITIS, LYME DISEASE, NEUROMYELITIS OPTICA (DEVIC'S DISEASE), OPTIC NEURITIS, PARAPROTEINEMIC DEMYELINATING NEUROPATHY, POST-POLIO SYNDROME, RECURRENT SPONTANEOUS MISCARRIAGE, RHEUMATIC FEVER, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS, SYSTEMIC LUPUS ERYTHEMATOSUS.

Pending CMS Approval

REQUIRED MEDICAL INFORMATION

PRIMARY IMMUNODEFICIENCY: DOCUMENTATION OF IG DEFICIENCY AND AN INABILITY TO AMOUNT AN IMMUNOLOGIC RESPONSE TO INCITING ANTIGENS AND DOCUMENTATION OF SEVERE INFECTIONS DESPITE TX WITH PROPHYLACTIC ANTIBIOTICS. ACUTE ITP: (1) ACTIVE BLEEDING AND PLATELET COUNT LESS THAN 30,000/MM3 OR PRE-OP TX PRIOR TO SURGICAL PROCEDURE OR DOCUMENTED HISTORY OF SIGNIFICANT BLEEDING AND A PLATELET COUNT OF LESS THAN 30,000/MM3 OR A PLATELET COUNT OF LESS THAN 20,000/MM3 AND (2) DOCUMENTATION OF USE WITH A CORTICOSTEROID OR A CONTRAINDICATION OR FAILURE ON CORTICOSTEROID. CHRONIC ITP: (1) DURATION OF IMMUNE THROMBOCYTOPENIA (ITP) GREATER THAN 12 MONTHS AND (2) NO CONCURRENT ILLNESS OR DISEASE EXPLAINING THROMBOCYTOPENIA AND (3) ACTIVE BLEEDING AND A PLATELET COUNT LESS THAN 30,000/MM3 OR DOCUMENTED HISTORY OF SIGNIFICANT BLEEDING AND A PLATELET COUNT OF LESS THAN 30,000/MM3 OR A PLATELET COUNT OF LESS THAN 20,000/MM3 OR AS A PREOPERATIVE TREATMENT PRIOR TO MAJOR INVASIVE

SURGICAL PROCEDURES. CLL: DX OF CLL, AND IGG LEVEL LESS THAN 500 MG/DL, AND HX OF BACTERIAL INFECTION REQUIRING ORAL OR IV ABX TX W/IN LAST 6 MONTHS. CIDP: DX OF CIDP, DOCUMENTED EVIDENCE OF FOCAL OR SYMMETRIC NEUROLOGIC DEFICITS THAT ARE PROGRESSIVE OR RELAPSING OVER 12 WEEKS OR LONGER, AND EMG ABNORMALITIES CONSISTENT WITH CIDP. MMN: SYMPTOMATIC DISEASE FOR A MIN. OF 2 MONTHS WITH FINDINGS OF CONDUCTION BLOCK ON A SINGLE NERVE OR PROBABLE CONDUCTION BLOCK IN 2 OR MORE NERVES OR NORMAL SENSORY NERVE CONDUCTION IN UPPER LIMB SEGMENTS AND NORMAL SENSORY NERVE ACTION POTENTIAL AMPLITUDE. KAWASAKI: MUST BEGIN TX W/IN 10 DAYS OF THE ONSET OF FEVER.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

FOR CIDP AND MULTIFOCAL MOTOR NEUROPATHY: MUST BE PRESCRIBED BY A NEUROLOGIST OR RHEUMATOLOGIST

COVERAGE DURATION

6 MONTHS.

OTHER CRITERIA

IVIG MAY BE COVERED UNDER MEDICARE PART B OR MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. CONTINUATION OF COVERAGE WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF A MEAURABLE RESPONSE OR IMPROVMENT IN SIGNS AND SYMPTOMS.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

IWILFIN(GHP2027)

MEDICATION(S)
IWILFIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

IXEMPRA(GHP2027)

MEDICATION(S)
IXEMPRA KIT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JADENU(GHP2027)

MEDICATION(S)
DEFERASIROX 180 MG PACKET, DEFERASIROX 180 MG TAB, DEFERASIROX 360 MG PACKET, DEFERASIROX 360 MG TAB, DEFERASIROX 90 MG PACKET, DEFERASIROX 90 MG TAB, DEFERASIROX GRANULES

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) OR diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia

AGE RESTRICTION
for transfusional hemosiderosis: must be 2 years of age or older. For non-transfusional dependent thalassemia: must be 10 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
For transfusional hemosiderosis: documentation of a serum ferritin level greater than 1000 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 500 MCG/L, but decreased from baseline. For non-transfusion dependent thalassemia: documentation of LIC (liver iron concentration) greater than 5 milligrams of iron per gram of dry liver tissue weight (FE/Gdw) AND serum ferritin greater than 300 MCG/L. Continuation of coverage requires documentation of a serum ferritin level greater than 300 MCG/L, but decreased from baseline.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

JAYPIRCA(GHP2027)

MEDICATION(S)
JAYPIRCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JELMYTO(GHP2027)

MEDICATION(S)
JELMYTO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JEMPERLI(GHP2027)

MEDICATION(S)
JEMPERLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JEVTANA(GHP2027)

MEDICATION(S)
JEVTANA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JIDEYTRO(GHP2027)

MEDICATION(S)
JIDEYTRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ROS-1 gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JOENJA(GHP2027)

MEDICATION(S)
JOENJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF ACTIVATED PHOSPHOINOSITIDE 3-KINASE DELTA SYNDROME (APDS) AND DOCUMENTATION OF WEIGHT GREATER THAN OR EQUAL TO 45 KG AND DOCUMENTATION OF MUTATION IN PIK3CD OR PIK3R1 GENE.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN SYMPTOMS OF APDS WHILE ON JOENJA THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JYLAMVO(GHP2027)

MEDICATION(S)
JYLAMVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

JYNARQUE(GHP2027)

MEDICATION(S)
TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Documentation of End Stage Renal Disease

REQUIRED MEDICAL INFORMATION
Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) as confirmed by cysts and family history or genetic testing AND documentation that the member is at high risk for rapidly progressing ADPKD.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
Nephrologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
For New Starts Only: Documentation of eGFR greater than or equal to 25 mL/min/1.73 m2. Risk for rapidly progressing ADPKD should be documented with one of the following: Mayo classification class 1C, 1D, or 1E OR Total kidney volume greater than 750 mL OR PROPKD score greater than 6 OR kidney length greater than 16.5 cm as measured by ultrasound (if CT and MRI contraindicated). Reauthorization will require documentation that continued therapy is medically appropriate and no documentation of progression to end-stage renal disease (ESRD).

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

KADCYLA(GHP2027)

MEDICATION(S)
KADCYLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KALBITOR(GHP2027)

MEDICATION(S)
KALBITOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT KALBITOR IS BEING USED TO TREAT AN ACUTE ATTACK OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR MEMBERS 18 YEARS OF AGE OR OLDER, FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ICATIBANT.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

KALYDECO(GHP2027)

MEDICATION(S)
KALYDECO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CYSTIC FIBROSIS AND DOCUMENTATION OF ONE MUTATION IN CFTR GENE THAT IS RESPONSIVE TO IVACAFTOR POTENTIATION PER PRODUCT LABELING AS EVIDENCED BY AN FDA CLEARED CF MUTATION TEST, AND DOCUMENTATION THAT THE PATIENT IS NOT HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KERENDIA(GHP2027)

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES. DOCUMENTATION OF HEART FAILURE WITH LEFT VENTRICULAR EJECTION FRACTION OF 40% OR MORE

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR HF: BY OR IN CONSULTATION WITH A CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
MEDICAL RECORD DOCUMENTATION OF SERUM POTASSIUM LESS THAN OR EQUAL TO 5.0 MEQ/L OR LESS THAN OR EQUAL TO 5.5 MEQ/L IF ALREADY ESTABLISHED ON THERAPY. FOR CKD DOCUMENTATION OF PERSISTENT ALBUMINURIA (ALBUMIN TO CREATININE RATIO CONSISTENTLY GREATER THAN 30 MG/G) DESPITE TREATMENT WITH MAXIMALLY TOLERATED ACE INHIBITOR OR ARB or DOCUMENTATION OF INTOLERANCE TO ACEI OR ARB. For Heart Failure: Documentation that member is inadequately controlled with a sodium glucose co-transporter-2 (SGLT-2) inhibitor OR has an intolerance to or contraindication to SGLT-2 inhibitor therapy

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

KEVZARA(GHP2027)

MEDICATION(S)
KEVZARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DX OF POLYMYALGIA RHEUMATICA (PMR) MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY/EUROPEAN UNION LEAGUE AGAINST RHEUMATISM (ACR/EULAR) CLASSIFICATION CRITERIA. DX OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA) MADE IN ACCORDANCE WITH THE INTERNATIONAL LEAGUE OF ASSOCIATIONS FOR RHEUMATOLOGY (ILAR) CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF pJIA.

Pending CMS Approval

AGE RESTRICTION
FOR RA AND PMR: 18 YEARS OF AGE OR OLDER. FOR pJIA: 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB

PRODUCT, RINVOQ, XELJANZ). FOR PMR: DOCUMENTATION OF ONE OF THE FOLLOWING: (1) THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SYSTEMIC CORTICOSTEROIDS OR (2) DOCUMENTATION THAT MEMBER IS UNABLE TO TOLERATE A CORTICOSTEROID TAPER. FOR pJIA: DOCUMENTATION OF WEIGHT GREATER THAN OR EQUAL TO 63 KG AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR pJIA (FORMULARY ADALIMUMAB PRODUCT, ENBREL, FORMULARY TOCILIZUMAB PRODUCT, RINVOQ, XELJANZ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

KEYTRUDA(GHP2027)

MEDICATION(S)
KEYTRUDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KEYTRUDA QLEX(GHP2027)

MEDICATION(S)
KEYTRUDA QLEX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, Nephrologist or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KHAPZORY(GHP2027)

MEDICATION(S)
KHAPZORY 175 MG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
INTOLERANCE TO OR CONTRAINDICATION TO PREFERRED LEVOLEUCOVORIN CALCIUM PRODUCTS.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

KIMMTRAK(GHP2027)

MEDICATION(S)
KIMMTRAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KINERET(GHP2027)

MEDICATION(S)
KINERET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF NEONATAL-ONSET MULTISYSTEM INFLAMMATORY DISEASE (NOMID). DX OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS), AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DIAGNOSIS OF DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) SUPPORTED BY DOCUMENTATION OF A HOMOZYGOUS OR COMPOUND HETEROZYGOUS MUTATION INVOLVING IL 1 RN (INTERLUEKIN 1 RECEPTOR ANTAGONIST GENE).

Pending CMS Approval

AGE RESTRICTION
FOR RA - MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR NOMID OR CAPS: PRESCRIBED BY IMMUNOLOGIST, RHEUMATOLOGIST, PEDIATRICIAN OR ALLERGIST. FOR RHEUMATOID ARTHRITIS: PRESCRIBED BY RHEUMATOLOGIST. FOR DIRA: RHEUMATOLOGIST, GENETICIST, DERMATOLOGIST OR A PHYSICIAN SPECIALIZING IN THE TREATMENT OF AUTOINFLAMMATORY DISORDERS.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RHEUMATOID ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB PRODUCT, RINVOQ, XELJANZ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

KISQALI(GHP2027)

MEDICATION(S)
KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (200 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, Hormone Receptor expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KLISYRI(GHP2027)

MEDICATION(S)
KLISYRI (250 MG), KLISYRI (350 MG)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of actinic keratosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to topical fluorouracil AND imiquimod.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

KOMZIFTI(GHP2027)

MEDICATION(S)
KOMZIFTI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KORLYM(GHP2027)

MEDICATION(S)
MIFEPRISTONE 300 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PREGNANCY

REQUIRED MEDICAL INFORMATION
DX OF ENDOGENOUS CUSHING'S SYNDROME AND DOCUMENTATION OF FAILED SURGICAL TREATMENT FOR CUSHING'S SYNDROME OR THAT PATIENT IS NOT A CANDIDATE FOR SURGERY. DOCUMENTATION OF A NEGATIVE PREGNANCY TEST WITHIN 14 DAYS OF INITIATING THERAPY IN WOMEN OF REPRODUCTIVE POTENTIAL

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KOSELUGO(GHP2027)

MEDICATION(S)
KOSELUGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of Neurofibromatosis type 1 as defined by having either (1) two of the following, or (2) a parent with neurofibromatosis type 1 with one of the following: 1) Six or more café-au-lait macules (more than 5 mm diameter in prepubertal individuals and more than 15 mm in post-pubertal individuals), 2) Freckling in axillary or inguinal regions, 3) two or more neurofibromas of any type or one plexiform neurofibroma, 4) optic pathway glioma, 5) two or more Lisch nodules (iris hamartomas) or two or more choroidal abnormalities, 6) a distinctive bony lesion (i.e., sphenoid dysplasia) anterolateral bowing of the tibia, or long bone pseudoarthritis, or 7) a heterozygous pathogenic NF1 variant allele fraction of 50% in apparently normal tissue. Documentation of symptomatic plexiform neurofibromas (PN) not amenable to complete resection.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
WRITTEN BY OR IN CONSULTATION WITH AN ONCOLOGIST, NEUROLOGIST OR GENETICIST

COVERAGE DURATION
6 Months

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

KRAZATI(GHP2027)

MEDICATION(S)
KRAZATI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of KRAS Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KRISTALOSE(GHP2027)

MEDICATION(S)
KRISTALOSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of therapeutic failure on, intolerance to, or contraindication to lactulose liquid.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

KRYSTEXXA(GHP2027)

MEDICATION(S)
KRYSTEXXA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CHRONIC, SYMPTOMATIC GOUT. DOCUMENTATION OF USE IN COMBINATION WITH ORAL METHOTREXATE OR INTOLERANCE TO OR CONTRAINDICATION TO METHOTREXATE. DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY XANTHINE OXIDASE INHIBITORS AT THE MAXIMUM MEDICALLY APPROPRIATE DOSE.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT HIGH-RISK PATIENTS (E.G., PATIENTS OF AFRICAN, MEDITERRANEAN AND SOUTHERN ASIAN ANCESTRY) HAVE BEEN SCREENED FOR G6PD DEFICIENCY. DOCUMENTATION THAT PRESCRIBED DOSE IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. REAUTHORIZATION WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND ONGOING URIC ACID LEVEL MONITORING PRIOR TO EACH INFUSION. THE TWO MOST RECENT URIC ACID LEVELS (FROM

Pending CMS Approval

WITHIN THE PAST 8 WEEKS) MUST BE SUBMITTED. IN INDIVIDUALS WHOSE URIC ACID LEVEL IS ABOVE 6 MG/DL FOR TWO CONSECUTIVE LAB DRAWS, THERAPY SHOULD BE DISCONTINUED AND REAUTHORIZATION WILL NOT BE APPROVED.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

KUVAN(GHP2027)

MEDICATION(S)
JAVYGTOR 500 MG PACKET, SAPROPTERIN DIHYDROCHLORIDE, ZELVYSIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
BASELINE BLOOD PHE LEVEL LESS THAN 360 UMOL/L.

REQUIRED MEDICAL INFORMATION
Diagnosis of hyperphenylalaninemia. Documentation of blood PHE levels

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST

COVERAGE DURATION
INITIALLY 2 MONTHS THEN EVERY 12 MONTHS IF PATIENT IS A RESPONDER

OTHER CRITERIA
INITIAL REAUTHORIZATION WILL REQUIRE A REDUCTION IN BLOOD PHE LEVELS FROM BASELINE or DOCUMENTATION OF AN INCREASE IN PHE TOLERANCE (such as addition of Phe in diet with stable Phe level). YEARLY REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF SUSTAINED REDUCTION IN BLOOD PHE LEVELS or DOCUMENTATION OF IMPROVEMENT IN NEUROPSYCHIATRIC SYMPTOMS or AN INCREASE IN PHE TOLERANCE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

KYPROLIS(GHP2027)

MEDICATION(S)
KYPROLIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LAMZEDE(GHP2027)

MEDICATION(S)
LAMZEDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF ALPHA-MANNOSIDOSIS SUPPORTED BY ONE OF THE FOLLOWING: (1) DOCUMENTATION OF ENZYME ASSAY DEMONSTRATING ALPHA-MANNOSIDASE ACTIVITY LESS THAN 10% OF NORMAL ACTIVITY (LESS THAN 0.54 NMOL/MIN/MG) OR (2) DOCUMENTATION OF MOLECULAR GENETIC TESTING THAT REVEALS PATHOGENIC VARIANTS IN THE MAN2B1 GENE. DOCUMENTATION THAT MEMBER IS BEING TREATED FOR NON-CENTRAL NERVOUS SYSTEM MANIFESTATIONS OF ALPHA-MANNOSIDOSIS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR BIOCHEMICAL GENETICIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINISTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION (I.E., IMPROVEMENT OR STABILIZATION IN MOTOR FUNCTION, IMPROVEMENT IN FORCED VITAL CAPACITY PERCENTAGE, REDUCTION IN FREQUENCY OF

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INFECTIONS, ETC.).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LAZCLUZE(GHP2027)

MEDICATION(S)
LAZCLUZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LENVIMA(GHP2027)

MEDICATION(S)
LENVIMA (10 MG DAILY DOSE), LENVIMA (12 MG DAILY DOSE), LENVIMA (14 MG DAILY DOSE), LENVIMA (18 MG DAILY DOSE), LENVIMA (20 MG DAILY DOSE), LENVIMA (24 MG DAILY DOSE), LENVIMA (4 MG DAILY DOSE), LENVIMA (8 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR ENDOMETRIAL CA: Documentation of DNA instability or defective mismatch repair genes. FOR HEPATOCELLULAR CA: Documentation of Child-Pugh liver disease stage. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LEQEMBI SQ(GHP2027)

MEDICATION(S)
LEQEMBI IQLIK, LEQEMBI IQLIK (500 MG DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Alzheimer's disease with evidence of amyloid beta pathology via PET scan or lumbar puncture

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist)

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that medication will not be used in combination with other monoclonal antibodies for the treatment of Alzheimer's disease. For initial approval: documentation of completion of at least 18 months of Leqembi intravenous therapy. Documentation confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the intitiation of intravenous Leqembi therapy AND documentation of either 1) Amyloid-related imaging abnormalities (ARIA) have not been observed OR 2) if ARIA has been observed: attestation from provider that continued therapy is medically necessary AND follow up MRI demonstrates radiographic resolution or stabilization. Reauthorization will require documentation of continued disease improvement or lack of disease progression AND documentation that medication is not being used with other monoclonal antibodies for the treatment of Alzheimer's

Pending CMS Approval

disease

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LEQVIO(GHP2027)

MEDICATION(S)
LEQVIO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HYPERLIPIDEMIA (INCLUDING HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA). DOCUMENTATION THAT LEQVIO IS BEING USED TO REDUCE LDL-C AS AN ADJUNCT TO DIET AND STATIN THERAPY. DOCUMENTATION OF A BASELINE LDL DRAWN WITHIN 3 MONTHS OF THE START OF THERAPY SHOWING ONE OF THE FOLLOWING: (1) LDL GREATER THAN 100 IF USING LEQVIO FOR PRIMARY PREVENTION OR (2) LDL GREATER THAN 70 IF USING LEQVIO FOR SECONDARY PREVENTION.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR INITIAL, 12 MONTH REAUTH

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO REPATHA AND PRALUENT. REAUTHORIZATION WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

LETAIRIS(GHP2027)

MEDICATION(S)
AMBRISENTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION. DOCUMENTATION OF ONE OF THE FOLLOWING: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL or DOCUMENTATION OF USE AS FIRST LINE THERAPY IN COMBINATION WITH ADCIRCA IN PATIENTS WITH WHO GROUP 1 PAH

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

LEUKINE(GHP2027)

MEDICATION(S)
LEUKINE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For acceleration of myeloid recovery in patients undergoing allogeneic bone marrow transplantation from HLA-matched related donors. For treatment of delayed or failed neutrophil recovery in patients who have undergone allogeneic or autologous bone marrow transplantation. For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis in patients undergoing autologous hematopoietic stem cell transplantation. In patients with AML receiving induction or consolidation therapy. Hematopoietic syndrome of acute radiation syndrome (H-ARS) with documentation of an acute exposure to myelosuppressive doses of radiation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LIBTAYO(GHP2027)

MEDICATION(S)
LIBTAYO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LIDODERM(GHP2027)

MEDICATION(S)
LIDOCAINE 5 % PATCH, LIDOCAN, TRIDACAINE II, TRIDACAINE III

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF POST-HERPETIC NEURALGIA

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LIFYORLI(GHP2027)

MEDICATION(S)
LIFYORLI (125 MG DOSE), LIFYORLI (150 MG DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LINEZOLID(GHP2027)

MEDICATION(S)
LINEZOLID 100 MG/5ML RECON SUSP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Vancomycin-Resistant Enterococcus (VRE) faecium infection which has been diagnosed and documented with Infectious Disease consultation. Diagnosis of nosocomial pneumonia caused by Staphylococcus aureus (MSSA and MRSA) or Streptococcus pneumoniae which has been diagnosed and documented with Infectious Disease consultation. Diagnosis of complicated skin and structure infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (MSSA and MRSA), Streptococcus pyogenes, or Streptococcus agalactiae which has been diagnosed and documented with Infectious Disease consultation. Diagnosis of uncomplicated skin and skin structure infections caused by Staphylococcus aureus (MSSA only) which has been diagnosed and documented with Infectious Disease consultation. Diagnosis of community acquired pneumonia caused by Streptococcus pneumonia or Staphylococcus aureus (MSSA only) which has been diagnosed and documented with infectious disease consultation.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 MONTH

OTHER CRITERIA
Documentation of culture and sensitivity showing the member's infection is not susceptible to

alternative antibiotic treatments OR documentation of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that linezolid therapy was started during an inpatient setting.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

LIRAGLUTIDE(GHP2027)

MEDICATION(S)
LIRAGLUTIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Type 2 Diabetes Mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LIVTENCITY(GHP2027)

MEDICATION(S)
LIVTENCITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF POST-TRANSPLANT CYTOMEGALOVIRUS (CMV) INFECTION AND DOCUMENTATION THAT INFECTION IS REFRACTORY TO PREVIOUS TREATMENT WITH GANCICLOVIR, VALGANCICLOVIR, CIDOFOVIR OR FOSCARNET.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
HEMATOLOGIST, ONCOLOGIST, TRANSPLANT SURGEON OR INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
8 WEEKS

OTHER CRITERIA
DOCUMENTATION THAT PATIENT HAS RECEIVED A HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) OR SOLID ORGAN TRANSPLANT. DOCUMENTATION OF MEMBER WEIGHT OF 35 KG OR MORE. DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH ANOTHER CMV ANTIVIRAL. IF THE REQUEST IS ABOVE 400 MG TWICE DAILY DOSING, DOCUMENTATION OF ONE OF THE FOLLOWING: (1) FOR REQUESTS OF 800 MG TWICE DAILY DOSING: DOCUMENTATION THAT THE MEMBER IS CONCURRENTLY RECEIVING CARBAMAZEPINE OR (2) FOR REQUESTS OF 1200 MG TWICE DAILY DOSING: DOCUMENTATION THAT THE MEMBER IS CONCURRENTLY RECEIVING PHENYTOIN OR

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PHENOBARBITAL.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LOARGYS(GHP2027)

MEDICATION(S)
LOARGYS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Arginase 1 Deficiency as evidenced by one of the following: 1)Pathogenic variants in ARG1 on molecular genetic testing OR 2) Diminished erythrocyte arginase enzyme activity (i.e., less than 1% of normal in red blood cell extracts).

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
Metabolic disease specialist

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
Documentation of baseline plasma arginine levels of 250 umol/L or greater. Documentation that medication will be used in conjunction with a protein-restriced diet. Documentation that dosing is consistent with FDA approved labeling and patient weight. Reauthorization will require documentation of continued disease improvement or lack of disease progression AND documentation that dosing is consistent with FDA approved labeling, patient weight, and plasma arginine levels.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LONSURF(GHP2027)

MEDICATION(S)
LONSURF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LOQTORZI(GHP2027)

MEDICATION(S)
LOQTORZI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LORBRENA(GHP2027)

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ALK Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LUCEMYRA(GHP2027)

MEDICATION(S)
LOFEXIDINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of use to mitigate opioid withdrawal symptoms in patients abruptly discontinuing opioids.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 DAYS

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to clonidine.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

LUMAKRAS(GHP2027)

MEDICATION(S)
LUMAKRAS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of KRAS Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LUMIZYME(GHP2027)

MEDICATION(S)
LUMIZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF LATE-ONSET (NON-INFANTILE) POMPE DISEASE OR A DIAGNOSIS OF INFANTILE-ONSET POMPE DISEASE SUPPORTED BY GAA ASSAY PERFORMED ON DRIED BLOOD SPOTS, SKIN FIBROBLASTS OR MUSCLE BIOPSY AND BASELINE PULMONARY FUNCTION TESTING (PFT) AND MUSCLE STRENGTH EVALUATION (I.E., PERCENT-PREDICTED FORCED VITAL CAPACITY (%FVC), 6-MINUTE WALK TEST (6MWT), GSGC (GAIT STAIRS, GOWER, CHAIR)) AND FOR LATE-ONSET POMPE DISEASE ONLY: GENETIC TESTING TO IDENTIFY THE SPECIFIC MUTATION TO CONFIRM THE DIAGNOSIS OF LATE-ONSET POMPE DISEASE.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR BIOCHEMICAL GENETICIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT THE MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON WEIGHT AND DOCUMENTATION THAT LUMIZYME WILL NOT BE USED IN COMBINATION WITH OTHER ENZYME REPLACEMENT THERAPY (E.G. NEXVIAZYME). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN PULMONARY

FUNCTION TESTING AND/OR MUSCLE STRENGTH EVALUATION AND DOCUMENTATION OF RECEIVING AN APPROPRIATE DOSE BASED ON PATIENTS WEIGHT AND DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH OTHER ENZYME REPLACEMENT THERAPY (I.E. NEXVIAZYME).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

LUMRYZ(GHP2027)

MEDICATION(S)
LUMRYZ, LUMRYZ STARTER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of excessive daytime sleepiness associated with narcolepsy OR diagnosis of cataplexy with narcolepsy.

AGE RESTRICTION
7 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to sodium oxybate (Xyrem) OR Xywav. Reauthorizations will require documentation of reduction in frequency of cataplexy attacks OR documentation of reduction in symptoms of excessive daytime sleepiness.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

LUNSUMIO(GHP2027)

MEDICATION(S)
LUNSUMIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LUNSUMIO VELO(GHP2027)

MEDICATION(S)
LUNSUMIO VELO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LYBALVI(GHP2027)

MEDICATION(S)
LYBALVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF USE FOR ONE OF THE FOLLOWING: 1) SCHIZOPHRENIA OR 2) ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER OR 3) MAINTENANCE TREATMENT OF BIPOLAR I DISORDER.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (I.E., OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE)

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

LYNOZYFIC(GHP2027)

MEDICATION(S)
LYNOZYFIC

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 Months

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LYNPARZA TABLETS(GHP2027)

MEDICATION(S)
LYNPARZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, BRCA pathogenic variant, HRD genomic instability. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

LYTGOBI(GHP2027)

MEDICATION(S)
LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FGFR genomic alteration. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MARGENZA(GHP2027)

MEDICATION(S)
MARGENZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MAVYRET(GHP2027)

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF ACUTE OR CHRONIC HEPATITIS C INFECTION. DOCUMENTATION OF METAVIR LIVER FIBROSIS OR CIRRHOSIS ASSESSMENT BY A NON-INVASIVE TEST. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 6 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT, BASIC METABOLIC PANEL. DOCUMENTATION OF A BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Pending CMS Approval

AGE RESTRICTION
MUST BE 3 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

COVERAGE DURATION
PER AASLD/IDSA GUIDELINES

OTHER CRITERIA
DOCUMENTATION OF ANY POTENTIAL DRUG INTERACTIONS THAT MAY IMPACT DRUG THERAPY ADDRESSED BY THE PRESCRIBER (SUCH AS DISCONTINUATION OF THE

INTERACTING DRUG, DOSE REDUCTION OF THE INTERACTING DRUG, OR COUNSELING OF THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT) PER AASLD/IDSA GUIDANCE (e.g., HIV MEDICATIONS, STATINS, ESTROGEN CONTAINING MEDICATIONS). DOCUMENTATION OF EITHER 1) COMPLETED HEPATITIS B SERIES OR 2) HEPATITIS B SCREENING (SAB, SAG AND CAB) AND QUANTITATIVE HEPATITIS B VIRUS (HBV) DNA IF POSITIVE FOR HEPATITIS B SAG AND EITHER DOCUMENTATION OF TREATMENT FOR HEPATITIS B IF THERE IS DETECTABLE HEPATITIS B VIRUS OR DOCUMENTATION OF BEING VACCINATED AGAINST HEPATITIS B IF NEGATIVE FOR HEPATITIS B SAB. IF THE MEMBER IS 12 YEARS OF AGE AND OLDER OR WEIGHS MORE THAN 45 KG AND THE REQUEST IS FOR PACKETS: DOCUMENTATION OF WHY TABLET FORMULATION CANNOT BE USED.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

MEKINIST(GHP2027)

MEDICATION(S)
MEKINIST

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MEKTOVI(GHP2027)

MEDICATION(S)
MEKTOVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MEPSEVII(GHP2027)

MEDICATION(S)
MEPSEVII

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MUCOPOLYSACCHARIDOSIS VII (MPS VII, SLY SYNDROME) CONFIRMED BY THE FOLLOWING: 1) URINARY GLYCOSAMINOGLYCANS (GAGS) AT LEAST THREE TIMES THE UPPER LIMIT OF NORMAL, 2) ENZYME ACTIVITY ASSAY (BETA-GLUCURONIDASE DEFICIENCY) OR GENETIC TESTING (MUTATION OF CHROMOSOME 7Q21.11) 3) AT LEAST ONE OF THE FOLLOWING CLINICAL SIGNS OR SYMPTOMS: ENLARGED LIVER AND SPLEEN, JOINT LIMITATIONS, AIRWAY OBSTRUCTION OR PULMONARY DYSFUNCTION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MUCOPOLYSACCHARIDOSIS

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
DOCUMENTATION OF A BASELINE EVALUATION, INCLUDING A STANDARDIZED ASSESSMENT OF MOTOR FUNCTION (I.E., 6-MINUTE WALK TEST, URINARY GAGS LEVEL, AND PULMONARY FUNCTION TEST). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY AND DOCUMENTATION OF IMPROVEMENT OR MAINTENANCE OF MOTOR FUNCTION, URINARY GAGS LEVEL, PULMONARY FUNCTION, OR OTHER CLINICAL SIGNS OR

Pending CMS Approval

SYMPTOMS (SUCH AS DECREASED LIVER/SPLEEN SIZE, IMPROVEMENT IN JOINT FUNCTION, ETC.)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

METHYLPHENIDATE(GHP2027)

MEDICATION(S)
METHYLPHENIDATE, METHYLPHENIDATE HCL ER (LA) 60 MG CAP ER 24H

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of attention-deficit hyperactivity disorder (ADHD).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of a failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

MIPLYFFA(GHP2027)

MEDICATION(S)
MIPLYFFA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF NEIMANN-PICK DISEASE TYPE C (NPC)1 OR NPC2 CONFIRMED BY GENETIC TESTING DEMONSTRATING ONE OF THE FOLLOWING (1) MUTATIONS IN BOTH ALLELES OF NPC1 OR NPC2 OR (2) MUTATION IN ONE ALLELE AND EITHER A POSITIVE FILIPIN-STAINING OR ELEVATED CHOLESTANE TRIOL/OXYSTEROLS (GREATER THAN 2 TIMES THE UPPER LIMIT OF NORMAL) AND DOCUMENTATION OF AT LEAST ONE NEUROLOGICAL SIGN OF NPC (SUCH AS BUT NOT LIMITED TO LOSS OF FINE MOTOR SKILLS, SWALLOWING, SPEECH, AMBULATION) AND DOCUMENTATION OF ABILITY TO WALK INDEPENDENTLY OR WITH ASSISTANCE.

Pending CMS Approval

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A PHYSICIAN WHO SPECIALIZES IN TREATMENT OF NPC OR RELATED DISORDERS

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF WEIGHT GREATER THAN OR EQUAL TO 8 KG AND THAT DOSE IS WEIGHT APPROPRIATE. DOCUMENTATION THAT MEMBER HAS COMPLETED THE NPC CLINICAL SEVERITY SCALE (NPCCSS) ASSESSMENT TO DETERMINE BASELINE SCORE OF

DISEASE SEVERITY. DOCUMENTATION THAT MEMBER IS CURRENTLY RECEIVING MIGLUSTAT AND MIPLYFFA WILL BE USED IN COMBINATION WITH MIGLUSTAT. DOCUMENTATION THAT MIPLYFFA WILL NOT BE USED IN COMBINATION WITH AQNEURSA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN NEUROLOGICAL SIGNS OF NPC (SUCH AS BUT NOT LIMITED TO STABLIZATION OR IMPROVEMENT IN NPCCSS SCORE, FINE MOTOR SKILLS, SWALLOWING, SPEECH, AND/OR AMBULATION) AND DOCUMENTATION THAT MIPLYFFA CONTINUES TO BE USED IN COMBINATION WITH MIGLUSTAT AND DOCUMENTATION THAT MIPLYFFA CONTINUES TO BE PRESCRIBED BY OR IN CONSULTATION WITH A PHYSICIAN WHO SPECIALIZES IN THE TREATMENT OF NPC OR RELATED DISORDERS AND DOCUMENTATION THAT MEMBER IS NOT USING MIPLYFFA IN COMBINATION WITH AQNEURSA.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

MIRCERA(GHP2027)

MEDICATION(S)
MIRCERA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for treatment of anemia associated with chronic kidney disease in adults on dialysis or not on dialysis. Documentation of use for treatment of anemia associated with chronic kidney disease in pediatric patients on hemodialysis who are converting from another erythropoiesis stimulating agents (ESA) after hemoglobin stabilization. Hemoglobin (HGB) must be less than or equal to 10 gm/dL for new starts or less than 12 gm/dL for continuation of therapy. Documentation of adequate iron stores with serum ferritin greater than 100 ng/ml or transferrin level saturation greater than 20%.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Reauthorization will require repeat HGB (within 3 months of reauthorization) of less than 12 gm/dL AND either serum ferritin greater than 100 ng/ml OR TSAT level greater than or equal to 20 % (within 6 months of reauthorization). THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED

Pending CMS Approval

DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

MIRVASO(GHP2027)

MEDICATION(S)
BRIMONIDINE TARTRATE 0.33 % GEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for the treatment of persistent (nontransient) facial erythema of rosacea.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MODEYSO(GHP2027)

MEDICATION(S)
MODEYSO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of H3 K27M mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MONJUVI(GHP2027)

MEDICATION(S)
MONJUVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MOUNJARO(GHP2027)

MEDICATION(S)
MOUNJARO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Type 2 Diabetes Mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MYLOTARG(GHP2027)

MEDICATION(S)
MYLOTARG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

MYQORZO(GHP2027)

MEDICATION(S)
MYQORZO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF NYHA CLASS II-III OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY AND DOCUMENTATION OF LEFT VENTRICULAR EJECTION FRACTION (LVEF) GREATER THAN OR EQUAL TO 55 PERCENT.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
CARDIOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: BETA BLOCKERS, NON-DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS, OR DISOPYRAMIDE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF LVEF GREATER THAN OR EQUAL TO 50 PERCENT AND DOCUMENTATION OF CLINICAL IMPROVEMENT OR MAINTENANCE OF CONDITION.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

MYTESI(GHP2027)

MEDICATION(S)
MYTESI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of non-infective diarrhea associated with HIV infections AND documentation that member is receiving anti-retroviral therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to loperamide AND diphenoxylate-atropine.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

NAGLAZYME(GHP2027)

MEDICATION(S)
NAGLAZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MUCOPOLYSACCHARIDOSIS VI (MAROTEAUX-LAMY DISEASE)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NERLYNX(GHP2027)

MEDICATION(S)
NERLYNX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of HER2 Protein overexpression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NEULASTA(GHP2027)

MEDICATION(S)
NEULASTA ONPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

REQUIRED MEDICAL INFORMATION
PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME. HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE,

BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CRCL LESS THAN 50 ML/MIN).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

NEXAVAR(GHP2027)

MEDICATION(S)
SORAFENIB TOSYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NEXLETOL(GHP2027)

MEDICATION(S)
NEXLETOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), INCLUDING ACUTE CORONARY SYNDROMES (A HISTORY OF MYOCARDIAL INFARCTION OR UNSTABLE ANGINA), CORONARY OR OTHER ARTERIAL REVASCULARIZATION, STROKE, TRANSIENT ISCHEMIC ATTACK, OR PERIPHERAL ARTERIAL DISEASE PRESUMED TO BE OF ATHEROSCLEROTIC ORIGIN OR HIGH RISK FOR A CARDIOVASCULAR DISEASE (CVD)EVENT WITHOUT ESTABLISHED CVD OR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH). FOR HEFH ONE OF THE FOLLOWING: GENETIC TESTING TO CONFIRM MUTATION IN THE LDL RECEPTOR, PCSK9, OR APOB GENE OR DOCUMENTATION OF DEFINITE HEFH (SCORE GREATER THAN 8) ON THE DIAGNOSTIC CRITERIA SCORING SYSTEM AS DEFINED BY THE DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. DOCUMENTATION OF A BASELINE LDL DRAWN WITHIN 3 MONTHS OF THE START OF THERAPY SHOWING AN LDL GREATER THAN 100 IF USING FOR HEFH AND USING FOR PRIMARY PREVENTION OR AN LDL GREATER THAN 70 IF USING FOR SECONDARY PREVENTION. FOR STATIN TOLERANT PATIENTS, DOCUMENTATION OF AN INABILITY TO ACHIEVE AND MAINTAIN LDL GOAL WITH ONE OF THE FOLLOWING (1) MAXIMUM TOLERATED DOSE OF A HIGH INTENSITY STATIN (ATORVASTATIN 40 MG OR HIGHER OR ROSUVASTATIN 20 MG OR HIGHER) OR (2) A MAXIMALLY TOLERATED DOSE OF ANY STATIN GIVEN THAT THE PATIENT HAS HAD A PREVIOUS TRIAL OF EITHER ATORVASTATIN OR ROSUVASTATIN, WITH PRESCRIBERS DOCUMENTATION REGARDING LENGTH OF PREVIOUS TRIALS OF STATINS. PATIENT MUST INTEND TO CONTINUE ON MAXIMAL STATIN THERAPY ONCE BEMPEDOIC ACID THERAPY IS STARTED. FOR STATIN INTOLERANT PATIENTS, DOCUMENTATION OF REASON FOR STATIN INTOLERANCE.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of therapeutic failure of a trial of ezetemibe alone. Therapeutic failure is defined as an inability to reach target LDL goals (less than 100 mg/dL for patients with HeFH in primary prevention or less than 70 mg/dL for ASCVD or for patients with HeFH using as secondary prevention) despite at least a 3 month trial. Intolerance to statins is defined as increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase (CK) elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persist after two retrials with a different dose or different dosing strategy (every other day) of alternative moderate- or high-intensity statin. Contraindications to statins are defined as active liver disease, previous history of rhabdomyolysis, or hypersensitivity.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

NEXLIZET(GHP2027)

MEDICATION(S)
NEXLIZET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), INCLUDING ACUTE CORONARY SYNDROMES (A HISTORY OF MYOCARDIAL INFARCTION OR UNSTABLE ANGINA), CORONARY OR OTHER ARTERIAL REVASCULARIZATION, STROKE, TRANSIENT ISCHEMIC ATTACK, OR PERIPHERAL ARTERIAL DISEASE PRESUMED TO BE OF ATHEROSCLEROTIC ORIGIN OR HIGH RISK FOR A CARDIOVASCULAR DISEASE (CVD)EVENT WITHOUT ESTABLISHED CVD OR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH). FOR HEFH ONE OF THE FOLLOWING: GENETIC TESTING TO CONFIRM MUTATION IN THE LDL RECEPTOR, PCSK9, OR APOB GENE OR DOCUMENTATION OF DEFINITE HEFH (SCORE GREATER THAN 8) ON THE DIAGNOSTIC CRITERIA SCORING SYSTEM AS DEFINED BY THE DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. DOCUMENTATION OF A BASELINE LDL DRAWN WITHIN 3 MONTHS OF THE START OF THERAPY SHOWING AN LDL GREATER THAN 100 IF USING FOR HEFH AND USING FOR PRIMARY PREVENTION OR AN LDL GREATER THAN 70 IF USING FOR SECONDARY PREVENTION. FOR STATIN TOLERANT PATIENTS, DOCUMENTATION OF AN INABILITY TO ACHIEVE AND MAINTAIN LDL GOAL WITH ONE OF THE FOLLOWING (1) MAXIMUM TOLERATED DOSE OF A HIGH INTENSITY STATIN (ATORVASTATIN 40 MG OR HIGHER OR ROSUVASTATIN 20 MG OR HIGHER) OR (2) A MAXIMALLY TOLERATED DOSE OF ANY STATIN GIVEN THAT THE PATIENT HAS HAD A PREVIOUS TRIAL OF EITHER ATORVASTATIN OR ROSUVASTATIN, WITH PRESCRIBERS DOCUMENTATION REGARDING LENGTH OF PREVIOUS TRIALS OF STATINS. PATIENT MUST INTEND TO CONTINUE ON MAXIMAL STATIN THERAPY ONCE BEMPEDOIC ACID THERAPY IS STARTED. FOR STATIN INTOLERANT PATIENTS, DOCUMENTATION OF REASON FOR STATIN INTOLERANCE.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of therapeutic failure of a trial of ezetemibe alone. Therapeutic failure is defined as an inability to reach target LDL goals (less than 100 mg/dL for patients with HeFH in primary prevention or less than 70 mg/dL for ASCVD or for patients with HeFH using as secondary prevention) despite at least a 3 month trial. Intolerance to statins is defined as increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase (CK) elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persist after two retrials with a different dose or different dosing strategy (every other day) of alternative moderate- or high-intensity statin. Contraindications to statins are defined as active liver disease, previous history of rhabdomyolysis, or hypersensitivity.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

NEXVIAZYME(GHP2027)

MEDICATION(S)
NEXVIAZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF LATE-ONSET POMPE DISEASE SUPPORTED BY AN ACID ALPHA-GLUCOSIDASE (GAA) ASSAY PERFORMED ON DRIED BLOOD SPOTS, SKIN FIBROBLASTS OR MUSCLE BIOPSY AND GENETIC TESTING SHOWING A MUTATION IN THE GAA GENE.

AGE RESTRICTION
MUST BE 1 YEAR OF AGE OR OLDER

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST OR BIOCHEMICAL GENETICIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF BASELINE PULMONARY FUNCTION TESTING AND MUSCLE STRENGTH EVALUATION (I.E., PERCENT-PREDICTED FORCED VITAL CAPACITY (%FVC), 6-MINUTE WALK TEST (6MWT), GSGC (GAIT STAIRS, GOWER, CHAIR)). DOCUMENTATION OF RECEIVING AN APPROPRIATE DOSE BASED ON PATIENTS WEIGHT. DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH OTHER ENZYME REPLACEMENT THERAPY (I.E. LUMIZYNE). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN PULMONARY FUNCTION TESTING AND/OR MUSCLE STRENGTH EVALUATION AND DOCUMENTATION OF RECEIVING AN APPROPRIATE DOSE BASED ON PATIENTS WEIGHT AND DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN

Pending CMS Approval

COMBINATION WITH OTHER ENZYME REPLACEMENT THERAPY (I.E. LUMIZYME).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

NGENLA(GHP2027)

MEDICATION(S)
NGENLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NIKTIMVO(GHP2027)

MEDICATION(S)
NIKTIMVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of chronic graft-versus-host disease (cGVHD)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hematologist, Oncologist, or transplant specialist

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
Documentation that member weighs 40 kg or greater. Documentation that medication will not be used in combination with any of the following: ruxolitinib, ibrutinib, belumosudi, or rituximab. Documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: Jakafi, Imbruvica, Rezurock, formulary rituximab product. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NINLARO(GHP2027)

MEDICATION(S)
NINLARO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NORDITROPIN(GHP2027)

MEDICATION(S)
NORDITROPIN FLEXPRO 10 MG/1.5ML SOLN PEN, NORDITROPIN FLEXPRO 15 MG/1.5ML SOLN PEN, NORDITROPIN FLEXPRO 5 MG/1.5ML SOLN PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NORTHERA(GHP2027)

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH) CAUSE BY ONE OF THE FOLLOWING: PRIMARY AUTONOMIC FAILURE, DOPAMINE BETA-HYDROXYLASE DEFICIENCY OR NON-DIABETIC AUTONOMIC NEUROPATHY

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
CARDIOLOGIST OR NEUROLOGIST

COVERAGE DURATION
4 WEEKS INITIAL AND 3 MONTHS CONTINUATION

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MIDODRINE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED OR SUSTAINED IMPROVEMENT IN THE SYMPTOMS OF NOH.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

NOXAFIL(GHP2027)

MEDICATION(S)
POSACONAZOLE 100 MG TAB DR, POSACONAZOLE 40 MG/ML SUSPENSION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF USE FOR PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS IN SEVERELY IMMUNOCOMPROMISED PATIENTS (HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) RECIPIENTS WITH GRAFT-VERSUS-HOST-DISEASE (GVHD) OR THOSE WITH HEMATOLOGIC MALIGNANCIES WITH PROLONGED NEUTROPENIA FROM CHEMOTHERAPY) OR DIAGNOSIS OF OROPHARYNGEAL CANDIDIASIS OR TREATMENT OF INVASIVE ASPERGILLOSIS.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
OROPHARYNGEAL CANDIDA: 1 MONTH. ASPERGILLOSIS TX: 12 WEEKS. PROPHYLAXIS: 6 MONTHS

OTHER CRITERIA
For oropharyngeal candidiasis: failure on, intolerance to, or contraindication to fluconazole. Reauthorization for prophylaxis of invasive Aspergillus and Candida infections beyond 6 months will require documentation of medical necessity and continued disease risk from neutropenia or immunosuppression.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

NPLATE(GHP2027)

MEDICATION(S)
NPLATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF IMMUNE THROMBOCYTOPENIA PURPURA (ITP). DOCUMENTATION OF HEMATOPOIETIC SYNDROME OF ACTUE RADIATION SYNDROM (HS-ARS).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
FOR ITP: HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
HS-ARS: ONE TIME AUTH. ITP: 3 MONTHS INITIAL, 6 MONTHS CONTINUATION

OTHER CRITERIA
FOR HS-ARS: DOCUMENTATION OF SUSPECTED OR CONFIRMED ACUTE EXPOSURE TO MYELOSUPPRESSIVE DOSES OF RADIATION (ESTIMATED AS RADIATION LEVELS GREATER THAN 2 GRAY (GY)). FOR ITP: ONE OF THE FOLLOWING, 1)DOCUMENTATION OF SYMPTOMATIC ITP WITH BLEEDING SYMTPOMS WITH PLATELET COUNT LESS THAN 30,000/MICROL OR 2)DOCUMENTED HISTORY OF SIGNIFICANT BLEEDING WITH A PLATELET COUNT OF LESS THAN 30,000/MICROL OR 3)PLATELET COUNT OF LESS THAN 20,000/MICROL. FOR ITP: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS AND ELTROMBOPAG. SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY SUCH AS A PLATELET COUNT NECESSARY TO REDUCE THE RISK FOR BLEEDING OR A HEMATOLOGICAL RESPONSE.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

NUBEQA(GHP2027)

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NUCALA(GHP2027)

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SEVERE EOSINOPHILIC ASTHMA AND DOCUMENTATION THAT MEDICATION IS BEING USED AS ADD-ON MAINTENANCE TREATMENT AND DOCUMENTATION OF A BLOOD EOSINOPHIL COUNT OF 300 CELLS/MCL OR GREATER DURING THE 12 MONTH PERIOD BEFORE SCREENING OR 150 CELLS/MCL OR GREATER WITHIN 3 MONTHS OF THE START OF THERAPY OR DIAGNOSIS OF EOSINOPHILIC GRANULOMATOSIS (EGPA) CONFIRMED BY BIOPSY EVIDENCE OF VASCULITIS AND 4 OR MORE OF THE FOLLOWING CRITERIA: ASTHMA, EOSINOPHILIA, MONONEUROPATHY OR POLYNEUROPATHY, MIGRATORY OR TRANSIENT PULMONARY OPACITIES DETECTED RADIOGRAPHICALLY, PARANASAL SINUS ABNORMALITY OR BIOPSY CONTAINING A BLOOD VESSEL SHOWING THE ACCUMULATION OF EOSINOPHILS IN EXTRAVASCULAR AREAS. DIAGNOSIS OF HYPEREOSINOPHILIC SYNDROME (HES) FOR GREATER THAN OR EQUAL TO 6 MONTHS AND DOCUMENTATION THAT MEMBER HAS BEEN EVALUATED FOR AND DOES NOT HAVE AN IDENTIFIABLE NON-HEMATOLOGIC SECONDARY CAUSE OR FIP1 LIKE 1-PLATELET DERIVED GROWTH FACTOR RECEPTOR (FIP1L1-PDGFRALPHA) KINASE-POSITIVE HES. DIAGNOSIS OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP) AND DOCUMENTATION OF USE AS ADD-ON MAINTENANCE TREATMENT. DIAGNOSIS OF INADEQUATELY CONTROLLED COPD WITH AN EOSINOPHILIC PHENOTYPE AND DOCUMENTATION OF USE AS ADD-ON MAINTENANCE TREATMENT AND DOCUMENTATION OF A BLOOD EOSINOPHIL COUNT OF 300 CELLS/MCL OR GREATER DURING THE 12 MONTH PERIOD BEFORE SCREENING OR 150 CELLS/MCL OR GREATER WITHIN 3 MONTHS OF THE START OF THERAPY.

Pending CMS Approval

AGE RESTRICTION
ASTHMA:6 YEARS OF AGE OR OLDER. EGPA, COPD OR CRSwNP:18 YEARS OR OLDER.

HES:12 YEARS OR OLDER

PRESCRIBER RESTRICTION

FOR ASTHMA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST. FOR EGPA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST, OR RHEUMATOLOGIST. FOR CRSWNP: BY OR IN CONSULTATION WITH ALLERGIST, PULMONOLOGIST OR OTOLARYNGOLOGIST. FOR COPD: ALLERGIST OR PULMONOLOGIST.

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT NUCALA IS NOT BEING USED IN COMBINATION WITH DUPILUMAB, OMALIZUMAB, BENRALIZUMAB, TEZEPELUMAB, DEPEMOKIMAB, OR RESLIZUMAB. FOR EOSINOPHILIC ASTHMA: DOCUMENTATION OF CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST A 3-MONTH TRIAL OF MAXIMALLY TOLERATED INHALED CORTICOSTEROIDS AND/OR ORAL SYSTEMIC CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST OR TWO OR MORE EXACERBATIONS IN THE PREVIOUS 12 MONTHS REQUIRING ADDITIONAL MEDICAL TREATMENT (ORAL CORTICOSTEROIDS, EMERGENCY DEPARTMENT OR URGENT CARE VISITS, OR HOSPITALIZATION) DESPITE CURRENT THERAPY OR INTOLERANCE TO INHALED CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST. FOR EGPA: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO SYSTEMIC GLUCOCORTICOID THERAPY. FOR HES: (1)DOCUMENTATION OF A BLOOD EOSINOPHIL COUNT OF 1000 CELLS/MCL OR HIGHER AND (2)DOCUMENTATION OF AT LEAST TWO HES FLARES WITHIN THE PREVIOUS 12 MONTHS WITH A WORSENING OF CLINICAL SYMPTOMS OF HES OR INCREASING BLOOD EOSINOPHIL LEVELS REQUIRING AN ESCLATION IN THERAPY AND (3)DOCUMENTATION THAT MEMBER IS ON STABLE HES THERAPY INCLUDING, BUT NOT LIMITED TO ORAL CORTICOSTEROIDS, IMMUNOSUPPRESSIVES OR CYCTOXIC THERAPY. FOR CRSWNP: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO INTRANASAL CORTICOSTEROIDS. FOR COPD: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 1) SPIRIVA or INCRUSE ELLIPTA AND 2) ONE LONG ACTING BETA AGONISTS.SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

NUEDEXTA(GHP2027)

MEDICATION(S)
DEXTROMETHORPHAN-QUINIDINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PSEUDOBULBAR AFFECT

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NULIBRY(GHP2027)

MEDICATION(S)
NULIBRY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A AS CONFIRMED BY GENETIC TESTING INDICATING A MUTATION IN THE MOLYBDENUM COFACTOR SYNTHESIS GENE 1 (MOSC1) GENE OR DOCUMENTATION OF BOTH OF THE FOLLOWING: 1) DOCUMENTATION OF BIOCHEMICAL AND CLINICAL FEATURES CONSISTENT WITH A DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A, INCLUDING BUT NOT LIMITED TO ENCEPHALOPATHY, INTRACTABLE SEIZURES, ELEVATED URINARY S-SULFOCYSTEINE LEVELS, AND DECREASED URIC ACID LEVELS AND 2) DOCUMENTATION THAT THE MEMBER WILL BE TREATED PRESUMPTIVELY WHILE AWAITING GENETIC CONFIRMATION.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEONATOLOGIST, GENETICIST OR PEDIATRIC NEUROLOGIST

COVERAGE DURATION
PRESUMPTIVE DX: 1 MONTH. CONFIRMED DX: 12 MONTHS.

OTHER CRITERIA
REAUTHORIZATION FOLLOWING INITIAL PRESUMPTIVE DIAGNOSIS WILL REQUIRE DOCUMENTATION OF GENETIC TESTING CONFIRMING A DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A. REAUTHORIZATION FOR GENETICIALLY

CONFIRMED MOCD TYPE A WILL REQUIRE DOCUMENTATION OF A CLINICALLY SIGNIFICANT POSITIVE RESPONSE OR LACK OF DISEASE PROGRESSION WHILE ON THERAPY.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

NULOJIX(GHP2027)

MEDICATION(S)
NULOJIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF RENAL TRANSPLANT

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF EPSTEIN-BARR VIRUS (EBV) SEROPOSITIVITY

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NUPLAZID(GHP2027)

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) established by or in consultation with a neurologist AND documentation that psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN SIGNS AND SYMPTOMS OF PARKINSON'S DISEASE PSYCHOSIS.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

NURTEC(GHP2027)

MEDICATION(S)
NURTEC

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA. ATTESTATION OF USE FOR THE ACUTE TREATMENT OF MIGRAINE OR ATTESTATION OF USE FOR THE PREVENTION OF EPISODIC MIGRAINE (DEFINED AS NO MORE THAN 14 HEADACHE DAYS PER MONTH) AND ATTESTATION THAT MEMBER EXPERIENCES 4 OR MORE MIGRAINE DAYS PER MONTH.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
ACUTE: REMAINDER OF CONTRACT YEAR. PREVENTION: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
FOR MIGRAINE TREATMENT: THERAPEUTIC FAILURE ON TWO FORMULARY TRIPTANS (E.G., NARATRIPTAN, RIZATRIPTAN, SUMATRIPTAN, ZOLMITRIPTAN) OR ATTESTATION OF INTOLERANCE TO OR CONTRAINDICATION TO ONE TRIPTAN. ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP ANTAGONIST INDICATED FOR THE ACUTE TREATMENT OF MIGRAINE. FOR MIGRAINE PREVENTION: NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH. ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR

Pending CMS Approval

ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE. REAUTHORIZATION WILL REQUIRE ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

NUVIGIL(GHP2027)

MEDICATION(S)
ARMODAFINIL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OCREVUS(GHP2027)

MEDICATION(S)
OCREVUS, OCREVUS ZUNOVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PRIMARY PROGRESSIVE MS OR DIAGNOSIS OF A RELAPSING FORM OF MS (INCLUDING CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF HEPATITIS B SCREENING. FOR RELAPSING FORM OF MS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO , OR CONTRAINDICATION TO ONE FORMULARY ALTERNATIVE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN SIGNS AND SYMPTOMS OR MAINTENANCE OF CONDITION WHILE ON THERAPY.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ODOMZO(GHP2027)

MEDICATION(S)
ODOMZO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OFEV(GHP2027)

MEDICATION(S)
NINTEDANIB ESYLATE, OFEV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF IDIOPATHIC PULMONARY FIBROSIS (IPF) CONFIRMED BY EITHER A USUAL INTERSTITIAL PNEUMONIA PATTERN ON HIGH RESOLUTION CT SCAN OR BOTH HRCT AND SURGICAL LUNG BIOPSY PATTERN SUGGESTIVE OF IPF OR PROBABLE IPF MADE BY AN INTERDISCIPLINARY TEAM INCLUDING, BUT NOT LIMITED TO SPECIALISTS FROM PULMONARY MEDICINE, RADIOLOGY, THORACIC SURGERY, PATHOLOGY OR RHEUMATOLOGY AND DOCUMENTATION THAT THERE ARE NO OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE SUCH AS DOMESTIC AND OCCUPATIONAL ENVIRONMENTAL EXPOSURES, CONNECTIVE TISSUE DISEASE OR DRUG TOXICITY. Diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND documentation of related interstitial lung disease confirmed by: 1) greater than or equal to 10 % fibrosis on a chest high resolution CT scan, 2) FVC greater than or equal to 40% of predicted normal, and 3) DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal. Diagnosis of chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype AND documentation of ILD confirmed by all of the following: 1)10% or more fibrosis on a chest high resolution computer tomography AND 2) FVC more than 45% of predicted normal AND 3) Diffusion capacity of the lung for carbon monoxide (DLCO) of 30-80% of predicted normal.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
PULMONOLOGIST or RHEUMATOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF ILD PROGRESSION WITH DOCUMENTATION OF THE FOLLOWING: 1) FVC DECLINE OF 10% OR GREATER OR 2)FVC DECLINE BETWEEN 5-10% WITH DOCUMENTATION OF WORSENING SYMPTOMS OR INCREASING FIBROTIC CHANGES ON IMAGING OR 3) DOCUMENTATION OF BOTH WORSENING SYMPTOMS AND INCREASING FIBROTIC CHANGES ON IMAGING.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OGSIVEO(GHP2027)

MEDICATION(S)
OGSIVEO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OJEMDA(GHP2027)

MEDICATION(S)
OJEMDA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OJJAARA(GHP2027)

MEDICATION(S)
OJJAARA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of platelet count. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OLUMIANT(GHP2027)

MEDICATION(S)
OLUMIANT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderate to severe Rheumatoid Arthritis made in accordance with the American College of Rheumatology criteria for the classification and diagnosis of Rheumatoid Arthritis. DIAGNOSIS OF SEVERE ALOPECIA AREATA (AA), DEFINED AS AT LEAST 50 PERCENT SCALP HAIR LOSS AS MEASURED BY THE SEVERITY OF ALOPECIA TOOL (SALT).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR RA: RHEUMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB PRODUCT, RINVOQ, XELJANZ) AND DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR CONTINUED THERAPY, DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION WHILE ON THERAPY.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

OMNITROPE(GHP2027)

MEDICATION(S)
OMNITROPE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OMVOH(GHP2027)

MEDICATION(S)
OMVOH 300 MG/15ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of moderately to severely active ulcerative colitis.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to a minimum 3 month trial of two preferred agents for ulcerative colitis (formulary adalimumab product, Simponi, Xeljanz, Rinvoq). Reauthorization will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ONIVYDE(GHP2027)

MEDICATION(S)
ONIVYDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ONUREG(GHP2027)

MEDICATION(S)
ONUREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OPDIVO(GHP2027)

MEDICATION(S)
OPDIVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OPDIVO QVANTIG(GHP2027)

MEDICATION(S)
OPDIVO QVANTIG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OPDUALAG(GHP2027)

MEDICATION(S)
OPDUALAG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OPIPZA(GHP2027)

MEDICATION(S)
OPIPZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for an FDA approved indication

AGE RESTRICTION
For MDD: 18 years of age or older. For Schizophrenia: 13 years of age or older. For Autism or Tourettes: 6 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of inability to tolerate or swallow aripiprazole tablets OR documentation of why a film formulation is needed.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

OPSUMIT(GHP2027)

MEDICATION(S)
MACITENTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF WHO FUNCTIONAL CLASS II, III, OR IV PULMONARY ARTERIAL HYPERTENSION AND NEGATIVE PREGNANCY TEST IN FEMALES OF CHILDBEARING POTENTIAL

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CARDIOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION THAT OPSUMIT WILL BE USED IN COMBINATION WITH OR THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ORGOVYX(GHP2027)

MEDICATION(S)
ORGOVYX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Urologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ORKAMBI(GHP2027)

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CYSTIC FIBROSIS. DOCUMENTATION THAT THE MEMBER IS HOMOZYGOUS FOR THE F508DEL CFTR MUTATION AS DOCUMENTED BY AN FDA-CLEARED TEST.

AGE RESTRICTION
MUST BE 1 YEAR OF AGE OR OLDER

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ORLADEYO(GHP2027)

MEDICATION(S)
ORLADEYO 110 MG CAP, ORLADEYO 150 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
MUST BE 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS BEING USED AS PROPHYLACTIC THERAPY. Documentation that medication is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or lanadelumab (Takhzyro) therapy for hereditary angioedema. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ORSERDU(GHP2027)

MEDICATION(S)
ORSERDU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, estrogen receptor expression, ESR1 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OTEZLA(GHP2027)

MEDICATION(S)
OTEZLA, OTEZLA/OTEZLA XR INITIATION PK, OTEZLA XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ACTIVE PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DOCUMENTATION OF MILD PLAQUE PSORIASIS CHARACTERIZED BY LESS THAN 3% BODY SURFACE AREA. DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 3% OR GREATER INVOLVEMENT OF BODY SURFACE AREA OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, SCALP OR GENITALS. DIAGNOSIS OF ORAL ULCERS ASSOCIATED WITH BEHCET'S DISEASE.

Pending CMS Approval

AGE RESTRICTION
MODERATE TO SEVERE PP AND PSA: 6 YRS OR OLDER. MILD PP AND BEHCETS: 18 YRS OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR MILD PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 2 TOPICAL THERAPIES USED FOR THE TREATMENT OF PSORIASIS, ONE OF WHICH IS A CORICOSTEROID OF AT LEAST MEDIUM POTENCY. FOR MODERATE TO SEVERE PLAQUE PSORIASIS: DOCUMENTATION THAT DOSING IS APPROPRIATE BASED ON PATIENT WEIGHT

AND THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE OR PHOTOTHERAPY. FOR ALL INDICATIONS, FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION OF CLINICAL OR SUSTAINED IMPROVEMENT OF SIGNS AND SYMPTOMS OF DISEASE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

OXERVATE(GHP2027)

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of neurotrophic keratitis (NK) as confirmed by a decrease or loss in corneal sensitivity AND one of the following: 1) superficial keratopathy, 2) persistent epithelial defects or 3) corneal ulcers.

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
OPHTHALMOLOGIST OR OPTOMETRIST

COVERAGE DURATION
8 WEEKS

OTHER CRITERIA
REAUTHORIZATION FOR TREATMENT BEYOND 8 WEEKS WILL REQUIRE DOCUMENTATION OF MEDICAL OR SCIENTIFIC LITERATURE TO SUPPORT THE USE OF THIS AGENT BEYOND THE FDA APPROVED TREATMENT DURATION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

OXLUMO(GHP2027)

MEDICATION(S)
OXLUMO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF PRIMARY HYPEROXALURIA TYPE 1 (PH1) AS CONFIRMD BY ONE OF THE FOLLOWING: MOLECULAR GENETIC TESTING THAT CONFIRMS A MUTATION OF ALANIN:GLYOXYLATE AMINOTRANSFERASE GENE (AGXT) OR A LIVER BIOPSY TO CONFIRM ABSENT OR SIGNIFICANTLY REDUCED ALANIN-GLYOXYLATE AMINOTRANSFERASE (AGT).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
SPECIALIST WITH EXPERIENCE MANAGING HYPEROXALURIA (I.E. NEPHROLOGIST, UROLOGIST, GENETICIST, HEPATOLOGIST)

COVERAGE DURATION
6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF METABOLIC SCREENING THAT DEMONSTRATES ONE OF THE FOLLOWING: MARKEDLY INCREASED URINARY OXALATE EXCRETION (I.E. GENERALLY GREATER THAN 0.7 MMOL/1.73M2/DAY OR GREATER THAN THE UPPER LIMIT OF NORMAL) OR INCREASED URINARY OXALATE TO CREATININE RATIO (I.E. GREATER THAN THE AGE-SPECIFIC UPPER LIMIT OF NORMAL). DOCUMENTATION THAT MEMBER DOES NOT HAVE A HISTORY OF LIVER TRANSPLANT. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND

Pending CMS Approval

DOCUMENTATION OF NOT RECEIVING A LIVER TRANSPLANT.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

OXTELLAR XR(GHP2027)

MEDICATION(S)
OXCARBAZEPINE ER, OXTELLAR XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of partial-onset seizures.

AGE RESTRICTION
6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of therapeutic failure on, intolerance to, or contraindication to two formulary anticonvulsants, one of which must be oxcarbazepine IR.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

OXYCONTIN(GHP2027)

MEDICATION(S)
OXYCODONE HCL ER, OXYCONTIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY LONG-ACTING OPIOIDS.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

OZEMPIC(GHP2027)

MEDICATION(S)
OZEMPIC, OZEMPIC (0.25 OR 0.5 MG/DOSE) 2 MG/3ML SOLN PEN, OZEMPIC (1 MG/DOSE), OZEMPIC (2 MG/DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Type 2 Diabetes Mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PADCEV(GHP2027)

MEDICATION(S)
PADCEV

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PANRETIN(GHP2027)

MEDICATION(S)
PANRETIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CUTANEOUS LESIONS IN PATIENTS WITH AIDS RELATED KAPOSI'S SARCOMA.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

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MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, AKYNZEO 300-0.5 MG CAP, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, ATGAM, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE SODIUM, BLEOMYCIN SULFATE, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CLADRIBINE, CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, CYTARABINE, CYTARABINE (PF), DEFEROXAMINE MESYLATE, DEXTROSE 10 % SOLUTION, DEXTROSE 250 MG/ML SOLUTION, DEXTROSE 50 % SOLUTION, DEXTROSE 70 % SOLUTION, DEXTROSE-SODIUM CHLORIDE 10-0.2 % SOLUTION, DEXTROSE-SODIUM CHLORIDE 10-0.45 % SOLUTION, DIPHTHERIA-TETANUS TOXOIDS DT, DOBUTAMINE-DEXTROSE, DOBUTAMINE HCL, DOXORUBICIN HCL, ENGERIX-B, ENVARSUS XR, EPOPROSTENOL SODIUM, FLOXURIDINE, FLUOROURACIL 1 GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FOSCARNET SODIUM, GAMASTAN, GANCICLOVIR SODIUM, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPLISAV-B, IMOVAX RABIES, INSULIN ASPART, INTRALIPID, IPRATROPIUM BROMIDE 0.02 % SOLUTION, KIRSTY 100 UNIT/ML SOLUTION, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, MERILOG, METHYLPREDNISOLONE 16 MG TAB, METHYLPREDNISOLONE 32 MG TAB, METHYLPREDNISOLONE 4 MG TAB, METHYLPREDNISOLONE 8 MG TAB, MILRINONE LACTATE, MILRINONE LACTATE IN DEXTROSE, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG RECON SOLN, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE MOFETIL HCL, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, NUTRILIPID, ONDANSETRON 4 MG TAB DISP, ONDANSETRON 8 MG TAB DISP, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 8 MG TAB, PENTAMIDINE ISETHIONATE, PREDNISOLONE 15 MG/5ML SOLUTION, PREDNISOLONE SODIUM PHOSPHATE 15 MG/5ML SOLUTION, PREDNISOLONE SODIUM PHOSPHATE 25 MG/5ML SOLUTION, PREDNISOLONE SODIUM PHOSPHATE 5 MG/5ML

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SOLUTION, PREDNISOLONE SODIUM PHOSPHATE 6.7 (5 BASE) MG/5ML SOLUTION, PREDNISONE 10 MG TAB, PREDNISONE 1 MG TAB, PREDNISONE 20 MG TAB, PREDNISONE 2.5 MG TAB, PREDNISONE 50 MG TAB, PREDNISONE 5 MG/5ML SOLUTION, PREDNISONE 5 MG TAB, PREHEVBRIO, PREMASOL, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, RABAVERT, RECOMBIVAX HB, SIMULECT, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 1 MG TAB, SIROLIMUS 2 MG TAB, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TACROLIMUS 5 MG/ML SOLUTION, TDVAX, TENIVAC, TETANUS-DIPHTHERIA TOXOIDS TD, THYMOGLOBULIN, TRAVASOL, TROPHAMINE, VINBLASTINE SULFATE, VINCRISTINE SULFATE

DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

Pending CMS Approval

PEDMARK(GHP2027)

MEDICATION(S)
PEDMARK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF LOCALIZED, NON-METASTATIC SOLID TUMOR. DOCUMENTATION THAT THE MEMBER WILL RECEIVE A CISPLATIN INFUSION WITH AN INFUSION TIME LESS THAN OR EQUAL TO 6 HOURS. DOCUMENTATION THAT PEDMARK IS BEING USED TO REDUCE THE RISK OF OTOTOXICITY ASSOCIATED WITH CISPLATIN.

AGE RESTRICTION
1 MONTH OF AGE TO LESS THAN 18 YEARS OF AGE

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINISTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED LITERATURE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUMENTATION THAT THE MEMBER IS CONTINUING TO RECEIVE A CISPLATIN-BASED CHEMOTHERAPY REGIMEN.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

PEMAZYRE(GHP2027)

MEDICATION(S)
PEMAZYRE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FGFR genomic alteration. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PERFOROMIST(GHP2027)

MEDICATION(S)
FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF COPD

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SEREVENT OR DOCUMENTATION OF INABILITY TO USE AN INHALER.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PIASKY(GHP2027)

MEDICATION(S)
PIASKY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO EMPAVELI.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PIQRAY(GHP2027)

MEDICATION(S)
PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of HER2 Protein expression, Hormone Receptor expression, PIK3CA gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

POLIVY(GHP2027)

MEDICATION(S)
POLIVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

POMALYST(GHP2027)

MEDICATION(S)
POMALIDOMIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PPI(GHP2027)

MEDICATION(S)
ESOMEPRAZOLE MAGNESIUM 10 MG PACKET, ESOMEPRAZOLE MAGNESIUM 20 MG PACKET, ESOMEPRAZOLE MAGNESIUM 40 MG PACKET, ESOMEPRAZOLE MAGNESIUM 5 MG PACKET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) For members that have difficulty swallowing or have an NG tube, documentation of a failure on, intolerance to, or contraindication to lansoprazole ODT OR (2) documentation of a contraindication to, intolerance to, or failure on the maximal doses of two generic formulary alternatives (omeprazole capsules, pantoprazole tablets, lansoprazole capsules, lansoprazole ODT, esomeprazole capsules, or rabeprazole tablets), one of which must contain the same active ingredient as the product requested, if available.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

PRETOMANID(GHP2027)

MEDICATION(S)
PRETOMANID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of pulmonary infection due to Mycobacterium tuberculosis AND documentation of one of the following (1) extensively drug resistant tuberculosis (XDR-TB) OR (2) treatment-intolerant or nonresponsive multidrug resistant tuberculosis (TINR MDR-TB).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PREVYMIS(GHP2027)

MEDICATION(S)
PREVYMIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant AND documentation that member is a confirmed CMV seropositive recipient (R+) AND documentation that medication is being used for CMV prophylaxis AND therapy is being initiated between Day 0 and Day 28 post-transplantation. DOCUMENTATION THAT MEMBER IS A RECIPIENT OF A KIDNEY TRANSPLANT AND DOCUMENTATION THAT MEMBER IS AT HIGH RISK OF CMV (DEFINED AS CMV SEROPOSITIVE DONOR AND CMV SERONEGATIVE RECIPIENT (D+/R-)) AND DOCUMENTATION THAT MEDICATION IS BEING USED FOR CMV PROPHYLAXIS AND DOCUMENTATION THAT THERAPY IS BEING INITIATED BETWEEN DAY 0 AND DAY 7 POST-TRANSPLANTATION.

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AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A HEMATOLOGIST, ONCOLOGIST, INFECTIOUS DISEASE OR TRANSPLANT SPECIALIST

COVERAGE DURATION
200 DAYS

OTHER CRITERIA
Documentation that medication is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), or pitavastatin or simvastatin (if co-administered with

cyclosporine).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

PRIALT(GHP2027)

MEDICATION(S)
PRIALT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
INADEQUATE RESPONSE TO OR INTOLERANCE TO SYSTEMIC (ORAL) ANALGESICS AND INTRATHECAL MORPHINE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PROCYSBI(GHP2027)

MEDICATION(S)
PROCYSBI 25 MG CAP DR, PROCYSBI 75 MG CAP DR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF NEPHROPATHIC CYSTINOSIS

AGE RESTRICTION
MUST BE 1 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEPHROLOGIST, GENETICIST OR METABOLIC SPECIALIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF ONE OF THE FOLLOWING: 1) INTOLERANCE TO CYSTAGON OR 2) DOCUMENTATION OF FAILURE TO ACHIEVE WBC CYSTINE LEVELS LESS THAN 1 NMOL HALF-CYSTINE/MG PROTEIN ON MAXIMALLY TOLERATED DOSE OF CYSTAGON.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PROMACTA(GHP2027)

MEDICATION(S)
ELTROMBOPAG OLAMINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIC PURPURA (ITP) OR PERSISTENT ITP WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS. DIAGNOSIS OF CHRONIC HEPATITIS C WITH THROMBOCYTOPENIA AND PLAN TO INITIATE OR CONTINUE INTERFERON-BASED THERAPY AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS. DIAGNOSIS OF APLASTIC ANEMIA WITH A PLATELET COUNT LESS THAN 30,000/MICROL AND FAILURE ON ONE PRIOR IMMUNOSUPPRESSIVE THERAPY SUCH AS BUT NOT LIMITED TO CYCLOSPORINE OR FOR USE AS FIRST LINE TREATMENT IN COMBINATION WITH STANDARD IMMUNOSUPPRESSIVE THERAPY (SUCH AS BUT NOT LIMITED TO CYCLOSPORINE).

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
FOR ITP AND APLASTIC ANEMIA: PRESCRIBED BY HEMATOLOGIST OR ONCOLOGIST. FOR CHRONIC HEPATITIS C: PRESCRIBED BY GASTROENTEROLOGIST, HEMATOLOGIST, HEPATOLOGIST OR INFECTIOUS DISEASE PHYSICIAN.

COVERAGE DURATION
3 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
For chronic or persistent ITP: documentation of a therapeutic failure on one previous treatment,

including, but not limited to: IVIG, Rhogam (if RhD-positive and spleen intact), rituximab, or splenectomy. SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY SUCH AS A PLATELET COUNT NECESSARY TO REDUCE THE RISK FOR BLEEDING or A HEMATOLOGICAL RESPONSE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

PROVIGIL(GHP2027)

MEDICATION(S)
MODAFINIL 100 MG TAB, MODAFINIL 200 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PULMOZYME(GHP2027)

MEDICATION(S)
PULMOZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CYSTIC FIBROSIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

PYRUKYND(GHP2027)

MEDICATION(S)
PYRUKYND, PYRUKYND TAPER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PYRUVATE KINASE DEFICIENCY (PKD).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A HEMATOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION OF A HEMOGLOBIN LEVEL LESS THAN OR EQUAL TO 10 G/DL. DOCUMENTATION OF AT LEAST 2 MUTANT ALLELES IN THE PKLR GENE, WITH AT LEAST 1 BEING A MISSENSE MUTATION AND DOCUMENTATION THAT MEMBER IS NOT HOMOZYGOUS FOR THE R479H MUTATION. REAUTHORIZATION WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF PROVIDER ASSESSED IMPROVEMENT IN HEMOGLOBIN FROM BASELINE OR REDUCTION IN TRANSFUSION BURDEN.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

QBREXZA(GHP2027)

MEDICATION(S)
QBREXZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF PRIMARY AXILLARY HYPERHIDROSIS.

AGE RESTRICTION
9 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

QELBREE(GHP2027)

MEDICATION(S)
QELBREE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of one of the following: (1) difficulty swallowing OR (2) failure on, intolerance to, or contraindication to two formulary alternatives, one of which must be atomoxetine. Documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

QINLOCK(GHP2027)

MEDICATION(S)
QINLOCK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

QSYMIA(GHP2027)

MEDICATION(S)
PHENTERMINE-TOPIRAMATE ER, PHENTERMINE-TOPIRAMATE ERXDNU, QSYMIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR ADULTS: DOCUMENTATION OF ONE OF THE FOLLOWING: (1) BODY MASS INDEX (BMI) GREATER THAN OR EQUAL TO 30 KG/M2 OR (2) BMI GREATER THAN OR EQUAL TO 27 KG/M2 AND AT LEAST ONE WEIGHT-RELATED COMORBIDITY (E.G., HYPERTENSION, TYPE 2 DIABETES MELLITUS, OR DYSLIPIDEMIA). DOCUMENTATION OF USE AS ADJUNCT THERAPY TO REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY FOR CHRONIC WEIGHT MANAGEMENT. FOR PEDIATRICS: DOCUMENTATION OF BMI IN THE 95TH PERCENTILE OR HIGHER FOR AGE AND SEX.

Pending CMS Approval

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR ADULTS: DOCUMENTATION THAT MEMBER HAS PARTICIPATED IN COMPREHENSIVE LIFESTYLE MODIFICATIONS INCLUDING REDUCED-CALORIE DIET, PHYSICAL ACTIVITY, AND BEHAVIORAL HEALTH FOR AT LEAST 3 MONTHS PRIOR TO BEGINNING QSYMIA. FOR PEDIATRICS AND ADULTS: FAILURE ON WEGOVY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER CONTINUES TO EXPERIENCE CLINICAL BENEFIT FROM

QSYMIA BASED ON THE PRESCRIBERS ASSESSMENT AND DOCUMENTATION THAT MEMBER HAS EXPERIENCED AT LEAST A 3 PERCENT REDUCTION IN WEIGHT FROM BASELINE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

QUDEXY(GHP2027)

MEDICATION(S)
TOPIRAMATE ER 100 MG CP24 SPRNK, TOPIRAMATE ER 150 MG CP24 SPRNK, TOPIRAMATE ER 200 MG CP24 SPRNK, TOPIRAMATE ER 25 MG CP24 SPRNK, TOPIRAMATE ER 50 MG CP24 SPRNK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PARTIAL ONSET SEIZURES, PRIMARY GENERALIZED TONIC CLONIC SEIZURES, OR LENNOX GASTAUT SYNDROME or DIAGNOSIS OF MIGRAINE PROPHYLAXIS

AGE RESTRICTION
12 YEARS OR OLDER FOR MIGRAINE PROPHYLAXIS, 2 YEARS OF AGE OR OLDER FOR OTHER INDICATIONS

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR SEIZURES: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ANTICONVULSANTS USED FOR THE REQUESTED DIAGNOSIS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

QUININE(GHP2027)

MEDICATION(S)
QUININE SULFATE 324 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR TREATMENT OF UNCOMPLICATED PLASMODIUM FALCIPARUM MALARIA

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 DAYS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

QULIPTA(GHP2027)

MEDICATION(S)
QULIPTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA AND ATTESTATION THAT MEMBER EXPERIENCES 4 OR MORE MIGRAINES PER MONTH.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH. ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE. REAUTHORIZATION WILL REQUIRE ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND ATTESTATION THAT THE MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTATIVE TREATMENT OF MIGRAINE.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

RADICAVA(GHP2027)

MEDICATION(S)
RADICAVA ORS, RADICAVA ORS STARTER KIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AMYOTROPIC LATERAL SCLEROSIS (ALS) AND DOCUMENTATION OF BASELINE FUNCTIONAL STATUS (AS EVIDENCED BY A SCORING SYSTEM SUCH AS ALSFRS-R, OR BY PHYSICIAN DOCUMENTATION OF SUBJECTIVE REPORTS ON SPEECH, MOTOR FUNCTION, PULMONARY FUNCTION, ETC.) AND DOCUMENTATION THAT RADICAVA IS BEING GIVEN IN COMBINATION WITH RILUZOLE OR INTOLERANCE TO OR CONTRAINDICATION TO RILUZOLE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER IS TOLERATING THERAPY WITH PRESCRIBED EDARAVONE REGIMEN AND DOCUMENTATION OF REGULAR PHYSICIAN FOLLOW-UP.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

RADICAVA IV(GHP2027)

MEDICATION(S)
EDARAVONE 30 MG/100ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF ALS (AMYOTROPHIC LATERAL SCLEROSIS) AND DOCUMENTATION OF BASELINE FUNCTIONAL STATUS (AS EVIDENCED BY A SCORING SYSTEM SUCH AS ALSFRS-R, OR BY PHYSICIAN DOCUMENTATION OF SUBJECTIVE REPORTS ON SPEECH, MOTOR FUNCTION, PULMONARY FUNCTION, ETC.)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT RADICAVA IS BEING GIVEN IN COMBINATION WITH RILUZOLE, OR HAVE AN INTOLERANCE OR CONTRAINDICATION TO RILUZOLE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER IS TOLERATING REGIMEN WITH DOCUMENTATION OF REGULAR PHYSICAN FOLLOW-UP.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

RALDESY(GHP2027)

MEDICATION(S)
RALDESY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of major depressive disorder.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Remainder of Contract Year

OTHER CRITERIA
Documentation of inability to tolerate or swallow tablets OR documentation of why a tablet formulation could not be used.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

REBLOZYL(GHP2027)

MEDICATION(S)
REBLOZYL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF BETA THALASSEMIA AND DOCUMENTATION THAT PATIENT REQUIRES REGULAR RED BLOOD CELL (RBC) TRANSFUSIONS. DIAGNOSIS OF VERY LOW TO INTERMEDIATE RISK MYELODYSPLASTIC SYNDROMES WITH RING SIDEROBLASTS (MDS-RS) OR WITH MYELODYSPLASTIC/MYELOPROLIFERATIVE NEOPLASM WITH RING SIDEROBLASTS AND THROMBOCYTOSIS (MDS/MPN-RS-T) WITH ONE OF THE FOLLOWING: 1) DOCUMENTATION OF 15% OR MORE RING SIDEROBLASTS OR 2) 5% OR MORE RING SIDEROBLASTS AND AN SF3B1 MUTATION. DOCUMENTATION OF REQUIRING TWO OR MORE RED BLOOD CELL (RBC) UNITS OVER 8 WEEKS.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A HEMATOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION OF BASELINE NUMBER OF TRANSFUSIONS AND RED BLOOD CELL (RBC) UNITS REQUIRED FOR THE PREVIOUS 6 MONTHS. DOCUMENTATION THAT MEDICATION IS BEING DOSES CONSISTENT WITH FDA APPROVED LABELING. FOR ANEMIA ASSOCIATED WITH MDS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR

CONTRAINDICATION TO AN ERYTHROPOIESIS STIMULATING AGENT. REAUTHORIZATION WILL REQUIRE AN INITIAL DECREASE IN RED BLOOD CELL (RBC) TRANSFUSION BURDEN, FOLLOWED BY A SUSTAINED REDUCTION OF RED BLOOD CELL (RBC) TRANSFUSION BURDEN AND THAT MEDICATION CONTINUES TO BE DOSED CONSISTENT WITH FDA APPROVED LABELING.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

REBYOTA(GHP2027)

MEDICATION(S)
REBYOTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT REBYOTA WILL BE USED FOR THE PREVENTION OF RECURRENCE OF C. DIFFICILE INFECTIONS AND DOCUMENTATION OF A DIAGNOSIS OF RECURRENT C. DIFFICILE INFECTION BASED ON THE RESULTS OF AN APPROPRIATE LABORATORY STOOL TEST WITHIN 30 DAYS OF PRIOR AUTHORIZATION REQUEST.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
INFECTIOUS DISEASE SPECIALIST OR GASTROENTEROLOGIST

COVERAGE DURATION
1 MONTH

OTHER CRITERIA
DOCUMENTATION THAT AN APPROPRIATE STANDARD OF CARE ANTIBACTERIAL REGIMEN WAS USED FOR THE TREATMENT OF RECURRENT C. DIFFICILE INFECTION (SUCH AS BUT NOT LIMITED TO ORAL FIDAXOMICIN, ORAL VANCOMYCIN, ORAL METRONIDAZOLE) AND DOCUMENTATION THAT PRESCRIBED DOSE AND ADMINISTRATION IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED LITERATURE.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

RECARBRIO(GHP2027)

MEDICATION(S)
RECARBRIO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF COMPLICATED URINARY TRACT INFECTION CAUSED BY THE FOLLOWING SUCEPTIBLE GRAM NEGATIVE MICROORGANISMS: ENTEROBACTER CLOACAE, ESCHERICHIA COLI, KLEBSIELLA AEROGENES, KLEBSIELLA PENUMONIAE OR PSEUDOMONAS AERUGINOSA OR COMPLICATED INTRA-ABDOMINAL INFECTION CAUSED BY THE FOLLOWING SUSCEPTIBLE GRAM NEGATIVE MICROORGANISMS: BACTEROIDES CACCAE, BACTEROIDES FRAGILIS, BACTEROIDES OVATUS, BACTEROIDES STERCORIS, BACTEROIDES THETAIOTAOMICRON, BACTEROIDES UNIFORMIS, BACTEROIDES VULGATUS, CITROBACTER FREUNDII, ENTEROBACTER CLOACAE, ESCHERICHIA COLI, FUSOBACTERIUM NUCLEATUM, KLEBSIELLA AEROGENES, KLEBSIELLA OXYTOCA, KLEBSIELLA PNEUMONIAE, PARABACTEROIDES DISTASONIS OR PSEUDOMONAS AERUGINOSA OR DIAGNOSIS OF HOSPITAL ACQUIRED BACTERIAL PNEUMONIA OR VENTILATOR ASSOCIATED BACTERIAL PNEUMONIA CAUSED BY THE FOLLOWING SUSCEPTIBLE GRAM-NEGATIVE MICROORGANISMS: ACINETOBACTER CALCOACETICUS-BAUMANNII COMPLEX, ENTEROBACTER CLOACAE, ESCHERICHIA COLI, HAEMOPHILUS INFLUENZA, KLEBSIELLA AEROGENES, KLEBSIELLA OXYTOCA, KLEBSIELLA PNEUMONIAE, PSEUDOMONAS AERUGINOSA, AND SERRATIA MARCESCENS.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

COVERAGE DURATION
2 WEEKS

OTHER CRITERIA
DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO PREFERRED ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY. DOCUMENTATION OF A THERAPEUTIC FAILURE ON IMIPENEM-CILASTIN OR MEDICAL RATIONALE OF WHY IMIPENEM-CILASTIN CANNOT BE USED.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

REDEMPLO(GHP2027)

MEDICATION(S)
REDEMPLO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of familial chylomicronemia syndrome (FCS) as confirmed by genetic testing (i.e., variants in LPL, apoC-II, GPIHBP1, apoA-V, or LMF1) OR if genetic testing is inconclusive, a diagnosis of FCS confirmed by a North American FCS (NAFCS) score greater than or equal to 45.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a lipidologist, endocrinologist, gastroenterologist or cardiologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that medication will not be used concomitantly with Tryngolza. Documentation of fasting triglycerides greater than or equal to 880 mg/dL. Documentation or prescriber attestation that member is adhering to a low fat diet of 20 grams of fat per day or less. Reauthorizations will require provider attestation or documentation of a positive response to therapy (i.e. reduction in fasting triglycerides from baseline, reduction in acute pancreatitis episodes) AND documentation or prescriber attestation that member is adhering to a low fat diet of 20 grams of fat per day or less AND documentation that medication is not being used concomitantly with Tryngolza.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

REGRANEX(GHP2027)

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of lower extremity diabetic neuropathic ulcers (i.e., diabetic foot ulcer) that extend into the subcutaneous tissue or beyond and have an adequate blood supply.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

REMODULIN(GHP2027)

MEDICATION(S)
TREPROSTINIL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF WHO GROUP 1 PULMONARY ARTERIAL HYPERTENSION (PAH).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF USE IN COMBINATION WITH OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND AN APPROPRIATE SECOND LINE AGENT (AN ENDOTHELIN RECEPTOR ANTAGONIST OR UPTRAVI) USED WITH SILDENAFIL.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

REPATHA(GHP2027)

MEDICATION(S)
REPATHA, REPATHA SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of hypercholesterolemia or attestation that member is at increased risk of major adverse cardiovascular (CV) events. Diagnosis of heterozygous familial hypercholesterolemia (HeFH). Diagnosis of homozygous familial hypercholesterolemia (HoFH).

AGE RESTRICTION
For HeFH or HoFH: Must be 10 years of age or older. For All Others: Must be 18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Attestation that Repatha is not being used in combination with another PCSK9 inhibitor. Attestation that the member cannot achieve LDL-C goal while being treated with one high-intensity statin OR attestation that member is statin intolerant as demonstrated by (1) statin-associated rhabdomyolysis to one statin or (2) trial of both rosuvastatin and atorvastatin that resulted in skeletal-muscle related symptoms on both agents which resolved upon discontinuation. Reauthorization will require prescriber attestation of clinically significant response to treatment and attestation of no significant adverse events related to therapy and attestation that Repatha continues to not be used in combination with another PCSK9 inhibitor.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

RETEVMO(GHP2027)

MEDICATION(S)
RETEVMO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of RET Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

REVATIO(GHP2027)

MEDICATION(S)
SILDENAFIL CITRATE 10 MG/12.5ML SOLUTION, SILDENAFIL CITRATE 10 MG/ML RECON SUSP, SILDENAFIL CITRATE 20 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
RAYNAUDS PHENOMENON

EXCLUSION CRITERIA
CONCOMITANT USE OF ORGANIC NITRATES

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION. DIAGNOSIS OF SECONDARY RAYNAUDS PHENOMENON.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH: PULMONOLOGIST OR CARDIOLOGIST. RAYNAUDS: RHEUMATOLOGIST.

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR RAYNAUDS: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

REVCOVI(GHP2027)

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF ADENOSINE DEAMINASE DEFICIENCY-ASSOCIATED SEVERE COMBINED IMMUNE DEFICIENCY (ADA-SCID) CONFIRMED BY EITHER A VERY LOW PRESENCE OR ABSENCE OF ADA (ADENOSINE DEAMINASE) ACTIVITY IN RED BLOOD CELLS OR OTHER SAMPLES AND AN INCREASE IN ADENOSINE, DEOXYADENOSINE, AND DEOXYADENOSINE TRIPHOSPHATE (DATP) LEVELS IN RED BLOOD CELLS, PLASMA, OR URINE OR BIALLELIC MUTATIONS IN THE ADA1 GENE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH AN IMMUNOLOGIST, GENETICIST, OR A PHYSICIAN WHO SPECIALIZES IN INHERITED METABOLIC DISORDERS

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT DOSING IS CONSISTENT WITH FDA APPROVED LABELING. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED OR SUSTAINED IMPROVEMENT SUCH AS BUT NOT LIMITED TO TROUGH PLASMA ADA AND DAXP LEVELS WHILE ON THERAPY AND DOCUMENTATION OF PLANNED HEMATOPOIETIC CELL TRANSPLANTATION OR GENE THERAPY OR DOCUMENTATION OF NOT BEING A SUITABLE

Pending CMS Approval

CANDIDATE FOR HEMATOPOIETIC CELL TRANSPLANTATION AND GENE THERAPY AT THE TIME OF THE REQUEST.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

REVLIMID(GHP2027)

MEDICATION(S)
LENALIDOMIDE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

REVUFORJ(GHP2027)

MEDICATION(S)
REVUFORJ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR ACUTE LEUKEMIA: Documentation of KMT2A gene mutation OR a susceptible NPM1 mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

REXULTI(GHP2027)

MEDICATION(S)
REXULTI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA. ADJUNCTIVE TREATMENT FOR MAJOR DEPRESSIVE DISORDER (MDD). DIAGNOSIS OF AGITATION ASSOCIATED WITH DEMENTIA DUE TO ALZHEIMER'S DISEASE AND DOCUMENTATION THAT REXULTI WILL NOT BE TAKEN ON AN AS-NEEDED (PRN) BASIS.

AGE RESTRICTION
Schizophrenia: 13 years of age or older. MDD:18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR MDD: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF ADD ON ANTIDEPRESSANT THERAPY WITH ARIPIPRAZOLE. FOR SCHIZOPHRENIA, DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY MEDICATIONS ONE OF WHICH MUST BE ARIPIPRAZOLE (ARIPIPRAZOLE, OLANZAPINE, RISPERIDONE, QUETIAPINE IR, OR ZIPRASIDONE).

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

REZDIFFRA(GHP2027)

MEDICATION(S)
REZDIFFRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH). Documentation of moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that diagnosis is confirmed by one of the following: 1)liver biopsy or 2) a non-invasive test (such as, but not limited to ultrasound elastography or biomarker labs). Documentation that the member does not have decompensated cirrhosis. Reauthorization will require documentation or physician attestation of continued disease improvement or lack of disease progression (such as, but not limited to, MASH resolution AND no worsening of fibrosis, OR no worsening of MASH AND improvement in fibrosis by at least 1 stage).

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

REZLIDHIA(GHP2027)

MEDICATION(S)
REZLIDHIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of IDH1 mutation expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

REZUROCK(GHP2027)

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF CHRONIC GRAFT-VERSUS-HOST DISEASE (GVHD) AND DOCUMENTATION OF THERAPEUTIC FAILURE OF TWO OR MORE PRIOR LINES OF SYSTEMIC THERAPY.

AGE RESTRICTION
MUST BE 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
HEMATOLOGIST, ONCOLOGIST, OR TRANSPLANT SPECIALIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS REAUTH

OTHER CRITERIA
IF REQUEST IS FOR 200 MG TWICE DAILY DOSING, DOCUMENTATION OF ONE OF THE FOLLOWING:1) DOCUMENTATION THAT MEMBER IS CURRENTLY RECEIVING A STRONG CYP3A4 INDUCER OR 2) DOCUMENTATION THAT MEMBER IS CONCURRENTLY TAKING WITH MAINTENANCE PROTON PUMP INHIBITOR (PPI) AND CONTINUED MAINTENANCE TREATMENT WITH A PPI IS MEDICALLY NECESSARY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUE DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND IF REQUEST IS FOR 200 MG TWICE DAILY DOSING, DOCUMENTATION OF ONE OF THE FOLLOWING:1) DOCUMENTATION THAT MEMBER IS CURRENTLY RECEIVING A STRONG CYP3A4 INDUCER OR 2) DOCUMENTATION THAT MEMBER IS CONCURRENTLY

Pending CMS Approval

TAKING WITH MAINTENANCE PROTON PUMP INHIBITOR (PPI) AND CONTINUED MAINTENANCE TREATMENT WITH A PPI IS MEDICALLY NECESSARY.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

REZZAYO(GHP2027)

MEDICATION(S)
REZZAYO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CANDIDEMIA OR INVASIVE CANDIDIASIS (OTHER THAN ENDOCARDITIS, OSTEOMYELITIS, OR MENINGITIS) AND DOCUMENTATION THAT MEMBER HAS LIMITED OR NO ALTERNATIVE TREATMENT OPTIONS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
4 WEEKS (ONE COURSE OF THERAPY)

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RINVOQ(GHP2027)

MEDICATION(S)
RINVOQ, RINVOQ LQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MODERATE TO SEVERE RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA. DIAGNOSIS OF ACTIVE PSORIATIC ARTHRITIS AND ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS. DIAGNOSIS OF MODERATE TO SEVERE ULCERATIVE COLITIS. DIAGNOSIS OF ANKYLOSING SPONDYLITIS. DIAGNOSIS OF NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS WITH DOCUMENTATION OF EITHER C-REACTIVE PROTEIN (CRP) LEVEL ABOVE THE UPPER LIMIT OF NORMAL OR SACROILIITIS ON MAGNETIC RESONANCE IMAGING (MRI). DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHNS DISEASE (CD). DIAGNOSIS OF POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS (pcJIA). DIAGNOSIS OF GIANT CELL ARTERITIS (GCA).

Pending CMS Approval

AGE RESTRICTION
AD: 12 YRS OR OLDER, PSA AND pcJIA: 2 YRS OR OLDER, ALL OTHERS: 18 YRS OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST, IMMUNOLOGIST, OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH ANOTHER JAK INHIBITOR OR BIOLOGIC IMMUNOMODULATOR. DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE. FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR ENBREL. FOR PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR ENBREL AND DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON PATIENT AGE AND WEIGHT. FOR AD: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DAILY AT LEAST MEDIUM POTENCY TOPICAL CORTICOSTEROIDS OR CALCINEURIN INHIBITOR (I.E. TACROLIMUS) IF TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE AND THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE SYSTEMIC THERAPY FOR AD. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ENBREL OR FORMULARY ADALIMUMAB PRODUCT. FOR NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF CIMZIA. FOR CD: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT. IF TNF BLOCKERS ARE CLINICALLY INADVISABLE, DOCUMENTATION OF ONE PRIOR SYSTEMIC THERAPY FOR CD PRIOR TO USE OF RINVOQ. FOR UC: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT. IF TNF BLOCKERS ARE CLINICALLY INADVISABLE, DOCUMENTATION OF ONE PRIOR SYSTEMIC THERAPY FOR UC PRIOR TO USE OF RINVOQ. FOR pcJIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR ENBREL AND DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON PATIENT AGE AND WEIGHT. FOR GCA: DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH A TAPERING COURSE OF ORAL GLUCOCORTICOIDS OR AS MONOTHERAPY AFTER COMPLETION OF THER STEROID TAPER. REAUTHORIZATION WILL REQUIRE DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

RISPERIDONE(GHP2027)

MEDICATION(S)
RISPERIDONE MICROSPHERES ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
SCHIZOPHRENIA OR BIPOLAR I DISORDER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

RITUXAN(GHP2027)

MEDICATION(S)
RIABNI, RUXIENCE, TRUXIMA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND DOCUMENTATION THAT METHOTREXATE WILL BE CONTINUED DURING RITUXIMAB THERAPY. DX OF ACUTE LYMPHOBLASTIC LEUKEMIA, HAIRY CELL LEUKEMIA OR CHRONIC LYMPHOCYTIC LEUKEMIA. DX OF MICROSCOPIC POLYARTERITIS NODOSA USED IN COMBO WITH GLUCOCORTICOIDS. DX OF DIFFUSE NON-HODGKINS LYMPHOMA. DX OF HODGKIN LYMPHOMA. DX OF GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS OR MICROSCOPIC POLYANGIITIS (MPA) USED IN COMBINATION WITH GLUCOCORTICOIDS. DX OF CHRONIC ITP AND PLATELET COUNT OF LESS THAN 30,000/MICROL WITH ACTIVE BLEEDING OR PLATELET COUNT OF LESS THAN 20,000/MICROL WITH INCREASED RISK OF BLEEDING AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS AND IVIG. DX OF MULTIPLE SCLEROSIS. DX OF MODERATE TO SEVERE PEMPHIGUS VULGARIS (PV).

Pending CMS Approval

AGE RESTRICTION
FOR RA AND PV: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR RA: RHEUMATOLOGIST, FOR PV: DERMATOLOGIST

COVERAGE DURATION
FOR RA AND ITP: 3 MONTHS. FOR CLL, NHL AND MS: INDEFINITE, ALL OTHER DIAGNOSES: 12 MONTHS

OTHER CRITERIA

FOR RA, MPN, GPA, MPA, ITP, and PV: DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO (2) PREFERRED BIOLOGIC AGENTS INDICATED FOR RHEUMATOID ARTHRITIS (HUMIRA*, ENBREL*, RINVOQ*, XELJANZ*). ONE COURSE OF THERAPY IS DEFINED AS TWO INFUSIONS GIVEN ON DAY 1 AND ANOTHER ON DAY 15. ADDITIONAL COURSES MAY BE CONSIDERED MEDICALLY NECESSARY IF AT LEAST 6 MONTHS HAS ELAPSED SINCE THE PREVIOUS TREATMENT COURSE AND DOCUMENTATION OF IMPROVEMENT. FOR PV: DOCUMENTATION OF A CONTRAINDICATION TO, INTOLERANCE OR THERAPEUTIC FAILURE ON CORTICOSTEROIDS AND A 12-WEEK TRIAL OF AT LEAST ONE NONSTEROIDAL IMMUNOMODULATORY MEDICATION (I.E. AZATHIOPRINE, CYCLOPHOSPHAMIDE OR MYCOPHENOLATE)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

RITUXAN HYCELA(GHP2027)

MEDICATION(S)
RITUXAN HYCELA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ROLVEDON(GHP2027)

MEDICATION(S)
ROLVEDON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

REQUIRED MEDICAL INFORMATION
PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY

TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN)

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ROMVIMZA(GHP2027)

MEDICATION(S)
ROMVIMZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist, or Urologist (if Prostate Cancer). Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 Months

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ROZLYTREK(GHP2027)

MEDICATION(S)
ROZLYTREK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: NTRK Gene fusions, ROS-1 Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RUBRACA(GHP2027)

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRCA pathogenic variant. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RUCONEST(GHP2027)

MEDICATION(S)
RUCONEST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation that medication is being used for the treatment of an acute attack of hereditary angioedema.

AGE RESTRICTION
13 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For members 18 years of age or older, documentation of failure on, intolerance to, or contraindication to icatibant.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

RUXOLITINIB(GHP2027)

MEDICATION(S)
JAKAFI, JAKAFI XR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of platelet count. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYBELSUS(GHP2027)

MEDICATION(S)
RYBELSUS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Type 2 Diabetes Mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYBREVANT FASPRO(GHP2027)

MEDICATION(S)
RYBREVANT FASPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
For NSCLC: documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYBREVANT(GHP2027)

MEDICATION(S)
RYBREVANT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYDAPT(GHP2027)

MEDICATION(S)
RYDAPT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Allergist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FLT3 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYKINDO(GHP2027)

MEDICATION(S)
RYKINDO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF SCHIZOPHRENIA. DX BIPOLAR 1 DISORDER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON OR INTOLERANCE TO THE ORAL EQUIVALENT OF THE REQUESTED INJECTABLE THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

RYLAZE(GHP2027)

MEDICATION(S)
RYLAZE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

RYTELO(GHP2027)

MEDICATION(S)
RYTELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MYELODYSPLASTIC SYNDROMES (MDS). DOCUMENTATION OF LOW TO INTERMEDIATE-1 RISK DISEASE. DOCUMENTATION THAT MEMBER HAS TRANSFUSION-DEPENDENT ANEMIA, REQUIRING 4 OR MORE RED BLOOD CELL UNITS OVER 8 WEEKS.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR INITIAL, 12 MONTH REAUTH

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, CONTRAINDICATION TO, OR INELIGIBILITY FOR AN ERYTHROPOIESIS STIMULATING AGENT. DOCUMENTATION THAT RYTELO IS BEING DOSED CONSISTENT WITH FDA-APPROVED LABELING. FAILURE ON, INTOLERANCE TO, CONTRAINDICATION TO, OR INELIGIBILITY FOR REBLOZYL (LUSPATERCEPT-AAMT). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. RYTELO WILL NO LONGER BE COVERED IF THE MEMBER DOES NOT EXPERIENCE A DECREASE IN TRANSFUSION BURDEN AFTER 24 WEEKS OF TREATMENT (ADMINISTRATION OF 6 DOSES) OR IF UNACCEPTABLE TOXICITY OCCURS AT ANY TIME.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SABRIL(GHP2027)

MEDICATION(S)
VIGABATRIN, VIGADRONE, VIGPODER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF REFRACTORY COMPLEX PARTIAL SEIZURES. DX OF INFANTILE SPASMS.

AGE RESTRICTION
INFANTILE SPASMS - 1 MONTH TO 2 YEARS OF AGE

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR REFRACTORY COMPLEX PARTIAL SEIZURES MUST BE ON CONCOMMITANT THERAPY WITH ANOTHER SEIZURE CONTROL MEDICATION

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SANCUSO(GHP2027)

MEDICATION(S)
SANCUSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of administration of a moderately to highly emetogenic chemotherapy for up to 5 consecutive days.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to ondansetron and oral granisetron.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SANDOSTATIN LAR(GHP2027)

MEDICATION(S)
OCTREOTIDE ACETATE 20 MG KIT, OCTREOTIDE ACETATE 30 MG KIT, SANDOSTATIN LAR DEPOT 10 MG KIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF ONE OF THE FOLLOWING: ACROMEGALY, VASOACTIVE INTESTINAL PEPTIDE (VIP) SECRETING TUMOR, OR METASTATIC CARCINOID TUMOR.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THE USE OF OCTREOTIDE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SANTYL(GHP2027)

MEDICATION(S)
SANTYL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for debriding chronic dermal ulcers or severely burned areas.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Dermatologist OR burn or wound care specialist

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT THE PRESCRIBED DOSE IS MEDICALLY NECESSARY BASED ON THE WOUND LENGTH, WOUND WIDTH, AND INTENDED DURATION OF THERAPY.
REAUTHORIZATION WILL REQUIRE (1)DOCUMENTATION THAT THE MEMBER CONTINUES TO BE EVALUATED BY A BURN, WOUND CARE OR OTHER SPECIALIST WITH EXPERIENCE IN THE MANAGMENT OF SEVERE WOUNDS AND (2) DOCUMENTATION THAT THE PRESCRIBED DOSE IS MEDICALLY NECESSARY BASED ON THE WOUND LENGTH, WOUND WIDTH, AND INTENDED DURATION OF THERAPY.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SAPHNELO(GHP2027)

MEDICATION(S)
SAPHNELO 300 MG/2ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF MODERATE TO SEVERE SYSTEMIC LUPUS ERYTHEMATOSUS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER DOES NOT HAVE SEVERE ACTIVE LUPUS NEPHRITIS OR SEVERE ACTIVE CENTRAL NERVOUS SYSTEM LUPUS. DOCUMENTATION OF CURRENTLY RECEIVING A STABLE TREATMENT REGIMEN WITH CORTICOSTEROIDS, ANTIMALARIALS, OR IMMUNOSUPPRESSANTS. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH OTHER BIOLOGIC AGENTS, INCLUDING B-CELL TARGETED THERAPIES. REAUTHORIZATION WILL REQUIRE PROVIDER ASSESSMENT OF CLINICAL BENEFIT OF ONE OF THE FOLLOWING: IMPROVEMENT IN FUNCTIONAL IMPAIRMENT, DECREASE IN NUMBER OF EXACERBATIONS SINCE STARTING MEDICATION, OR DECREASE IN THE DAILY REQUIRED DOSE OF ORAL CORTICOSTEROIDS.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SAPHRIS(GHP2027)

MEDICATION(S)
ASENAPINE MALEATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF BIPOLAR DISORDER OR SCHIZOPHRENIA

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
MEDICAL RECORD DOCUMENTATION OF TRIAL ON TWO FORMULARY ALTERNATIVES (aripiprazole, ziprasidone, risperidone, quetiapine, olanzapine).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SARCLISA(GHP2027)

MEDICATION(S)
SARCLISA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SAXENDA(GHP2027)

MEDICATION(S)
LIRAGLUTIDE -WEIGHT MANAGEMENT, SAXENDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF USE AS ADJUNCT THERAPY TO REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY FOR CHRONIC WEIGHT MANAGEMENT. FOR ADULTS: DOCUMENTATION OF ONE OF THE FOLLOWING: (1) BODY MASS INDEX (BMI) GREATER THAN OR EQUAL TO 30 KG/M2 OR (2) BMI GREATER THAN OR EQUAL TO 27 KG/M2 AND AT LEAST ONE WEIGHT-RELATED COMORBIDITY (E.G., HYPERTENSION, TYPE 2 DIABETES MELLITUS, OR DYSLIPIDEMIA). FOR PEDIATRICS: DOCUMENTATION OF BODY WEIGHT ABOVE 60 KG AND AN INITIAL BMI CORRESPONDING TO 30 KG/M2 FOR ADULTS BY INTERNATIONAL CUT-OFFS (COLE CRITERIA).

Pending CMS Approval

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS PARTICIPATED IN COMPREHENSIVE LIFESTYLE MODIFICATIONS INCLUDING REDUCED-CALORIE DIET, PHYSICAL ACTIVITY, AND BEHAVIORAL HEALTH FOR AT LEAST 3 MONTHS PRIOR TO BEGINNING SAXENDA. FAILURE ON WEGOVY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER

CONTINUES TO EXPERIENCE CLINICAL BENEFIT FROM SAXENDA BASED ON THE PRESCRIBERS ASSESSMENT AND DOCUMENTATION THAT MEMBER HAS EXPERIENCED AT LEAST A 4 PERCENT REDUCTION IN WEIGHT FROM BASELINE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SCEMBLIX(GHP2027)

MEDICATION(S)
SCEMBLIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of T315I mutation expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SECUADO(GHP2027)

MEDICATION(S)
SECUADO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of schizophrenia

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Medical record documentation of a therapeutic failure on, intolerance to or contraindication to two formulary antipsychotics indicated for associated diagnosis.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SIGNIFOR(GHP2027)

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF CUSHING'S DISEASE AND DOCUMENTATION THAT PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KETOCONAZOLE. REAUTHORIZATION REQUIRES DOCUMENTATION OF IMPROVEMENT IN URINARY FREE CORTISOL LEVELS COMPARED TO BASELINE

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SIGNIFOR LAR(GHP2027)

MEDICATION(S)
SIGNIFOR LAR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF ACROMEGALY AND DOCUMENTATION OF AN INADEQUATE RESPONSE TO OR THE INABILITY TO BE TREATED WITH SURGERY OR RADIOTHERAPY. DOCUMENTATION OF A DIAGNOSIS OF CUSHING'S DISEASE AND DOCUMENTATION THAT PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR ACROMEGALY: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OCTREOTIDE AND SOMATULINE DEPOT. REAUTHORIZATION REQUIRES IMPROVEMENT OF IGF-1 OR GH LEVELS. FOR CUSHING'S DISEASE: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO KETOCONAZOLE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN URINARY FREE CORTISOL LEVELS COMPARED TO BASELINE

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SIMPONI ARIA(GHP2027)

MEDICATION(S)
SIMPONI ARIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS (RA) WITH CONCURRENT USE OF METHOTREXATE. DX OF PSORIATIC ARTHRITIS (PSA). DX OF ANKYLOSING SPONDYLITIS (AS). DX OF ACTIVE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA).

AGE RESTRICTION
FOR RA AND AS: 18 YEARS OF AGE OR OLDER. FOR PSA AND pJIA: 2 YEARS OF AGE OR OLDER.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR INITIAL, 12 MONTH REAUTH

OTHER CRITERIA
RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS INDICATED FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, RINVOQ, XELJANZ). FOR PSA MEMBERS 18 YEARS OF AGE OR OLDER: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR THE TREATMENT OF PSA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, COSENTYX, OTEZLA, SKYRIZI, TREMFYA, RINVOQ, XELJANZ). FOR AS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (ENBREL, FORMULARY ADALIMUMAB

Pending CMS Approval

PRODUCT, COSENTYX, RINVOQ, XELJANZ). FOR pJIA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR JIA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB SC PRODUCT, XELJANZ). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SIMPONI(GHP2027)

MEDICATION(S)
SIMPONI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSICIATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS AND BEING USED IN CONJUNCTION WITH METHOTREXATE. DX OF ACTIVE PSORIATIC ARTHRITIS AND DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION). DX OF ANKYLOSING SPONDYLITIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION). DX OF MODERATE TO SEVERE ULCERATIVE COLITIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION).

Pending CMS Approval

AGE RESTRICTION
FOR RA, PSA, AND AS: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, GASTROENTEROLOGIST, DERMATOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR RA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, FORMULARY TOCILIZUMAB

PRODUCT, RINVOQ, XELJANZ). FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (ENBREL, FORMULARY ADALIMUMAB PRODUCT, XELJANZ, RINVOQ). FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (ENBREL, FORMULARY ADALIMUMAB PRODUCT, OTEZLA, SKYRIZI, TREMFYA, RINVOQ, XELJANZ, FORMULARY USTEKINUMAB PRODUCT). FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE PREFERRED BIOLOGIC AGENT FOR RA (FORMULARY ADALIMUMAB PRODUCT, SKYRIZI, TREMFYA, FORMULARY USTEKINUMAB PRODUCT). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SIRTURO(GHP2027)

MEDICATION(S)
SIRTURO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF RESISTANCE TO ISONIAZID AND RIFAMPIN AND DOCUMENTATION THAT AN EFFECTIVE TREATMENT REGIMEN CANNOT BE ATTAINED WITH OTHER AVAILABLE TREATMENT OPTIONS AND DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH OTHER DRUGS TO WHICH THE PATIENT'S MULTI DRUG RESISTANT TB ISOLATE HAS BEEN SHOWN TO BE SUSCEPTIBLE IN VITRO

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
24 WEEKS

OTHER CRITERIA
IF IN VITRO TESTING RESULTS ARE UNAVAILABLE, DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH OTHER DRUGS TO WHICH THE PATIENTS MDR-TB ISOLATE IS LIKELY TO BE SUSCEPTIBLE

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SIVEXTRO(GHP2027)

MEDICATION(S)
SIVEXTRO 200 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF AN ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (INCLUDING CELLULITIS/ERYSIPELAS, WOUND INFECTION, AND MAJOR CUTANEOUS ABSCESS) CAUSED BY STAPHYLOCOCCUS AUREUS, STREPTOCOCCUS PYOGENES, STREPTOCOCCUS AGALACTIAE, STREPTOCOCCUS ANGINOSUS, STREPTOCOCCUS INTERMEDIUS, STREPTOCOCCUS CONSTELLATUS, OR ENTEROCOCCUS FAECALIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
DIAGNOSED AND DOCUMENTED WITH INFECTIOUS DISEASE CONSULTATION

COVERAGE DURATION
ONE-TIME COURSE OF THERAPY OF 6 DAYS

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SKYCLARYS(GHP2027)

MEDICATION(S)
SKYCLARYS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF FRIEDRICH'S ATAXIA AND DOCUMENTATION OF GENETIC TESTING CONFIRMING FRATAXIN (FXN) GENE MUTATION AND DOCUMENTATION OF BASELINE MODIFIED FRIEDRICH'S ATAXIA RATING SCALE (mFARS) SCORE.

AGE RESTRICTION
16 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER IS RESPONDING POSITIVELY TO THERAPY AS EVIDENCED BY SLOWED DISEASE PROGRESSION OR DOCUMENTATION OF A POSITIVE CLINICAL RESPONSE (I.E., THROUGH MODIFIED FUNCTIONAL ASSESSMENT RATING SCALE).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

SKYRIZI(GHP2027)

MEDICATION(S)
SKYRIZI, SKYRIZI (150 MG DOSE), SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 3% BSA OR DISEASE AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP OR GENITALS. DIAGNOSIS OF ACTIVE PSORIATIC ARTHRITIS WITH A HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE. DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST, RHEUMATOLOGIST, OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO MTX OR PHOTOTHERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SKYTROFA(GHP2027)

MEDICATION(S)
SKYTROFA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SOGROYA(GHP2027)

MEDICATION(S)
SOGROYA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF GROWTH FAILURE DUE TO INADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION. DIAGNOSIS OF GROWTH HORMONE DEFICIENCY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SOMAVERT(GHP2027)

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acromegaly AND either documentation of an inadequate or partial response to surgery or radiotherapy OR documentation of a clinical reason why the patient has not had surgery or radiotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Reauthorization will require documentation from prescriber indication improvement in condition OR documentation that patient's IGF-1 level has decreased or normalized since initiation of therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SORIATANE(GHP2027)

MEDICATION(S)
ACITRETIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SEVERE PSORIASIS WITH AT LEAST 3% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP OR GENITALS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
DERMATOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE TOPICAL CORTICOSTEROID AND AT LEAST 2 TO 3 MONTHS OF METHOTREXATE OR PHOTOTHERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SPEVIGO(GHP2027)

MEDICATION(S)
SPEVIGO 450 MG/7.5ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF GENERALIZED PUSTULAR PSORIASIS (GPP) AND DOCUMENTATION OF A GPP FLARE OF MODERATE TO SEVERE INTENSITY AND ALL OF THE FOLLOWING: (1) GPP PHYSICIAN GLOBAL ASSESSMENT (GPPPGA) TOTAL SCORE OF GREATER THAN OR EQUAL TO 3 (MODERATE TO SEVERE) AND (2) GPPPGA PUSTULATION SUBSCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO VERY HIGH DENSITY PUSTULES) AND (3) PRESENCE OF FRESH PUSTULES (NEW APPEARANCE OR WORSENING OF PUSTULES) AND (4) GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA COVERED WITH ERYTHEMA AND PRESENCE OF PUSTULES. DOCUMENTATION OF A DOSE AND DURATION OF THERAPY THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED LITERATURE.

Pending CMS Approval

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST

COVERAGE DURATION
1 WEEK

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER IS EXPERIENCING PERSISTENT SYMPTOMS OF AN ACUTE GPP FLARE OF MODERATE TO SEVERE INTENSITY

AND ALL OF THE FOLLOWING: (1) GPPPGA TOTAL SCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO SEVERE) AND (2) GPPPGA PUSTULATION SUBSCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO VERY HIGH DENSITY PUSTULES) AND (3) SPEVIGO WILL BE ADMINISTERED NO SOONER THAN 1 WEEK AFTER THE INITIAL DOSAGE WAS ADMINISTERED AND (4) DOCUMENTATION THAT MEMBER HAS NOT ALREADY RECEIVED TWO DOSES OF SPEVIGO FOR TREATMENT OF GPP FLARE. TREATMENT OF NEW GPP FLARES WILL REQUIRE REEVALUATION OF COVERAGE FOR A NEW INITIAL APPROVAL REQUIRING DOCUMENTATION OF A GPP FLARE OF MODERATE TO SEVERE INTENSITY AND ALL OF THE FOLLOWING: (1) GPPPGA TOTAL SCORE OF GREATER THAN OR EQUAL TO 3 (MODERATE TO SEVERE) AND (2) GPPPGA PUSTULATION SUBSCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO VERY HIGH DENSITY PUSTULES) AND (3) PRESENCE OF FRESH PUSTULES (NEW APPEARANCE OR WORSENING OF PUSTULES) AND (4) GREATER THAN OR EQUAL TO 5 PERCENT BODY SURFACE AREA COVERED WITH ERYTHEMA AND PRESENCE OF PUSTULES AND (5) AT LEAST 12 WEEKS HAVE ELAPSED SINCE LAST DOSE OF SPEVIGO. ONE SUBSEQUENT APPROVAL OF SPEVIGO FOR TREATMENT OF PERSISTENT SYMPTOMS OF REPEAT GPP FLARE WILL BE GIVEN WHEN THE FOLLOWING IS MET: DOCUMENTATION THAT MEMBER IS EXPERIENCING PERSISTENT SYMPTOMS OF AN ACUTE GPP FLARE OF MODERATE TO SEVERE INTENSITY AND ALL OF THE FOLLOWING: (1) GPPPGA TOTAL SCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO SEVERE) AND (2) GPPPGA PUSTULATION SUBSCORE OF GREATER THAN OR EQUAL TO 2 (MODERATE TO VERY HIGH DENSITY PUSTULES) AND (3) SPEVIGO WILL BE ADMINISTERED NO SOONER THAN 1 WEEK AFTER THE INITIAL DOSAGE WAS ADMINISTERED.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SPEVIGO SQ(GHP2027)

MEDICATION(S)
SPEVIGO 150 MG/ML SOLN PRSYR, SPEVIGO 300 MG/2ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF GENERALIZED PUSTULAR PSORIASIS (GPP).

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST

COVERAGE DURATION
12 Months

OTHER CRITERIA
Documentation of one of the following: continued therapy following a GPP flare treated with intravenous spesolimab-sbzo OR documenation that a member will receive a 600 mg subcutaneous loading dose. Documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reveiwed medical literature. Reauthorization will require documentation of clinical improvement or lack of progression in signs and symptoms of treated condition while on therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

SPRAVATO(GHP2027)

MEDICATION(S)
SPRAVATO (56 MG DOSE), SPRAVATO (84 MG DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF TREATMENT-RESISTANT MAJOR DEPRESSION DISORDER (MDD), CONSISTENT WITH THE FDA APPROVED INDICATION. DOCUMENTATION OF BASELINE DEPRESSION STATUS USING AN APPROPRIATE RATING SCALE (SUCH AS PHQ-9, CLINICALLY USEFUL DEPRESSION OUTCOME SCALE, QUICK INVENTORY OF DEPRESSIVE SYMPTOMATOLOGY-SELF REPORT 16 ITEM, MADRS, HAM-D). DOCUMENTATION OF MAJOR DEPRESSION DISORDER AND DOCUMENTATION OF A RECENT HOSPITAL ADMISSION (WITHIN 4 WEEKS) DUE TO DEPRESSIVE SYMPTOMS WITH ACUTE SUICIDAL IDEATION AND BEHAVIOR.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 MONTH INITIAL, 12 MONTHS CONTINUATION. MDD WITH SI: 1 MONTH

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINISTRATION THAT IS CONSISTENT WITH FDA APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. DOCUMENTATION THAT ALL POTENTIAL DRUG INTERACTIONS AND OTHER APPLICABLE SAFETY CONCERNS HAVE BEEN ASSESSED BY

THE PRESCRIBER AND ADDRESSED WITH THE MEMBER WHEN APPROPRIATE (SUCH AS DISCONTINUATION OF THE INTERACTING DRUG, DOSE REDUCTION OF THE INTERACTING DRUG, COUNSELING OF THE BENEFICIARY ABOUT THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT, AND EDUCATION ON POTENTIAL ADVERSE EFFECTS INCLUDING THE RISK FOR ABUSE, MISUSE, AND ADDICTION). FOR TREATMENT RESISTANT MDD: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST ONE AUGMENTATION THERAPY (SUCH AS BUT NOT LIMITED TO LITHIUM, ANTIPSYCHOTIC, OR STIMULANT) IN COMBINATION WITH AN ANTIDEPRESSANT AT AN OPTIMIZED DOSE FOR AT LEAST 6 WEEKS. TREATMENT-RESISTANT DEPRESSION AS DEFINED BY FAILURE OF AT LEAST TWO ANTIDEPRESSANTS FROM TWO DIFFERENT CLASSES AT AN OPTIMIZED DOSE FOR AT LEAST 6 WEEKS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT IN DEPRESSION SYMPTOMS AS MEASURED BY AN APPROPRIATE RATING SCALE (COMPARED TO PREVIOUS MEASUREMENT). FOR MDD WITH SI: DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH AN ORAL ANTIDEPRESSANT AND DOCUMENTATION THAT DOSING DOES NOT EXCEED FDA APPROVED TREATMENT DURATION OF 4 WEEKS OR THAT THERAPY WAS INITIATED AS AN INPATIENT. MDD WITH SI REAUTHORIZATION BEYOND FDA TREATMENT DURATION WILL REQUIRE DOCUMENTATION OF PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SPRYCEL(GHP2027)

MEDICATION(S)
DASATINIB, PHYRAGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

STELARA(GHP2027)

MEDICATION(S)
STELARA 130 MG/26ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 3% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP, OR GENITALS. DX OF ACTIVE PSORIATIC ARTHRITIS WITH DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DX OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE. Diagnosis of moderately to severely active ulcerative colitis.

AGE RESTRICTION
FOR PP AND PSA: MUST BE 6 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST, RHEUMATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE OR PHOTOTHERAPY. FOR PEDIATRIC PLAQUE PSORIASIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY TOPICAL

Pending CMS Approval

CORTICOSTEROIDS. FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 1 MONTH TRIAL OF ONE FORMULARY NSAID AND METHOTREXATE or DOCUMENTATION OF BEING PREVIOUSLY TREATED WITH A BIOLOGIC MEDICATION (E.G., TUMOR NECROSIS FACTOR INHIBITOR). FOR AXIAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 1 MONTH TRIAL OF TWO FORMULARY NSAIDS or DOCUMENTATION OF BEING PREVIOUSLY TREATED WITH A BIOLOGIC MEDICATION (E.G., TUMOR NECROSIS FACTOR INHIBITOR). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

STIVARGA(GHP2027)

MEDICATION(S)
STIVARGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

STRENSIQ(GHP2027)

MEDICATION(S)
STRENSIQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PERINATAL- OR INFANTILE- OR JUVENILE-ONSET HYPOPHOSPHATASIA (HPP) AND DOCUMENTATION THAT MEMBER WILL RECEIVE A WEIGHT AND DIAGNOSIS APPROPRIATE DOSING REGIMEN AND DOCUMENTATION OF ONE OF THE FOLLOWING: (1) A PATHOLOGICAL MUTATION IN THE ALKALINE PHOSPHATASE (ALPL) GENE AS DETERMINED BY GENETIC TESTING OR (2) LOW TOTAL SERUM ALKALINE PHOSPHATASE ACTIVITY AND ONE OF THE FOLLOWING: RADIOGRAPHIC EVIDENCE SUPPORTING THE DIAGNOSIS OF HYPOPHOSPHATASIA OR AN ELEVATED SUBTRATE OF TISSUE NON-SPECIFIC ALKALINE PHOSPHATASE (TNSALP), INCLUDING BUT NOT LIMITED TO PYRIDOXAL-5-PHOSPHATE (PLP), INORGANIC PYROPHOSPHATE (PPi), OR PHOPHOETHANOLAMINE (PEA) IN SERUM, TISSUES, OR URINE.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST, GENETICIST OR METABOLIC SPECIALIST

COVERAGE DURATION
3 MONTH INITIAL AND 12 MONTH CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF DISEASE ONSET PRIOR TO THE AGE OF 18 YEARS (IF MEMBER IS 18 YEARS OR OLDER AT TIME OF REQUEST, DOCUMENTATION MUST BE PROVIDED THAT

MEMBER BEGAN EXPERIENCING SYMPTOMS PRIOR TO 18 YEARS OLD). SUBSEQUENT APPROVAL WILL REQUIRE DOCUMENTATION OF CONTINUE DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUEMNTATION THAT MEMBER WILL RECEIVE A WEIGHT AND DIAGNOSIS APPROPRIATE DOSING REGIMEN.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SUBVENITE(GHP2027)

MEDICATION(S)
SUBVENITE 10 MG/ML SUSPENSION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of use for an FDA approved indication

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of inability to tolerate or swallow lamotrigine tablets and lamotrigine chewable dispersible tablets OR documentation of why a suspension formulation is needed.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SUCRAID(GHP2027)

MEDICATION(S)
SUCRAID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SUNOSI(GHP2027)

MEDICATION(S)
SUNOSI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of excessive daytime sleepiness associated with either narcolepsy or obstructive sleep apnea.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For sleepiness associated with narcolepsy: documentation of therapeutic failure on, intolerance to, or contraindication to either modafinil or armodafinil AND methylphenidate IR or amphetamine-dextroamphetamine IR. For sleepiness associated with obstructive sleep apnea: documentation that underlying airway obstruction has been treated for at least one month prior to initiation of therapy, and will continue to be treated AND documentation of a therapeutic failure on, intolerance to, or contraindication to modafinil or armodafinil.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SUSTOL(GHP2027)

MEDICATION(S)
SUSTOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT SUSTOL IS BEING USED FOR THE PREVENTION OF ACUTE OR DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL OR REPEAT COURSES OF MODERATELY EMETOGENIC CHEMOTHERAPY (MEC) OR ANTHRACYCLINE AND CYCLOPHOSPHAMIDE (AC) COMBINATION CHEMOTHERAPY REGIMENS AND DOCUMENTATION THAT MEMBER HAS A TREATMENT FAILURE OR CONTRAINDICATION TO PALONOSETRON (ALOXI). DOCUMENTATION THAT SUSTOL IS BEING USED FOR THE PREVENTION OF ACUTE OR DELAYED CHEMOTHERAPY INDUCED NAUSEA AND VOMITING FROM LOW OR MINIMALLY EMETOGENIC CHEMOTHERAPY FOR MEMBERS WHO HAVE A TREATMENT FAILURE OR CONTRAINDICATION TO (1) PALONOSETRON (ALOXI) AND (2) ONDANSETRON OR GRANISETRON.

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION THAT SUSTOL IS BEING GIVEN IN COMBINATION WITH OTHER ANTIEMETICS (DEXAMETHASONE).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

SUTENT(GHP2027)

MEDICATION(S)
SUNITINIB MALATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SYLVANT(GHP2027)

MEDICATION(S)
SYLVANT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MULTICENTRIC CASTLEMAN DISEASE

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
HEMATOLOGIST OR ONCOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT PATIENT IS HIV AND HHV-8 NEGATIVE AND DOCUMENTATION OF ANC GREATER THAN 1 X 1000000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 75 X 1000000000 (10 TO THE 9TH POWER) / L AND HGB LESS THAN 17 G/DL. SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF NO DISEASE PROGRESSION AND THE FOLLOWING CRITERIA, ANC GREATER THAN 1 X 1000000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 50 X 1000000000 (10 TO THE 9TH POWER) / L AND HGB LESS THAN 17 G/DL.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

SYMDEKO(GHP2027)

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cystic fibrosis AND documentation as evidenced by an FDA cleared CF mutation test of at least one mutation in CFTR gene that is responsive to tezacaftor/ivacaftor per product labeling OR documentation that the member is homozygous for the F508del CFTR mutation.

AGE RESTRICTION
MUST BE 6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Reauthorization will require documentation of improvement or stabilization in the signs of symptoms of cystic fibrosis.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

SYMLIN(GHP2027)

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
MEDICAL RECORD DOCUMENTATION OF USE AS AN ADJUNCT TREATMENT IN PATIENT'S WHO USE MEALTIME INSULIN THERAPY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE TO ACHIEVE DESIRED CONTROL DESPITE OPTIMAL MEALTIME INSULIN THERAPY, WHICH MAY BE WITH OR WITHOUT A CONCURRENT SULFONYLUREA AND/OR METFORMIN FOR THOSE WITH TYPE 2 DM

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SYMPAZAN(GHP2027)

MEDICATION(S)
SYMPAZAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF LENNOX-GASTAUT SYNDROME

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior anti-epileptic therapies for the treatment of Lennox-Gastaust, one of which must be clobazam tablets or solution

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

SYNAGIS(GHP2027)

MEDICATION(S)
SYNAGIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PROPHYAXIS OF SERIOUS LOWER RESPIRATORY TRACT DISEASE CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV) IN PEDIATRIC PATIENTS AT HIGH RISK, INCLUDING THOSE WITH BRONCHOPULMONARY DYSPLASIA OR COGENITAL HEART DISEASE, AND THOSE BORN PREMATURELY.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS NOT RECEIVED BEYFORTUS DURING THE CURRENT RSV SEASON.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TABRECTA(GHP2027)

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of MET exon 14 gene skipping mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TAFAMIDIS MEGLUMINE(GHP2027)

MEDICATION(S)
VYNDAMAX, VYNDAQEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis OR hereditary transthyretin-mediated amyloidosis as confirmed by ONE of the following: 1) bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD or 2) biopsy of tissue of the affected organ to confirm amyloid presence and chemical typing to confirm presence of transthyretin (TTR) protein.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
by or in consultation with a cardiologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of NYHA Class I, II, or III heart failure. Documentation that medication is not being used in combination with another transthyretin (TTR) stabilizer. Reauthorizations will require prescriber attestation that the patient continues to benefit from tafamidis therapy AND no documentation of NYHA class IV heart failure.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TAFINLAR(GHP2027)

MEDICATION(S)
TAFINLAR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TAGRISSO(GHP2027)

MEDICATION(S)
TAGRISSO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TAKHZYRO(GHP2027)

MEDICATION(S)
TAKHZYRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEREDITARY ANGIOEDEMA.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 1 YEAR CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS BEING USED AS PROPHYLACTIC THERAPY. Documentation that medication is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or berotralstat (Orladeyo) therapy for hereditary angioedema. DOCUMENTATION THAT MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON PATIENT'S AGE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

TALVEY(GHP2027)

MEDICATION(S)
TALVEY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TALZENNA(GHP2027)

MEDICATION(S)
TALZENNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: BRCA pathogenic variant, HER2 Protein expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TARCEVA(GHP2027)

MEDICATION(S)
ERLOTINIB HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TARPEYO(GHP2027)

MEDICATION(S)
TARPEYO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of primary immunoglobulin 1 nephropathy (IgAN) verified by biopsy.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEPHROLOGIST

COVERAGE DURATION
10 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER IS AT HIGH RISK OF DISEASE PROGRESSION AND DOCUMENTATION THAT MEMBER HAS RECEIVED A STABLE DOSE OF A RAS INHIBITOR AT A MAXIMALLY TOLERATED DOSE FOR AT LEAST 90 DAYS AND DOCUMENTATION THAT RAS INHIBITOR WILL CONTINUED TO BE USED IN COMBINATION WITH TARPEYO. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A GLUCOCORTICOID (e.g., prednisone or methylprednisolone). DOCUMENTATION THAT MEMBER HAS NOT PREVIOUSLY COMPLETED A 9 MONTH TREATMENT COURSE OF TARPEYO.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TASIGNA(GHP2027)

MEDICATION(S)
CAVHANZA, DANZITEN, NILOTINIB D-TARTRATE, NILOTINIB HCL, TASIGNA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TAVALISSE(GHP2027)

MEDICATION(S)
TAVALISSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CHRONIC IMMUNE THROMBOCYTOPENIA AND DOCUMENTATION OF A PLATELET COUNT LESS THAN 30,000/MICROL.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a hematologist

COVERAGE DURATION
3 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CORTICOSTEROIDS, IVIG, RHOGAM (IF RHD-POSITIVE AND SPLEEN INTACT), RITUXIMAB, SPLENECTOMY, ELTROMBOPAG OR ROMIPLOSTIM OR AVATROMBOPAG. SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY SUCH AS A PLATELET COUNT NECESSARY TO REDUCE THE RISK FOR BLEEDING.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TAVNEOS(GHP2027)

MEDICATION(S)
TAVNEOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF SEVERE ACTIVE ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY (ANCA)-ASSOCIATED VASCULITIS CLASSIFIED AS ONE OF THE FOLLOWING VARIANTS: GRANULOMATOSIS WITH POLYANGIITIS (GPA) OR MICROSCOPIC POLYANGIITIS (MPA) AND ADMINISTERED IN COMBINATION WITH STANDARD THERAPY SUCH AS, BUT NOT LIMITED TO RITUXIMAB, CYCLOPHOSPHAMIDE, METHOTREXATE, MYCOPHENOLATE, OR AZATHIOPRINE, AND/OR GLUCOCORTICOIDS.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF A POSITIVE TEST FOR ANTI-PROTEINASE 3 (PR3) OR ANTI-MYELOPEROXIDASE (MPO) AND DOCUMENTATION OF AT LEAST 1 MAJOR ITEM, 3 NON-MAJOR ITEMS, OR 2 RENAL ITEMS OF PROTEINURIA AND HEMATURIA ON THE BIRMINGHAM VASCULITIS ACTIVITY SCORE (BVAS). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUMENTATION THAT THE MEMBER IS RESPONDING POSITIVELY TO THERAPY AS

EVIDENCED BY A REDUCTION IN THE BIRMINGHAM VASCULITIS ACTIVITY SCORE (BVAS) AND RECORD DOCUMENTATION THAT TAVNEOS WILL CONTINUE TO BE ADMINISTERED IN COMBINATION WITH STANDARD THERAPY SUCH AS, BUT NOT LIMITED TO RITUXIMAB, CYCLOPHOSPHAMIDE, METHOTREXATE, MYCOPHENOLATE, OR AZATHIOPRINE, AND/OR GLUCOCORTICOIDS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TAZORAC(GHP2027)

MEDICATION(S)
TAZAROTENE 0.05 % CREAM, TAZAROTENE 0.1 % FOAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF ACNE, ACNE VULGARIS, ADULT ONSET ACNE, OR PLAQUE PSORIASIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR ACNE: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL RETINOIDS, INCLUDING BUT NOT LIMITED TO ADAPALENE AND TRETINOIN. FOR PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE TOPICAL CORTICOSTEROID AND AT LEAST 2 TO 3 MONTHS OF METHOTREXATE OR PHOTOTHERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

TECENTRIQ(GHP2027)

MEDICATION(S)
TECENTRIQ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TECENTRIQ HYBREZA(GHP2027)

MEDICATION(S)
TECENTRIQ HYBREZA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TECVAYLI(GHP2027)

MEDICATION(S)
TECVAYLI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TEGSEDI(GHP2027)

MEDICATION(S)
TEGSEDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND documentation of either biopsy of tissue or organ to confirm amyloid presence OR a clinical manifestation typical of hATTR (such as neuropathy or CHF) without a better alternative explanation. Documentation of medication being used to treat polyneuropathy. Documentation of familial amyloid polyneuropathy (FAP) stage 1-2 OR polyneuropathy disability score indicating the patient is not wheelchair bound or bedridden.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with neurologist, board certified medical geneticist, or specialist with experience treating hATTR

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation that medication will not be used in combination with other RNA interference treatments. Reauthorization will require medical necessity and no documentation of FAP stage 3 OR polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TEPEZZA(GHP2027)

MEDICATION(S)
TEPEZZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF GRAVE'S DISEASE AND DOCUMENTATION OF MODERATE TO SEVERE THYROID EYE DISEASE WITH DOCUMENTATION OF ONE OR MORE OF THE FOLLOWING: 1)LID RETRACTION OF GREATER THAN OR EQUAL TO 2 MM 2) MODERATE OR SEVERE SOFT-TISSUE INVOLVEMENT 3) PROPTOSIS GREATER THAN OR EQUAL TO 3 MM ABOVE NORMAL VALUES FOR RACE AND SEX, 4) PERIODIC OR CONSTANT DIPLOPIA

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
OPHTHALMOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER IS EUTHYROID OR HAS MILD HYPO- OR HYPERTHYROIDISM (FREE T4 AND FREE T3 LEVELS LESS THAN 50% ABOVE OR BELOW NORMAL LIMITS PRIOR TO STARTING TEPEZZA THERAPY. DOCUMENTATION OF BEING PRESCRIBED AN APPROPRIATE DOSE AND DURATION OF TEPEZZA PER PRODUCT LABELING. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SYSTEMIC STEROIDS or EVIDENCE OF SIGNIFICANT PROPTOSIS

Pending CMS Approval

GREATER THAN OR EQUAL TO 3 MM ABOVE NORMAL VALUES FOR RACE AND SEX or DIPLOPIA. REQUESTS FOR AUTHORIZATIONS EXCEEDING 8 TOTAL DOSES WILL REQUIRE DOCUMENTATION OF PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS INDICATING THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TEPMETKO(GHP2027)

MEDICATION(S)
TEPMETKO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of MET exon 14 gene skipping mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TEPYLUTE(GHP2027)

MEDICATION(S)
TEPYLUTE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TERLIVAZ(GHP2027)

MEDICATION(S)
TERLIVAZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HEPATORENAL SYNDROME CAUSING A RAPID REDUCTION IN KIDNEY FUNCTION. DOCUMENTATION OF A SERUM CREATININE LESS THAN OR EQUAL TO 5.0 MG PER DL. DOCUMENTATION OF ONE OF THE FOLLOWING: (1) TERLIVAZ WILL BE GIVEN IN COMBINATION WITH IV ALBUMIN OR DOCUMENTATION OF INTOLERANCE TO OR CONTRAINDICATION TO ALBUMIN.

Pending CMS Approval

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
HEPATOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
14 DAYS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS: (1) BASELINE OXYGEN SATURATION (SpO2) LESS THAN 90 PERCENT OR (2) VOLUME OVERLOAD OR (3) ACUTE-ON-CHRONIC LIVER FAILURE (ACLF) GRADE 3 OR (4) ONGOING CORONARY, PERIPHERAL, OR MESENTERIC ISCHEMIA. DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINISTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED LITERATURE.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TEVIMBRA(GHP2027)

MEDICATION(S)
TEVIMBRA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TEZSPIRE(GHP2027)

MEDICATION(S)
TEZSPIRE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SEVERE ASTHMA AND DOCUMENTATION THAT MEDICATION WILL BE USED AS AN ADD-ON MAINTENANCE TREATMENT.

AGE RESTRICTION
12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH BENRALIZUMAB, DUPILUMAB, MEPOLIZUMAB, OMALIZUMAB OR RESLIZUMAB. DOCUMENTATION OF ONE OF THE FOLLOWING: 1)INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE A 3 MONTH TRIAL OF: MEDIUM TO HIGH DOSE INHALED CORTICOSTEROIDS AND ANOTHER CONTROLLER MEDICATION (I.E, LONG-ACTING BETA AGONISTS, LONG-ACTING MUSCARINIC ANTAGONIST, OR LEUKOTRIENE RECEPTOR ANTAGONIST) WITH OR WITHOUT ORAL SYSTEMIC CORTICOSTEROIDS OR 2) TWO OR MORE EXACERBATIONS REQUIRING SYSTEMIC CORTICOSTEROID TREATMENT OR ONE EXACERBATION RESULTING IN HOSPITALIZATION IN THE PAST 12 MONTHS DESPITE CURRENT THERAPY OF MEDIUM TO HIGH DOSE INHALED CORTICOSTEROIDS AND ANOTHER

Pending CMS Approval

CONTROLLER MEDICATION (I.E, LONG-ACTING BETA AGONISTS, LONG-ACTING MUSCARINIC ANTAGONIST, OR LEUKOTRIENE RECEPTOR ANTAGONIST). SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TIBSOVO(GHP2027)

MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of IDH1 mutation expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TIVDAK(GHP2027)

MEDICATION(S)
TIVDAK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TOBI(GHP2027)

MEDICATION(S)
TOBI PODHALER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CYSTIC FIBROSIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TOBRAMYCIN NEB(GHP2027)

MEDICATION(S)
TOBRAMYCIN 300 MG/4ML NEBU SOLN, TOBRAMYCIN 300 MG/5ML NEBU SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF CYSTIC FIBROSIS

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TOLVAPTAN(GHP2027)

MEDICATION(S)
TOLVAPTAN 15MG TAB (JYNARQUE EQUIV.), TOLVAPTAN 30MG TAB (JYNARQUE EQUIV.), TOLVAPTAN (HYPONATREMIA)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Documentation of End Stage Renal Disease.

REQUIRED MEDICAL INFORMATION
Diagnosis of hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq per Liter or a less marked hyponatremia that is symptomatic and resistant to fluid restriction), including patients with heart failure and syndrome of inappropriate secretion of antidiuretic hormone (SIADH).

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEPHROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Reauthorization will require provider attestation or documentation that continued therapy is medically appropriate.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TORISEL(GHP2027)

MEDICATION(S)
TEMSIROLIMUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TRACLEER(GHP2027)

MEDICATION(S)
BOSENTAN, TRACLEER 32 MG TAB SOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TREMFYA(GHP2027)

MEDICATION(S)
TREMFYA, TREMFYA-CD/UC INDUCTION, TREMFYA ONE-PRESS, TREMFYA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 3% OR GREATER INVOLVEMENT OF BODY SURFACE AREA OR DISEASE INVOVLING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, SCALP, OR GENITALS. DOCUMENTATION OF ACTIVE PSORIATIC ARTHRITIS. DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS. DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHNS DISEASE.

AGE RESTRICTION
FOR PP AND PSA: 6 YEARS OF AGE OR OLDER, ALL OTHER DX: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST, RHEUMATOLOGIST, OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE OR PHOTOTHERAPY. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TRIKAFTA(GHP2027)

MEDICATION(S)
TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CYSTIC FIBROSIS AND DOCUMENTATION OF ONE OF THE FOLLOWING: (1) AT LEAST ONE F508DEL MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE AS DETERMINED BY AN FDA-CLEARED CYSTIC FIBROSIS MUTATION TEST OR (2) DOCUMENTATION OF A MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE AS DETERMINED BY AN FDA-CLEARED CYSTIC FIBROSIS MUTATION TEST THAT IS RESPONSIVE BASED ON IN VITRO DATA PER PRODUCT LABELING.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
By or in consultation with a pulmonologist or physician who specializes in the treatment of CF

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TRINTELLIX(GHP2027)

MEDICATION(S)
TRINTELLIX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

AGE RESTRICTION
MUST BE AT LEAST 18 YEARS OF AGE

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

TRIPTODUR(GHP2027)

MEDICATION(S)
TRIPTODUR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CENTRAL PRECOCIOUS PUBERTY

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH ENDOCRINOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LUPRON DEPOT-PED

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

TRODELVY(GHP2027)

MEDICATION(S)
TRODELVY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TROKENDI(GHP2027)

MEDICATION(S)
TOPIRAMATE ER 100 MG CAP ER 24H, TOPIRAMATE ER 200 MG CAP ER 24H, TOPIRAMATE ER 25 MG CAP ER 24H, TOPIRAMATE ER 50 MG CAP ER 24H, TROKENDI XR 100 MG CAP ER 24H, TROKENDI XR 200 MG CAP ER 24H, TROKENDI XR 50 MG CAP ER 24H

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut syndrome. Documentation of use for migraine prophylaxis.

AGE RESTRICTION
SEIZURES: 6 YEARS OF AGE OR OLDER, MIGRAINE: 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For seizures, documentation of failure on, intolerance to, or contraindication to two formulary anticonvulsants used for the requested diagnosis, one of which must be topiramate ER sprinkle capsules. For migraine, documentation of failure on, intolerance to, or contraindication to two formulary anticonvulsants used for the requested diagnosis, one of which must be topiramate ER sprinkle capsules.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TRULICITY(GHP2027)

MEDICATION(S)
TRULICITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Type 2 Diabetes Mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TRUQAP(GHP2027)

MEDICATION(S)
TRUQAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, Hormone receptor expression, PIK3CA gene mutation, AKT1 gene mutation, PTEN gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TRYNGOLZA(GHP2027)

MEDICATION(S)
TRYNGOLZA 80 MG/0.8ML SOLN A-INJ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of familial chylomicronemia syndrome (FCS) as confirmed by genetic testing (i.e., variants in LPL, apoC-II, GPIHBP1, apoA-V, or LMF1)

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with a lipidologist, endocrinologist or cardiologist

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of fasting triglycerides greater than or equal to 880 mg/dL. Documentation or prescriber attestation that member has received counseling on a low fat diet. DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH REDEMPLO. Reauthorizations will require provider attestation or documentation of a positive response to therapy (i.e. reduction in fasting triglycerides, reduction in symptoms or reduction in acute pancreatitis episodes) AND documentation or prescriber attestation that member has received counseling on a low fat diet AND DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH REDEMPLO.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TUKYSA(GHP2027)

MEDICATION(S)
TUKYSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of HER2 Protein overexpression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TURALIO(GHP2027)

MEDICATION(S)
TURALIO 125 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TYKERB(GHP2027)

MEDICATION(S)
LAPATINIB DITOSYLATE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein overexpression, hormone receptor expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

TYMLOS(GHP2027)

MEDICATION(S)
TYMLOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of postmenopausal osteoporosis OR male osteoporosis. Documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
24 MONTHS

OTHER CRITERIA
DOCUMENTATION OF AN ATTEMPT OF THERAPY WITH OR CONTRAINDICATION TO BISPHOSPHONATES or EITHER A PREVIOUS OSTEOPOROTIC FRACTURE OR HIGH RISK OF FRACTURE (T-SCORE LESS THAN -2.5 WITH DOCUMENTED RISK FACTORS). Duration of abaloparatide therapy should not exceed 2 years, if requesting use beyond 2 years of therapy: documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

TYSABRI(GHP2027)

MEDICATION(S)
TYRUKO, TYSABRI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
COMBINATION THERAPY WITH IMMUNOSUPPRESSANTS (E.G. 6-MERCAPTOPURINE, AZATHIOPRINE, CYCLOSPORINE, METHOTREXATE) OR INHIBITORS OF TNF-A

REQUIRED MEDICAL INFORMATION
DX OF RELAPSING/REMITING MS (INCLUDING CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE) AND DOCUMENTATION OF TYSABRI BEING USED AS MONOTHERAPY. DIAGNOSIS OF MODERATE TO SEVERE CROHN'S BASED ON CLINICAL SIGNS AND SYMPTOMS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR MS: WRITTEN BY A NEUROLOGIST. FOR CROHN'S: WRITTEN BY A GASTROENTEROLOGIST

COVERAGE DURATION
CROHNS: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION. MS: 12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER IS ENROLLED IN A RISK-MINIMIZATION PROGRAM, CALLED THE TOUCH PRESCRIBING PROGRAM. DOCUMENTATION OF TESTING FOR ANTI-JCV ANTIBODY WITHIN THE LAST 6 MONTHS PRIOR TO START OF THERAPY AND IF ANTI-JCV ANTIBODY POSITIVE, DOCUMENTATION THAT BENEFITS OF DRUG OUTWEIGH THE RISKS OF PML AND PATIENT IS AWARE OF PML RISK. FOR RELAPSING/REMITTING MS: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR

Pending CMS Approval

CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES FOR THE TREATMENT OF MS or DOCUMENTATION OF HIGHLY ACTIVE DISEASE COURSE REQUIRING AGGRESSIVE TREATMENT. FOR CROHNS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: FORMULARY ADALIMUMAB PRODUCT, CIMZIA, SKYRIZI, OR FORMULARY INFLIXIMAB PRODUCT. FOR REAUTHORIZATION, MUST SHOW IMPROVEMENT IN SIGNS AND SYMPTOMS OF DISEASE AND FOR PATIENTS WHO WERE PREVIOUSLY ANTI-JCV ANTIBODY NEGATIVE, DOCUMENTATION OF RETEST YEARLY. FOR THOSE PATIENTS WHO WERE ANTI-JCV ANTIBODY POSITIVE AT BASELINE OR RETEST, DOCUMENTATION THAT BENEFITS OF CONTINUING DRUG OUTWEIGH RISKS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

TYVASO DPI(GHP2027)

MEDICATION(S)
TYVASO DPI INSTITUTIONAL KIT, TYVASO DPI MAINTENANCE KIT, TYVASO DPI TITRATION KIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF FUNCTIONAL CLASS III OR IV PULMONARY ARTERY HYPERTENSION. DIAGNOSIS OF PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (WORLD HEALTH ORGANIZATION GROUP 3 PULMONARY HYPERTENSION).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR PAH: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OR USE IN COMBINATION WITH SILDENAFIL OR BOSENTAN.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

TYVASO(GHP2027)

MEDICATION(S)
TYVASO, TYVASO REFILL, TYVASO STARTER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF FUNCTIONAL CLASS III OR IV PULMONARY ARTERY HYPERTENSION. DIAGNOSIS OF PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (WORLD HEALTH ORGANIZATION GROUP 3 PULMONARY HYPERTENSION).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FOR PAH: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OR USE IN COMBINATION WITH SILDENAFIL OR BOSENTAN

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

TZIELD(GHP2027)

MEDICATION(S)
TZIELD

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF STAGE 2 TYPE 1 DIABETES (T1D) CONFIRMED BY BOTH OF THE FOLLOWING: (1) DOCUMENTATION OF AT LEAST TWO POSITIVE PANCREATIC ISLET CELL AUTOANTIBODIES AND (2) DOCUMENTATION OF DYSGLYCEMIA WITHOUT OVERT HYPERGLYCEMIA USING AN ORAL GLUCOSE TOLERANCE TEST (OGTT) [IF AN OGTT IS NOT AVAILABLE, AN ALTERNATIVE METHOD FOR DIAGNOSING DYSGLYCEMIA WITHOUT OVERT HYPERGLYCEMIA MAY BE APPROPRIATE] AND DOCUMENTATION OR PROVIDER ATTESTATION THAT THE CLINICAL HISTORY OF THE PATIENT DOES NOT SUGGEST TYPE 2 DIABETES (T2D).

Pending CMS Approval

AGE RESTRICTION
8 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST

COVERAGE DURATION
14 DAYS

OTHER CRITERIA
AUTHORIZATION OF TZIELD SHOULD NOT EXCEED THE FDA-APPROVED TREATMENT DURATION OF 14 DAYS. FOR REQUESTS EXCEEDING THE ABOVE LIMIT, DOCUMENTATION OF THE FOLLOWING IS REQUIRED: PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE

IMROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

UBRELVY(GHP2027)

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA AND ATTESTATION OF USE FOR THE ACUTE TREATMENT OF MIGRAINE

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
THERAPEUTIC FAILURE ON TWO FORMULARY TRIPTANS (E.G., NARATRIPTAN, RIZATRIPTAN, SUMATRIPTAN, ZOLMITRIPTAN) OR ATTESTATION OF INTOLERANCE TO OR CONTRAINDICATION TO ONE TRIPTAN. ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP ANTAGONIST INDICATED FOR THE ACUTE TREATMENT OF MIGRAINE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

YES

Pending CMS Approval

UNITUXIN(GHP2027)

MEDICATION(S)
UNITUXIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF TREATMENT OF PEDIATRIC PATIENTS WITH HIGH-RISK NEUROBLASTOMA WHO ACHIEVE AT LEAST A PARTIAL RESPONSE TO PRIOR FIRST-LINE MULTIAGENT, MULTIMODALITY THERAPY AND DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTOR (GM-CSF), INTERLEUKIN-2 (IL-2), AND 13-CIS-RETINOIC ACID (ISOTRETINOIN)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

Pending CMS Approval

UNLOXCYT(GHP2027)

MEDICATION(S)
UNLOXCYT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

UPTRAVI(GHP2027)

MEDICATION(S)
UPTRAVI 1000 MCG TAB, UPTRAVI 100 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 150 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF WHO GROUP I PULMONARY HYPERTENSION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF USE IN COMBINATION WITH, OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND/OR AND ENDOTHELIN RECEPTOR ANTAGONIST (BOSENTAN, AMBRISENTAN OR MACITENTAN).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

YES

Pending CMS Approval

UPTRAVI IV(GHP2027)

MEDICATION(S)
UPTRAVI 1800 MCG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF WHO GROUP I PULMONARY HYPERTENSION.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PULMONOLOGIST OR CARDIOLOGIST

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
DOCUMENTATION OF USE IN COMBINATION WITH, OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND/OR AN ENDOTHELIN RECEPTOR ANTAGONIST (BOSENTAN, AMBRISENTAN OR MACITENTAN) AND DOCUMENTATION THAT REQUEST IS FOR TEMPORARY USE OF INTRAVENOUS FORMULATION AND MEMBER IS UNABLE TO TAKE ORAL UPTRAVI TABLETS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT REQUEST IS FOR TEMPORARY USE OF INTRAVENOUS FORMULATION AND MEMBER CONTINUES TO BE UNABLE TO TAKE ORAL UPTRAVI TABLETS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

USTEKINUMAB(GHP2027)

MEDICATION(S)
SELARSDI, STARJEMZA, YESINTEK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 3% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE, SCALP OR GENITALS. DX OF ACTIVE PSORIATIC ARTHRITIS WITH DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DX OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE. Diagnosis of moderately to severely active ulcerative colitis.

AGE RESTRICTION
FOR PP AND PSA: MUST BE 6 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
DERMATOLOGIST, RHEUMATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY SUCH AS BUT NOT LIMITED TO METHOTREXATE OR CYCLOSPORINE OR PHOTOTHERAPY. FOR PEDIATRIC PLAQUE PSORIASIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY TOPICAL

Pending CMS Approval

CORTICOSTEROIDS. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

UZEDY(GHP2027)

MEDICATION(S)
UZEDY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF SCHIZOPHRENIA.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
(1) DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY OR (2) DOCUMENTATION OF STABILITY ON ORAL LEAD IN THERAPY AND DOCUMENTATION THAT MEMBER WOULD BENEFIT FROM INJECTABLE THERAPY (I.E., POOR ADHERENCE, TRANSITIONING BETWEEN CARE SETTINGS).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VALCHLOR(GHP2027)

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VANDETANIB(GHP2027)

MEDICATION(S)
CAPRELSA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VANFLYTA(GHP2027)

MEDICATION(S)
VANFLYTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FLT3 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VECTIBIX(GHP2027)

MEDICATION(S)
VECTIBIX

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VELCADE(GHP2027)

MEDICATION(S)
BORTEZOMIB 1 MG RECON SOLN, BORTEZOMIB 2.5 MG RECON SOLN, BORTEZOMIB 3.5 MG RECON SOLN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VEMURAFENIB(GHP2027)

MEDICATION(S)
ZELBORAF

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist, Hematologist, or Dermatologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of BRAF Point mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VENCLEXTA(GHP2027)

MEDICATION(S)
VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VENTAVIS(GHP2027)

MEDICATION(S)
VENTAVIS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF PRIMARY PULMONARY HYPERTENSION (WHO GROUP 1) WITH NYHA CLASS III OR CLASS IV SYMPTOMS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CARDIOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF ONE OF THE FOLLOWING: (1) USE IN COMBINATION WITH SILDENAFIL AND/OR AN ENDOTHELIN RECEPTOR ANTAGONIST (I.E., BOSENTAN, AMBRISENTAN, OR MACITENTAN) OR (2) FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND/OR AN ENDOTHELIN RECEPTOR ANTAGONIST.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VEOPOZ(GHP2027)

MEDICATION(S)
VEOPOZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CD55-DEFICIENT PROTEIN LOSING ENTEROPATHY (CHAPLE DISEASE) WITH A CONFIRMED GENOTYPE OF BIALLELIC CD55 LOSS-OF-FUNCTION MUTATION AND DOCUMENTATION THAT MEMBER IS VACCINATED WITH THE MENINGOCOCCAL VACCINE.

AGE RESTRICTION
MUST BE 1 YEAR OF AGE OR OLDER

PRESCRIBER RESTRICTION
HEMATOLOGIST, GASTROENTEROLOGIST, OR A PROVIDER SPECIALIZING IN RARE GENETIC HEMATOLOGIC DISEASES

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT VEOPOZ WILL NOT BE USED IN COMBINATION WITH SOLIRIS (ECULIZUMAB) AND DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINSTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION (I.E., IMPROVEMENT OR NO CLINICAL WORSENING OF CLINICAL SYMPTOMS, INCREASE IN OR STABILIZATION OF ALBUMIN AND IgG CONCENTRATION).

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

VEPPANU(GHP2027)

MEDICATION(S)
VEPPANU

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, estrogen receptor expression, ESR1 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VEREGEN(GHP2027)

MEDICATION(S)
VEREGEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of genital or perianal warts (condylomata acuminata).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of therapeutic failure on, intolerance to, or contraindication to podofilox and imiquimod

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VERQUVO(GHP2027)

MEDICATION(S)
VERQUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF SYMPTOMATIC CHRONIC NEW YORK HEART ASSOCIATION CLASS II-IV HEART FAILURE, DOCUMENTATION OF A LEFT VENTRICULAR EJECTION FRACTION (LVEF) LESS THAN OR EQUAL TO 45%, AND DOCUMENTATION OF ONE OF THE FOLLOWING: HOSPITAL ADMISSION DUE TO HEART FAILURE WITHIN THE PREVIOUS 6 MONTHS OR DOCUMENTATION OF OUTPATIENT INTRAVENOUS DIURETIC TREATMENT FOR HEART FAILURE WITHIN THE PREVIOUS 3 MONTHS.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH CARDIOLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO: 1) ONE FORMULARY ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACEI), ANGIOTENSIN RECEPTOR BLOCER (ARB) OR ANGIOTENSIN RECEPTOR AND NEPRILYSIN INHIBITOR (ARNI) AND 2) ONE FORMULARY BETA-BLOCKER.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

VERZENIO(GHP2027)

MEDICATION(S)
VERZENIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of the following: HER2 Protein expression, Hormone receptor expression. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VIIBRYD(GHP2027)

MEDICATION(S)
VILAZODONE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE ALTERNATIVE FROM TWO DIFFERENT CLASSES OF ANTIDEPRESSANTS (INCLUDING, BUT NOT LIMITED TO SSRI, MAOI, SNRI OR TCA).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VIJOICE(GHP2027)

MEDICATION(S)
VIJOICE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF PIK3CA-RELATED OVERGROWTH SPECTRUM (PROS) AND DOCUMENTATION OF MUTATION IN THE CATALYTIC ALPHA SUBUNIT OF PI3K (PIK3CA) GENE.

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF SEVERE OR LIFE-THREATENING DISEASE WHICH REQUIRES SYSTEMIC TREATMENT. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VILTEPSO(GHP2027)

MEDICATION(S)
VILTEPSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DUCHENNE'S MUSCULAR DYSTROPHY (DMD) CONFIRMED BY GENETIC TESTING AND DOCUMENTATION OF A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 53 SKIPPING. DOCUMENTATION THAT MEDICATION IS BEING GIVEN CONCURRENTLY WITH ORAL CORTICOSTEROIDS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST OR GENETIC SPECIALIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT PATIENT DOES NOT HAVE A SYMPTOMATIC CARDIAC ABNORMALITY. DOCUMENTATION OF DOSING CONSISTENT WITH THE FDA APPROVED LABELING (MAXIMUM DOSE OF 80 MG PER KG INFUSED ONCE WEEKLY). DOCUMENTATION THAT THE PATIENT IS AMBULATORY (E.G. ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND, DOES NOT HAVE FULL-TIME DEPENDENCE ON MOTORIZED WHEELCHAIRS OR SCOOTERS FOR MOBILITY) AS PROVEN BY DOCUMENTATION OF A 6-MINUTE WALK TEST DISTANCE (6MWT) WITHIN THE PAST 3 MONTHS OF INITIATION OF MEDICATION. REAUTHORIZATION WILL REQUIRE THE FOLLOWING: DOCUMENTATION OF

Pending CMS Approval

CONTINUED BENEFIT FROM TREATMENT WITH VILTOLARSEN AND DOCUMENTATION OF CONCURRENT USE WITH ORAL CORTICOSTEROIDS AND DOCUMENTATION OF NO SYMPTOMATIC CARDIAC ABNORMALITY AND DOCUMENTATION OF A DOSE CONSISTENT WITH FDA APPROVED LABELING, AND DOCUMENTATION THAT PATIENT REMAINS AMBULATORY (E.G. ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND, DOES NOT HAVE FULL-TIME DEPENDENCE ON MOTORIZED WHEELCHAIRS OR SCOOTERS FOR MOBILITY) AS PROVEN BY DOCUMENTATION OF A FOLLOW-UP 6-MINUTE WALK TEST DISTANCE (6MWT) WITHIN THE PAST 6 MONTHS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

VIMPAT(GHP2027)

MEDICATION(S)
LACOSAMIDE 200 MG/20ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF PARTIAL ONSET SEIZURES OR DOCUMENTTATION OF ADJUNCTIVE TREATMENT FOR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 WEEK

OTHER CRITERIA
DOCUMENTATION OF INABILITY TO USE ORAL FORMULATION OF MEDICATION.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VITRAKVI(GHP2027)

MEDICATION(S)
VITRAKVI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of NTRK Gene fusions. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VIZIMPRO(GHP2027)

MEDICATION(S)
VIZIMPRO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of EGFR Gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VONJO(GHP2027)

MEDICATION(S)
VONJO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of platelet count. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VOQUEZNA DUAL PAK(GHP2027)

MEDICATION(S)
VOQUEZNA DUAL PAK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Helicobacter pylori (H. pylori) infection.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
2 WEEKS

OTHER CRITERIA
Documentation of an FDA approved dosing regimen. Documentation of a therapeutic failure on, intolerance to, or contraindication to two prior therapies (e.g. Pylera, Talicia) for Helicobacter pylori (H. pylori) infection.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VOQUEZNA TRIPLE PAK(GHP2027)

MEDICATION(S)
VOQUEZNA TRIPLE PAK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of Helicobacter pylori (H. pylori) infection.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
2 WEEKS

OTHER CRITERIA
Documentation of an FDA approved dosing regimen. Documentation of a therapeutic failure on, intolerance to, or contraindication to two prior therapies (e.g. Pylera, Talicia) for Helicobacter pylori (H. pylori) infection.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VORANIGO(GHP2027)

MEDICATION(S)
VORANIGO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of IDH gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VORICONAZOLE(GHP2027)

MEDICATION(S)
VORICONAZOLE 200 MG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of invasive aspergillosis OR documentation of treatment of candidemia in nonneutropenic patients OR documentation of disseminated candida infections in the skin, abdomen, kidney, bladder wall or wounds OR Diagnosis of esophageal candidiasis OR documentation of treatment of serious fungal infections caused by Scedosporium apiospermum and Fusarium spp., including Fusarium solani in patients intolerant of, or refractory to, other therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VOSEVI(GHP2027)

MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF A DIAGNOSIS OF HEPATITIS C INFECTION WITH IDENTIFICATION OF GENOTYPE AND SUBTYPE. DOCUMENTATION OF METAVIR LIVER FIBROSIS OR CIRRHOSIS ASSESSMENT BY A NON-INVASIVE TEST. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 6 MONTHS: HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT, BASIC METABOLIC PANEL. DOCUMENTATION OF A BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BOARD CERTIFIED GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

COVERAGE DURATION
PER AASLD/IDSA GUIDELINES

OTHER CRITERIA
DOCUMENTATION OF ANY POTENTIAL DRUG INTERACTIONS THAT MAY IMPACT DRUG THERAPY ADDRESSED BY THE PRESCRIBER (SUCH AS DISCONTINUATION OF THE

INTERACTING DRUG, DOSE REDUCTION OF THE INTERACTING DRUG, OR COUNSELING OF THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT) PER AASLD/ISDA GUIDANCE (e.g., HIV MEDICATIONS, PPIs, ANTACIDS). DOCUMENTATION OF EITHER 1) COMPLETED HEPATITIS B SERIES OR 2) HEPATITIS B SCREENING (SAB, SAG AND CAB) AND QUANTITATIVE HEPATITIS B VIRUS (HBV) DNA IF POSITIVE FOR HEPATITIS B SAG AND EITHER DOCUMENTATION OF TREATMENT FOR HEPATITIS B IF THERE IS DETECTABLE HEPATITIS B VIRUS OR DOCUMENTATION OF BEING VACCINATED AGAINST HEPATITIS B IF NEGATIVE FOR HEPATITIS B SAB. DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MAVYRET FOR TREATMENT NAIVE PATIENTS OR DOCUMENTATION THAT PATIENT IS TREATMENT EXPERIENCED.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VOTRIENT(GHP2027)

MEDICATION(S)
PAZOPANIB HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VOWST(GHP2027)

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT VOWST WILL BE USED FOR THE PREVENTION OF RECURRENCE OF C. DIFFICILE INFECTIONS AND DIAGNOSIS OF RECURRENT C. DIFFICILE INFECTION BASED ON RESULTS OF AN APPROPRIATE LABORATORY STOOL TEST WITHIN 30 DAYS OF REQUEST AND DOCUMENTATION THAT AN APPROPRIATE STANDARD OF CARE ANTIBACTERIAL REGIMEN WAS USED FOR THE TREATMENT OF RECURRENT C. DIFFICILE INFECTION (I.E., ORAL FIDAXOMICIN, ORAL VANCOMYCIN, ORAL METRONIDZOLE).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
INFECTIOUS DISEASE SPECIALIST OR GASTROENTEROLOGIST

COVERAGE DURATION
1 TREATMENT COURSE (30 DAYS)

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINISTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

VOXZOGO(GHP2027)

MEDICATION(S)
VOXZOGO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3.

AGE RESTRICTION
17 YEARS OF AGE OR YOUNGER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of evidence that patient has open epiphyses AND documentation that prescribed dose is appropriate for patient's current weight. Reauthorization will require documentation of positive response to Voxzogo and documentation of evidence that patient continues to have open epiphyses AND documentation that prescribed dose is appropriate for patient's current weight.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

VPRIV(GHP2027)

MEDICATION(S)
VPRIV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF TYPE 1 GAUCHER DISEASE WITH AT LEAST ONE OF THE FOLLOWING - ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

AGE RESTRICTION
MUST BE 4 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
METABOLIC SPECIALIST, GENETICIST OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ELELYSO IF PATIENT IS 18 YEARS OF AGE OR OLDER.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

VYKAT XR(GHP2027)

MEDICATION(S)
VYKAT XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of hyperphagia in Prader Willi Syndrome (PWS).

AGE RESTRICTION
4 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
By or in consultation with: neurologist, psychiatrist, endocrinologist or physician with expertise in the treatment of PWS

COVERAGE DURATION
12 Months

OTHER CRITERIA
Documentation of Prader Willi Syndrome that is confirmed by genetic testing (such as DNA methylation analysis to detect deletion of the chromosome 15q11-q13 region, uniparental disomy in chromosome 15, or imprinting, translocation, or inversion mutations involving chromosome 15). Documentation of HbA1c or glucose monitoring at baseline. Documentation that patients dose will be titrated appropriately based on patient's weight OR that maintenance dose is appropriate based on patient's weight. Reauthorization will require documentation or provider assessment of improvement in patient's hyperphagia symptoms (such as, but not limited to, decrease in food-seeking behaviors or decreases or maintenace in patient weight) AND documentation of appropriate dosing based on patient's weight AND documentation of HbA1c and/or glucose monitoring within the last 6 months.

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

VYLOY(GHP2027)

MEDICATION(S)
VYLOY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

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VYONDYS(GHP2027)

MEDICATION(S)
VYONDYS 53

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DUCHENNE'S MUSCULAR DYSTROPHY (DMD) CONFIRMED BY GENETIC TESTING AND DOCUMENTATION OF A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 53 SKIPPING. DOCUMENTATION THAT MEDICATION IS BEING GIVEN CONCURRENTLY WITH ORAL CORTICOSTEROIDS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
NEUROLOGIST OR GENETIC SPECIALIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT PATIENT HAS STABLE PULMONARY AND CARDIAC FUNCTION. DOCUMENTATION OF DOSING CONSISTENT WITH THE FDA APPROVED LABELING (MAXIMUM DOSE OF 30 MG PER KG INFUSED ONCE WEEKLY). DOCUMENTATION THAT THE PATIENT IS AMBULATORY (E.G. ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND, DOES NOT HAVE FULL-TIME DEPENDENCE ON MOTORIZED WHEELCHAIRS OR SCOOTERS FOR MOBILITY) AS PROVEN BY DOCUMENTATION OF A 6-MINUTE WALK TEST DISTANCE (6MWT) WITHIN THE PAST 3 MONTHS OF INITIATION OF MEDICATION. REAUTHORIZATION WILL REQUIRE THE FOLLOWING: DOCUMENTATION OF CONTINUED BENEFIT FROM TREATMENT

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WITH GOLODIRSEN AND DOCUMENTATION OF CONCURRENT USE WITH ORAL CORTICOSTEROIDS AND DOCUMENTATION OF STABLE PULMONARY AND CARDIAC FUNCTION AND DOCUMENTATION OF A DOSE CONSISTENT WITH FDA APPROVED LABELING, AND DOCUMENTATION THAT PATIENT REMAINS AMBULATORY (E.G. ABLE TO WALK WITH ASSISTANCE, NOT WHEELCHAIR BOUND, DOES NOT HAVE FULL-TIME DEPENDENCE ON MOTORIZED WHEELCHAIRS OR SCOOTERS FOR MOBILITY) AS PROVEN BY DOCUMENTATION OF A FOLLOW-UP 6-MINUTE WALK TEST DISTANCE (6MWT) WITHIN THE PAST 6 MONTHS.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

VYVANSE(GHP2027)

MEDICATION(S)
LISDEXAMFETAMINE DIMESYLATE 10 MG CAP, LISDEXAMFETAMINE DIMESYLATE 20 MG CAP, LISDEXAMFETAMINE DIMESYLATE 30 MG CAP, LISDEXAMFETAMINE DIMESYLATE 40 MG CAP, LISDEXAMFETAMINE DIMESYLATE 50 MG CAP, LISDEXAMFETAMINE DIMESYLATE 60 MG CAP, LISDEXAMFETAMINE DIMESYLATE 70 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of attention-deficit hyperactivity disorder (ADHD). Diagnosis of binge eating disorder.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
BINGE EATING ONLY: 12 MONTHS

OTHER CRITERIA
For ADHD: Documentation of a failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine ER combination. Reauthorizations for binge eating disorder will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

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VYVGART(GHP2027)

MEDICATION(S)
VYVGART, VYVGART HYTRULO 180-2000 MG-UNIT/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF GENERALIZED MYASTHENIA GRAVIS (gMG) THAT IS ANTI-ACETYLCHOLINE RECEPTOR (AChR) ANTIBODY POSITIVE. DX OF CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP).

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR INITIAL, 12 MONTH REAUTH

OTHER CRITERIA
FOR MG: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BOTH OF THE FOLLOWING: ONE CORTICOSTEROID AND ONE NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUMENTATION THAT THE MEMBER IS RESPONDING POSITIVELY TO THERAPY AS EVIDENCED BY A REDUCTION (2-POINT) FROM BASELINE IN MG-ACTIVITIES OF DAILY LIVING (MG-ADL) TOTAL SCORE. FOR CIDP: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING: (1) INTRAVENOUS OR SUBCUTANEOUS IMMUNE GLOBULIN OR (2) CORTICOSTEROID THERAPY OR (3) NON-STEROIDAL IMMUNOSUPPRESSIVE THERAPY (INCLUDING BUT NOT

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LIMITED TO AZATHIOPRINE, CYCLOPHOSPHAMIDE, CYCLOSPORINE, METHOTREXATE, OR MYCOPHENOLATE). FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO RITUXIMAB. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR MAINTENANCE OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

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VYXEOS(GHP2027)

MEDICATION(S)
VYXEOS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

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WEGOVY_SUBQ (GHP_FEHB2027)

MEDICATION(S)
WEGOVY 0.25 MG/0.5ML SOLN A-INJ, WEGOVY 0.5 MG/0.5ML SOLN A-INJ, WEGOVY 1.7 MG/0.75ML SOLN A-INJ, WEGOVY 1 MG/0.5ML SOLN A-INJ, WEGOVY 2.4 MG/0.75ML SOLN A-INJ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ESTABLISHED CARDIOVASCULAR DISEASE (CVD) AND DOCUMENTATION WEGOVY WILL BE USED TO REDUCE THE RISK OF MAJOR ADVERSE CV EVENTS (CV DEATH, NON-FATAL MYOCARDIAL INFARCTION, OR NON-FATAL STROKE) AND BMI GREATER THAN OR EQUAL TO 27 KG/M2 WITHIN THE PAST 3 MONTHS) AND DOCUMENTATION THAT WEGOVY WILL BE USED IN COMBINATION WITH A REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY. DOCUMENTATION OF A DIAGNOSIS OF METABOLIC DYSFUNCTION-ASSOCIATED STEATOHEPATITIS (MASH) AND DOCUMENTATION OF ADVANCED LIVER FIBROSIS (CONSISTENT WITH STAGES F2 AND F3 FIBROSIS) AT THE TIME OF DIAGNOSIS AND DOCUMENTATION SHOWING THAT DIAGNOSIS WAS CONFIRMED BY ONE OF THE FOLLOWING: (1) LIVER BIOPSY OR (2) NON-INVASIVE TEST (NIT) (E.G., ULTRASOUND ELASTOGRAPHY, MAGNETIC RESONANCE ELASTOGRAPHY, BIOMARKER LABS, FIBROSURE) AND DOCUMENTATION THAT WEGOVY WILL BE USED IN COMBINATION WITH A REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY.

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AGE RESTRICTION
FOR WEIGHT LOSS: 12 YEARS OF AGE OR OLDER. FOR CVD AND MASH: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 MONTHS

OTHER CRITERIA

DOCUMENTATION THAT WEGOVY WILL NOT BE USED IN COMBINATION WITH ANY OTHER GLP1 RECEPTOR AGONIST. FOR CV EVENTS: DOCUMENTATION OF ESTABLISHED CVD DEFINED AS ONE OF THE FOLLOWING: ACUTE CORONARY SYNDROMES, HISTORY OF MYOCARDIAL INFARCTION, ONGOING ANGINA (STABLE OR UNSTABLE), PRIOR CORONARY OR OTHER ARTERIAL REVASCULARIZATION, PRIOR STROKE OR TIA, PERIPHERAL ARTERIAL DISEASE OF ATHEROSCLEROTIC ORIGIN. DOCUMENTATION THAT MEMBER IS RECEIVING STANDARD OF CARE FOR THEIR CVD (INCLUDING BUT NOT LIMITED TO LIPID LOWERING THERAPY, PLATELET AGGREGATION INHIBITORS, ANGIOTENSIN CONVERTING ENZYME INHIBITORS OR ANGIOTENSIN II RECEPTOR BLOCKERS, BETA BLOCKERS). FOR MASH: DOCUMENTATION THAT MEMBER DOES NOT HAVE DECOMPENSATED CIRRHOSIS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT WEGOVY IS NOT BEING USED SOLELY FOR WEIGHT LOSS AND PRESCRIBER ATTESTATION THAT MEMBER CONTINUES TO BENEFIT FROM WEGOVY FOR THE TREATMENT OF MASH OR TO REDUCE THE RISK OF CV EVENTS. FOR CV EVENTS: REAUTHORIZATION WILL REQUIRE THAT MEMBER CONTINUES TO BE RECEIVING STANDARD OF CARE FOR THEIR CVD (INCLUDING BUT NOT LIMITED TO LIPID LOWERING THERAPY, PLATELET AGGREGATION INHIBITORS, ANGIOTENSIN CONVERTING ENZYME INHIBITORS OR ANGIOTENSIN II RECEPTOR BLOCKERS, BETA BLOCKERS). For Weight Loss: Documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Wegovy. Documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management. If 18 years of age or older, documentation of one of the following: (1) body mass index (BMI) greater than or equal to 30 kg/m2 or documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition for the requested medication (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, or established cardiovascular disease). If 12 years to 17 years of age, documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex. Reauthorization will require documentation that the member continues to experience clinical benefit based on the prescriber's assessment, documentation that member has experienced at least a 5% reduction in weight from baseline, and documentation that member has titrated to the appropriate maintenance dosage based on patient response and tolerability.

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

WEGOVY_TABLET (GHP_FEHB2027)

MEDICATION(S)
WEGOVY 1.5 MG TAB, WEGOVY 25 MG TAB, WEGOVY 4 MG TAB, WEGOVY 9 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ESTABLISHED CARDIOVASCULAR DISEASE (CVD) AND DOCUMENTATION WEGOVY WILL BE USED TO REDUCE THE RISK OF MAJOR ADVERSE CV EVENTS (CV DEATH, NON-FATAL MYOCARDIAL INFARCTION, OR NON-FATAL STROKE) AND BMI GREATER THAN OR EQUAL TO 27 KG/M2 WITHIN THE PAST 3 MONTHS) AND DOCUMENTATION THAT WEGOVY WILL BE USED IN COMBINATION WITH A REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY.

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AGE RESTRICTION
FOR WEIGHT LOSS: 12 YEARS OF AGE OR OLDER. FOR CVD: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT WEGOVY WILL NOT BE USED IN COMBINATION WITH ANY OTHER GLP1 RECEPTOR AGONIST. DOCUMENTATION OF ESTABLISHED CVD DEFINED AS ONE OF THE FOLLOWING: ACUTE CORONARY SYNDROMES, HISTORY OF MYOCARDIAL INFARCTION, ONGOING ANGINA (STABLE OR UNSTABLE), PRIOR CORONARY OR OTHER ARTERIAL REVASCULARIZATION, PRIOR STROKE OR TIA, PERIPHERAL ARTERIAL DISEASE OF

ATHEROSCLEROTIC ORIGIN. DOCUMENTATION THAT MEMBER IS RECEIVING STANDARD OF CARE FOR THEIR CVD (INCLUDING BUT NOT LIMITED TO LIPID LOWERING THERAPY, PLATELET AGGREGATION INHIBITORS, ANGIOTENSIN CONVERTING ENZYME INHIBITORS OR ANGIOTENSIN II RECEPTOR BLOCKERS, BETA BLOCKERS). REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT WEGOVY IS NOT BEING USED SOLELY FOR WEIGHT LOSS AND PRESCRIBER ATTESTATION THAT MEMBER CONTINUES TO BENEFIT FROM WEGOVY AND DOCUMENTATION THAT MEMBER CONTINUES TO BE RECEIVING STANDARD OF CARE FOR THEIR CVD (INCLUDING BUT NOT LIMITED TO LIPID LOWERING THERAPY, PLATELET AGGREGATION INHIBITORS, ANGIOTENSIN CONVERTING ENZYME INHIBITORS OR ANGIOTENSIN II RECEPTOR BLOCKERS, BETA BLOCKERS). For Weight Loss: Documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Wegovy. Documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management. If 18 years of age or older, documentation of one of the following: (1) body mass index (BMI) greater than or equal to 30 kg/m2 or documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition for the requested medication (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, or established cardiovascular disease). If 12 years to 17 years of age, documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex. Reauthorization will require documentation that the member continues to experience clinical benefit based on the prescriber's assessment, documentation that member has experienced at least a 5% reduction in weight from baseline, and documentation that member has titrated to the appropriate maintenance dosage based on patient response and tolerability.

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

WELIREG(GHP2027)

MEDICATION(S)
WELIREG

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

WINREVAIR(GHP2027)

MEDICATION(S)
WINREVAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF WORLD HEALTH ORGANIZATION (WHO) GROUP 1 PULMONARY ARTERIAL HYPERTENSION.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
CARDIOLOGIST OR PULMONOLOGIST

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION OF A BASELINE 6-MINUTE WALKING DISTANCE. FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY ENDOTHELIN RECEPTOR ANTAGONIST (ERA) IN COMBINATION WITH ONE OF THE FOLLOWING: (1) ONE FORMULARY PHOSPHODIESTERASE-5 INHIBITOR (PDE5i) OR (2) ONE SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATOR. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AN IMPROVEMENT IN 6-MINUTE WALKING DISTANCE FROM BASELINE OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

XCOPRI(GHP2027)

MEDICATION(S)
XCOPRI, XCOPRI (250 MG DAILY DOSE), XCOPRI (350 MG DAILY DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of partial onset seizures

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
by or in consultation with a neurologist

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary anticonvulsant medications used to treat the same indication.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

XDEMVY(GHP2027)

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CHRONIC DEMODEX BLEPHARITIS (DB) EVIDENCED BY (1) PRESENCE OF AT LEAST MILD ERYTHEMA OF THE UPPER EYELID MARGIN AND (2) PRESENCE OF MITES UPON EXAMINATION OF EYELASHES BY LIGHT MICROSCOPY OR PRESENCE OF COLLARETTES ON SLIT LAMP EXAMINATION.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
OPHTHALMOLOGIST OR OPTOMETRIST

COVERAGE DURATION
6 WEEKS

OTHER CRITERIA
DOCUMENTATION OF A PRESCRIBED DOSE AND ADMINSTRATION THAT IS CONSISTENT WITH FDA-APPROVED PACKAGE LABELING, NATIONALLY RECOGNIZED COMPENDIA, OR PEER-REVIEWED MEDICAL LITERATURE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

N/A

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XELJANZ(GHP2027)

MEDICATION(S)
TOFACITINIB CITRATE 10 MG TAB, TOFACITINIB CITRATE 1 MG/ML SOLUTION, TOFACITINIB CITRATE 5 MG TAB, TOFACITINIB CITRATE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS OR DX OF MODERATE TO SEVERE PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DIAGNOSIS OFMODERATE TO SEVERE ULCERATIVE COLITIS. DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS. DIAGNOSIS OF ANKYLOSING SPONDYLITIS.

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AGE RESTRICTION
PcJIA and PSA: 2 YEARS OR AGE OR OLDER. ALL OTHER DX: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: DOCUMENTATION THAT MEDICATION IS BEING DOSED CONSISTENT WITH FDA-APPROVED LABELING AND THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF

FORMULARY ADALIMUMAB PRODUCT OR ENBREL. FOR PSA: DOCUMENTATION THAT MEDICATION IS BEING DOSED CONSISTENT WITH FDA-APPROVED LABELING AND THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR ENBREL. FOR PCJIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT OR ENBREL. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ENBREL OR FORMULARY ADALIMUMAB PRODUCT. FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF FORMULARY ADALIMUMAB PRODUCT. FOR CONTINUED THERAPY: MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

XENICAL(GHP2027)

MEDICATION(S)
ORLISTAT 120 MG CAP, XENICAL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF ONE OF THE FOLLOWING: (1) BODY MASS INDEX (BMI) GREATER THAN OR EQUAL TO 30 KG/M2 OR (2) BMI GREATER THAN OR EQUAL TO 27 KG/M2 AND AT LEAST ONE WEIGHT-RELATED COMORBIDITY (E.G., HYPERTENSION, TYPE 2 DIABETES MELLITUS, OR DYSLIPIDEMIA). DOCUMENTATION OF USE AS ADJUNCT THERAPY TO REDUCED CALORIE DIET FOR CHRONIC WEIGHT MANAGEMENT.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEMBER HAS PARTICIPATED IN COMPREHENSIVE LIFESTYLE MODIFICATIONS INCLUDING REDUCED-CALORIE DIET, PHYSICAL ACTIVITY, AND BEHAVIORAL HEALTH FOR AT LEAST 3 MONTHS PRIOR TO BEGINNING XENICAL. FAILURE ON WEGOVY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT MEMBER CONTINUES TO EXPERIENCE CLINICAL BENEFIT FROM XENICAL BASED ON THE PRESCRIBERS ASSESSMENT AND DOCUMENTATION THAT MEMBER HAS EXPERIENCED AT LEAST A 4 PERCENT REDUCTION IN WEIGHT FROM BASELINE.

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

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XENLETA(GHP2027)

MEDICATION(S)
XENLETA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) CAUSED BY THE FOLLOWING SUSCEPTIBLE MICROORGANISMS: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
INFECTIOUS DISEASE PROVIDER

COVERAGE DURATION
7 DAYS

OTHER CRITERIA
DOCUMENTATION OF ONE OF THE FOLLOWING: (1) CULTURE AND SENSITIVITY SHOWING THE MEMBERS INFECTION IS NOT SUSCEPTIBLE TO ALTERNATIVE ANTIBIOTIC TREATMENT OR (2) HX OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO ALTERNATIVE ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY OR (3) TREATMENT WITH XENLETA WAS INITIATED WITHIN AN INPATIENT SETTING.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

XENPOZYME(GHP2027)

MEDICATION(S)
XENPOZYME

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF DIAGNOSIS OF ACID SPHINGOMYELINASE DEFICIENCY (ASMD) AND DOCUMENTATION OF CLINICAL PRESENTATION CONSISTENT WITH ASMD TYPE B OR ASMD TYPE A/B AND DOCUMENTATION OF ONE OF THE FOLLOWING: (1) SPHINGOMYELIN PHOSPHODIESTERASE-1 (SMPD1) GENETIC MUTATION OR (2) ENZYME ASSAY DEMONSTRATING A DEFICIENCY OF ACID SPHINGOMYELINASE ACTIVITY AND DOCUMENTATION THAT XENPOZYME WILL BE USED FOR THE TREATMENT OF NON-CENTRAL NERVOUS SYSTEM MANIFESTATIONS OF ASMD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 MONTH INITIAL, 12 MONTH CONTINUATION

OTHER CRITERIA
REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

XEPI(GHP2027)

MEDICATION(S)
XEPI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF IMPETIGO.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 DAYS

OTHER CRITERIA
FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MUPIROCIN OINTMENT AND ORAL ANTIBIOTIC THERAPY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

XERESE(GHP2027)

MEDICATION(S)
XERESE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Cold Sores (Herpes Simplex 1 or Herpes Labialis).

AGE RESTRICTION
6 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For members 12 years of age or older, documentation of failure on, intolerance to, or contraindication to two of the following: acyclovir cream, penciclovir cream, valacyclovir, or famciclovir (famciclovir only if age greater than or equal to 18 years).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

XERMELO(GHP2027)

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of carcinoid syndrome diarrhea AND documentation that medication is being used in combination with a somatostatin analog

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of an inadequate response on a somatostatin analog monotherapy. Reauthorization will require documentation that medication is still being used in combination with a somatostatin analog AND documentation of sustained reduction in bowel movement frequency from baseline.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

XIFAXAN(GHP2027)

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of hepatic encephalopathy (HE) OR Irritable bowel syndrome with diarrhea (IBS-D) OR Traveler's diarrhea (TD).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
For TD: 3 days. For IBS-D: 14 days. For HE: remainder of contract year

OTHER CRITERIA
Documentation of a dose and duration of therapy consistent with product labeling for requested indication. Reauthorization for IBS-D will require documentation of having a recurrence of symptoms related to IBS-D AND documentation that member has not received more than two previous courses of this medication for the treatment of IBS-D.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

XOLAIR(GHP2027)

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MODERATE TO SEVERE PERSISTENT ASTHMA WITH EVIDENCE OF REVERSIBLE AIRWAY DISEASE AND DOCUMENTATION OF A SPECIFIC ALLERGY REACTIVITY BY POSTIVE SKIN OR BLOOD TEST FOR A SPECIFIC IGE. DIAGNOSIS OF MODERATE TO SEVERE CHRONIC IDIOPATHIC URTICARIA AND AT LEAST 6 WEEK HISTORY OF SYMPTOMS SUCH AS HIVES ASSOCIATED WITH ITCHING OR ANGIOEDEMA. DIAGNOSIS OF ADD-ON MAINTENANCE TREATMENT OF NASAL POLYPS. DIAGNOSIS OF USE FOR THE MAINTENANCE REDUCTION OF IGE MEDIATED FOOD ALLERGIES (type 1).

Pending CMS Approval

AGE RESTRICTION
ASTHMA: 6 YRS OR OLDER, URTICARIA: 12 YRS OR OLDER, POLYPS: 18 YRS OR OLDER, FOOD ALLERGY: 1 YR OF AGE OR OLDER

PRESCRIBER RESTRICTION
ASTHMA: ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST. URTICARIA: ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST. POLYPS: BY OR IN CONSULTATION WITH ALLERGIST, PULMONOLOGIST OR OTOLARYNGOLOGIST. FOOD ALLERGY: ALLERGIST OR IMMUNOLOGIST

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH

BENRALIZUMAB, DUPILUMAB, MEPOLIZUMAB, TEZEPELUMAB, DEPEMOKIMAB, OR RESLIZUMAB. DOCUMENTATION OF A DOSE CONSISTENT WITH FDA APPROVED LABELING. FOR ASTHMA: DOCUMENTATION THAT KNOWN ENVIRONMENTAL TRIGGERS HAVE BEEN ELIMINATED. DOCUMENTATION OF IGE LEVEL OF GREATER THAN 30 IU/ML AND LESS THAN 700 IU/ML FOR INDIVIDUALS AGE 12 AND OLDER OR IGE LEVEL OF GREATER THAN 30 IU/ML AND LESS THAN 1300 IU/ML FOR INDIVIDUALS AGE 6 THROUGH 11,DOCUMENTATION OF INADEQUATE CONTROL OR INTOLERANCE TO A 3 MONTH TRIAL OF COMBINATION PRODUCT GLUCOCORTICOID WITH LONG ACTING BETA AGONIST (SUCH AS ADVAIR, DULERA, OR BREO) AND LEUKOTRIENE RECEPTOR MODIFIER OR ANTAGONIST. FOR URTICARIA: FAILURE ON FOUR WEEK TRIAL OF MAXIMALLY TOLERATED DOSE OF ONE ANTIHISTAMINE. FOR CHRONIC IDIOPATHIC URTICARIA MUST HAVE TRIED AND FAILED 150 MG DOSE BEFORE 300 MG DOSE IS USED. FOR NASAL POLYPS: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INTRANASAL FLUTICASONE AND MOMETASONE. FOR FOOD ALLERGY: DOCUMENTATION THAT MEDICATION WILL BE USED IN CONJUNCTION WITH A FOOD ALLERGEN-AVOIDANT DIET. DOCUMENTATION OF IGE LEVEL OF GREATER THAN 30 IU/ML. DOCUMENTATION OF A POSITIVE SKIN PRICK TEST RESPONSE TO ONE OR MORE FOODS AND DOCUMENTATION OF A POSITIVE IN VITRO TEST FOR IGE TO ONE OR MORE FOODS. PRESCRIBER ATTESTATION THAT REACTION IS SIGNIFICANT ENOUGH FOR THE MEMBER TO REQUIRE AND RECEIVE A PRESCRIPTION FOR AN EPINEPHRINE PRODUCT. REAUTHORIZATION FOR ALL INDICATIONS WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF DISEASE.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CVS Approval

XOLREMDI(GHP2027)

MEDICATION(S)
XOLREMDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF WHIM (WARTS, HYPOGAMMAGLOBULINEMIA, INFECTIONS, AND MYELOKATHEXIS) SYNDROME AND DOCUMENTATION OF SYMPTOMS AND COMPLICATIONS ASSOCIATED WITH WHIM SYNDROME.

AGE RESTRICTION
MUST BE 12 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST

COVERAGE DURATION
6 MONTHS INITIAL, 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION OF MEMBER'S WEIGHT AND DOCUMENTATION OF BASELINE ABSOLUTE NEUTROPHIL COUNT (ANC) AND ABSOLUTE LYMPHOCYTE COUNT (ALC). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OR PROVIDER ATTESTATION OF CONTINUED DISEASE IMPROVEMENT (SUCH AS, BUT NOT LIMITED TO, A DECREASE IN INFECTIONS OR SUSTAINED IMPROVEMENT IN ANC AND ALC).

PART B PREREQUISITE
N/A

Pending CMS Approval

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

XOSPATA(GHP2027)

MEDICATION(S)
XOSPATA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of FLT3 gene mutation. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

XPOVIO(GHP2027)

MEDICATION(S)
XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY), XPOVIO (80 MG TWICE WEEKLY)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

XTANDI(GHP2027)

MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist, or Urologist (if Prostate Cancer). Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

XYREM(GHP2027)

MEDICATION(S)
SODIUM OXYBATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cataplexy in a patient with narcolepsy OR diagnosis of excessive daytime sleepiness in a patient with narcolepsy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
For excessive daytime sleepiness with narcolepsy: therapeutic failure on, intolerance to, or contraindication to modafinil. Reauthorization will require documentation of reduction in frequency of cataplexy attacks OR documentation of reduction in symptoms of excessive daytime sleepiness.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

XYWAV(GHP2027)

MEDICATION(S)
XYWAV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CATAPLEXY IN A PATIENT WITH NARCOLEPSY OR DIAGNOSIS OF EXCESSIVE DAYTIME SLEEPINESS IN A PATIENT WITH NARCOLEPSY OR DIAGNOSIS OF IDIOPATHIC HYPERSOMNIA.

AGE RESTRICTION
FOR IDIOPATHIC HYPERSOMNIA: 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
FOR EXCESSIVE DAYTIME SLEEPINESS WITH NARCOLEPSY: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MODAFINIL, METHYLPHENIDATE IR OR AMPHETAMINE/DEXTROAMPHETAMINE IR AND FOR EXCESSIVE DAYTIME SLEEPINESS WITH NARCOLEPSY OR CATAPLEXY WITH NARCOLEPSY: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SODIUM OXYBATE OR DOCUMENTATION OF REQUIRING A LOW SODIUM ALTERNATIVE SUCH AS DUE TO A CONCOMITANT DIAGNOSIS OF HEART FAILURE, HYPERTENSION, OR RENAL IMPAIRMENT. FOR IDIOPATHIC HYPERSOMNIA: DOCUMENTATION THAT MEMBER WAS EVALUATED AND TREATED FOR OTHER ETIOLOGIES OF EXCESSIVE DAYTIME SLEEPINESS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION

Pending CMS Approval

OF REDUCTION IN FREQUENCY OF CATPLEXY ATTACKS OR REDUCTION IN SYMPTOMS OF EXCESSIVE DAYTIME SLEEPINESS OR IDIOPATHIC HYPERSOMNIA.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

YCANTH(GHP2027)

MEDICATION(S)
CANTHARIDIN 0.7 % SOLUTION, YCANTH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MULLUSCUM CONTAGIOSUM (MC).

AGE RESTRICTION
2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 MONTHS

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

YERVOY(GHP2027)

MEDICATION(S)
YERVOY

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

YONDELIS(GHP2027)

MEDICATION(S)
YONDELIS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

YUVIWEL(GHP2027)

MEDICATION(S)
YUVIWEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3.

AGE RESTRICTION
GREATER THAN 2 YEARS OF AGE AND LESS THAN 18 YEARS OF AGE

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to Vosoritide. Documentation of evidence that patient has open epiphyses AND documentation that prescribed dose is appropriate for patient's current weight. Reauthorization will require documentation of positive response to Yuviwel and documentation of evidence that patient continues to have open epiphyses AND documentation that prescribed dose is appropriate for patient's current weight.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZALEPLON(GHP2027)

MEDICATION(S)
ZALEPLON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DOCUMENTATION OF FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO RAMELTEON (GENERIC ROZEREM) AND DOXEPIN (GENERIC SILENOR).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZALTRAP(GHP2027)

MEDICATION(S)
ZALTRAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZAVESCA(GHP2027)

MEDICATION(S)
MIGLUSTAT, YARGESA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF MILD TO MODERATE TYPE 1 GAUCHER DISEASE. DIAGNOSIS OF NEIMANN-PICK DISEASE TYPE C (NPC)1 OR NPC2 CONFIRMED BY GENETIC TESTING DEMONSTRATING ONE OF THE FOLLOWING (1) MUTATIONS IN BOTH ALLELES OF NPC1 OR NPC2 OR (2) MUTATION IN ONE ALLELE AND EITHER A POSITIVE FILIPIN-STAINING OR ELEVATED CHOLESTANE TRIOL/OXYSTEROLS (GREATER THAN 2 TIMES THE UPPER LIMIT OF NORMAL) AND DOCUMENTATION OF AT LEAST ONE NEUROLOGICAL SIGN OF NPC (SUCH AS BUT NOT LIMITED TO LOSS OF FINE MOTOR SKILLS, SWALLOWING, SPEECH, AMBULATION).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
FOR NPC: BY OR IN CONSULTATION WITH A PHYSICIAN WHO SPECIALIZES IN TREATMENT OF NPC OR RELATED DISORDERS

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
FOR GAUCHER DISEASE: FOR WHOM ENZYME REPLACEMENT THERAPY IS NOT A THERAPEUTIC OPTION (I.E. BECAUSE OF CONSTRAINTS SUCH AS ALLERGY, HYPERSENSITIVITY, OR POOR VENOUS ACCESS).

Pending CMS Approval

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZEJULA(GHP2027)

MEDICATION(S)
ZEJULA 100 MG TAB, ZEJULA 200 MG TAB, ZEJULA 300 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZEMBRACE(GHP2027)

MEDICATION(S)
ZEMBRACE SYMTOUCH

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of migraines with or without aura.

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of failure on, intolerance to, or contraindication to 2 different preferred alternative triptan products (one of which must be a generic sumatriptan injection).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZENBEXUS(GHP2027)

MEDICATION(S)
ZENBEXUS

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZEPBOUND(GHP2027)

MEDICATION(S)
ZEPBOUND 10 MG/0.5ML SOLN A-INJ, ZEPBOUND 12.5 MG/0.5ML SOLN A-INJ, ZEPBOUND 15 MG/0.5ML SOLN A-INJ, ZEPBOUND 2.5 MG/0.5ML SOLN A-INJ, ZEPBOUND 5 MG/0.5ML SOLN A-INJ, ZEPBOUND 7.5 MG/0.5ML SOLN A-INJ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF A DIAGNOSIS OF MODERATE TO SEVERE OBSTRUCTIVE SLEEP APNEA DEFINED AS APNEA-HYPOPNEA INDEX (AHI) OF 15 OR GREATER DESPITE STANDARD TREATMENTS (INCLUDING BUT NOT LIMITED TO PAP THERAPY) AND DOCUMENTATION OF BMI GREATER THAN 30 KG/M2 WITHIN THE PAST 3 MONTHS AND DOCUMENTATION THAT ZEPBOUND WILL BE USED IN COMBINATION WITH A REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY.

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION THAT WEGOVY WILL NOT BE USED IN COMBINATION WITH ANY OTHER GLP1 RECEPTOR AGONIST. FOR OSA: REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF A POSITIVE RESPONSE FROM BASELINE IN OSA SIGNS AND SYMPTOMS AND DOCUMENTATION THAT ZEPBOUND CONTINUES TO BE USED IN COMBINATION WITH

Pending CMS Approval

REDUCED CALORIE DIET AND INCREASED PHYSICAL ACTIVITY. For Weight Loss: Documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management. Documentation of one of the following: (1) body mass index (BMI) greater than or equal to 30 kg/m2 or (2) documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition for the requested medication (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, or established cardiovascular disease). Reauthorization for weight loss will require documentation that the member continues to experience clinical benefit based on the prescriber's assessment, documentation that member has experienced at least a 5% reduction in weight from baseline, and documentation that member has titrated to the appropriate maintenance dosage based on patient response and tolerability.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZEPOSIA(GHP2027)

MEDICATION(S)
ZEPOSIA, ZEPOSIA 7-DAY STARTER PACK, ZEPOSIA STARTER KIT 0.23MG &0.46MG 0.92MG(21) CAP THPK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF MULTIPLE SCLEROSIS. DIAGNOSIS OF MODERATE TO SEVERE ULCERATIVE COLITIS.

AGE RESTRICTION
FOR UC: MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
FOR UC: GASTROENTEROLOGIST

COVERAGE DURATION
FOR UC: 12 MONTHS. FOR MS: REMAINDER OF CONTRACT YEAR.

OTHER CRITERIA
FOR UC: DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR UC (FORMULARY ADALIMUMAB PRODUCT, SIMPONI, XELJANZ, RINVOQ, SKYRIZI, TREMFYA, FORMULARY USTEKINUMAB PRODUCT). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

PART B PREREQUISITE

Pending CMS Approval

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ZEPZELCA(GHP2027)

MEDICATION(S)
ZEPZELCA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZIIHERA(GHP2027)

MEDICATION(S)
ZIIHERA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZINPLAVA(GHP2027)

MEDICATION(S)
ZINPLAVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION THAT PATIENT IS AT HIGH RISK FOR CLOSTRIDUM DIFFICILE INFECTION RECURRENCE AS EVIDENCED BY ONE OF THE FOLLOWING: ONE RISK FACTOR FOR RECURRENT DISEASE (SUCH AS BUT NOT LIMITED TO: AGE 65 OR OLDER, GREATER THAN OR EQUAL TO 10 UNFORMED STOOLS PER 24 HOURS, SERUM CREATININE GREATER THAN OR EQUAL TO 1.2 MG/DL) OR AT LEAST ONE PREVIOUS C.DIFF INFECTION WITHIN THE PAST 6 MONTHS OR HISTORY OF AT LEAST 2 PREVIOUS C.DIFF INFECTIONS EVER. DOCUMENTATION THAT MEDICATION IS BEING ADMINISTERED CONCURRENTLY WITH A STANDARD OF CARE ANTIBACTERIAL TREATMENT FOR C.DIFF (ORAL VANCOMYCIN, METRONIDAZOLE, FIDAXOMICIN). DOCUMENTATION OF ONE OF THE FOLLOWING: PATIENT DOES NOT HAVE HEART FAILURE OR RATIONALE FOR USE IN A HEART FAILURE PATIENT (THAT RISKS OUTWEIGH BENEFITS). DOCUMENTATION THAT PATIENT HAS NOT RECEIVED A PREVIOUS DOSE OF ZINPLAVA.

Pending CMS Approval

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
PRESCRIBED BY GASTROENTEROLOGIST OR WITH CONSULTATION FROM INFECTIOUS DISEASE PROVIDER

COVERAGE DURATION
ONE FILL FOR ONE DOSE

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZOKINVY(GHP2027)

MEDICATION(S)
ZOKINVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DX OF HUTCHINSON-GILFORD PROGERIA SYNDROME CONFIRMED BY GENETIC TESTING. DX OF PROCESSING-DEFICIENT PROGEROID LAMINOPATHY CONFIRMED BY GENETIC TESTING AND ONE OF THE FOLLOWING: (1) HETEROZYGOUS LMNA MUTATION WITH PROGERIN-LIKE PROTEIN ACCUMULATION OR (2) HOMOZYGOUS OR COMPOUND HETEROZYGOUS ZMPSTE24 MUTATIONS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
DOCUMENTATION OF BODY SURFACE AREA (BSA) OF AT LEAST 0.39 M2. DOCUMENTATION THAT THE REQUESTED DOSE IS APPROPRIATE BASED ON THE MEMBERS BSA. DOCUMENTATION THAT ALL POTENTIAL DRUG INTERACTIONS HAVE BEEN ADDRESSED BY THE PRESCRIBER (SUCH AS DISCONTINUATION OF THE INTERACTING DRUG, DOSE REDUCTION OF THE INTERACTING DRUG, OR COUNSELING OF THE MEMBER OF THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT). REAUTHORIZATION WILL REQUIRE THAT THE REQUESTED DOSE IS APPROPRIATE BASED

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ON THE MEMBERS BSA AND DOCUMENTATION THAT ALL POTENTIAL DRUG INTERACTIONS HAVE BEEN ADDRESSED BY THE PRESCRIBER (SUCH AS DISCONTINUATION OF THE INTERACTING DRUG, DOSE REDUCTION OF THE INTERACTING DRUG, OR COUNSELING OF THE MEMBER OF THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT).

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZOLPIDEM(GHP2027)

MEDICATION(S)
ZOLPIDEM TARTRATE 10 MG TAB, ZOLPIDEM TARTRATE 1.75 MG SL TAB, ZOLPIDEM TARTRATE 3.5 MG SL TAB, ZOLPIDEM TARTRATE 5 MG TAB, ZOLPIDEM TARTRATE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DOCUMENTATION OF FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO RAMELTEON (GENERIC ROZEREM) AND DOXEPIN (GENERIC SILENOR).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZOMACTON(GHP2027)

MEDICATION(S)
ZOMACTON 5 MG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ENDOCRINOLOGIST OR NEPHROLOGIST

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZOMIG NASAL(GHP2027)

MEDICATION(S)
ZOLMITRIPTAN 5 MG SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a Food and Drug Administration (FDA)-approved indication.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For members 12 years to 17 years of age, documentation of failure on, intolerance to, or contraindication to rizatriptan and almotriptan. For members 18 years of age or older, documentation of failure on, intolerance to, or contraindication to sumatriptan.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZONISADE(GHP2027)

MEDICATION(S)
ZONISADE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF EPILEPSY.

AGE RESTRICTION
16 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF ONE OF THE FOLLOWING: (1) FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GENERIC ZONISAMIDE CAPSULES OR (2) INABILITY TO TOLERATE OR SWALLOW CAPSULES. IF REQUESTED DOSE EXCEEDS 400 MG PER DAY, DOCUMENTATION OF FAILURE OF 400 MG DAILY DOSE AND ADEQUATE MEDICAL AND SCIENTIFIC EVIDENCE IN THE MEDICAL LITERATURE TO SUPPORT DOSES ABOVE 400 MG PER DAY.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

Pending CMS Approval

YES

Pending CMS Approval

ZORTRESS(GHP2027)

MEDICATION(S)
EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTED KIDNEY TRANSPLANT NOT COVERED BY MEDICARE OR DOCUMENTED LIVER TRANSPLANT NOT COVERED BY MEDICARE

AGE RESTRICTION
MUST BE 18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
PHYSICIAN EXPERIENCED IN IMMUNOSUPPRESSIVE THERAPY AND MANAGEMENT OF TRANSPLANT PATIENTS

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
For kidney transplant: documentation that medication is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses of cyclosporine and corticosteroids OR documentation of a therapeutic failure on, contraindication to or intolerance to calcineurin inhibitors. For liver transplant: documentation that medication is not being administered earlier than 30 days post transplant AND one of the following: used in combination with low dose tacrolimus and corticosteroids OR documentation of a therapeutic failure on, contraindication to or intolerance to calcineurin inhibitors.

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

Pending CMS Approval

ZTALMY(GHP2027)

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF CDKL5 DEFICIENCY DISORDER (CDD) AND DOCUMENTATION OF GENETIC TESTING THAT CONFIRMS A CYCLIN-DEPENDENT KINASE-LIKE 5 (CDKL5) DEFICIENCY.

AGE RESTRICTION
MUST BE 2 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
NEUROLOGIST

COVERAGE DURATION
6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

OTHER CRITERIA
DOCUMENTATION THAT PATIENT IS EXPERIENCING BASELINE SEIZURES AND DOCUMENTATION OF BASELINE FREQUENCY OF SEIZURES. DOCUMENTATION THAT THE REQUESTED DAILY DOSE DOES NOT EXCEED THE FOLLOWING: IF WEIGHT LESS THAN OR EQUAL TO 28 KG, 63 MG PER KG PER DAY OR IF WEIGHT GREATER THAN 28 KG, 1800 MG PER DAY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF A SUSTAINED REDUCTION IN MONTHLY SEIZURE FREQUENCY COMPARED TO BASELINE AND DOCUMENTATION THAT THE REQUESTED DAILY DOSE DOES NOT EXCEED THE FOLLOWING: IF WEIGHT LESS THAN OR EQUAL TO 28 KG, 63 MG PER KG PER DAY OR IF WEIGHT GREATER THAN 28 KG, 1800 MG PER DAY.

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PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZULRESSO(GHP2027)

MEDICATION(S)
ZULRESSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF POSTPARTUM DEPRESSION (PPD) AS DEFINED BY 1) PATIENT EXPERIENCING A MAJOR DEPRESSIVE EPISODE AND 2) PATIENT EXPERIENCED ONSET OF SYMPTOMS WITHIN THE THIRD TRIMESTER OR WITHIN 4 WEEKS OF DELIVERY. DOCUMENTATION THAT PATIENT IS LESS THAN OR EQUAL TO 6 MONTHS POSTPARTUM AND DOCUMENTATION THAT CURRENT DEPRESSIVE EPISODE IS MODERATE TO SEVERE BASED ON A STANDARDIZED AND VALIDATED QUESTIONNAIRE/SCALE (E.G. A SCORE OF GREATER THAN 10 ON THE PATIENT HEALTH QUESTIONNAIRE (PHQ-9), A SCORE OF GREATER THAN 20 ON THE HAMILTON DEPRESSION RATING SCALE (HAM-D), ETC.)

Pending CMS Approval

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A PSYCHIATRIST

COVERAGE DURATION
ONE-TIME COURSE OF THERAPY OF 3 DAYS

OTHER CRITERIA
ADDITIONAL INFUSION(S) OF ZULRESSO FOR FUTURE CASES OF PPD ASSOCIATED WITH ADDITIONAL PREGNANCIES WILL BE REVIEWED FOR MEDICAL NECESSITY BASED ON THE ABOVE CRITERIA. MORE THAN ONE ADMINISTRATION OF ZULRESSO PER PREGNANCY/BIRTH IS CONSIDERED INVESTIGATIONAL AND NOT COVERED.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZURZUVAE(GHP2027)

MEDICATION(S)
ZURZUVAE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DIAGNOSIS OF POSTPARTUM DEPRESSION (PPD) AS DEFINED BY 1) PATIENT EXPERIENCING A MAJOR DEPRESSIVE EPISODE AND 2) PATIENT EXPERIENCED ONSET OF SYMPTOMS WITHIN THE THIRD TRIMESTER OR WITHIN 4 WEEKS OF DELIVERY. DOCUMENTATION THAT PATIENT IS LESS THAN OR EQUAL TO 12 MONTHS POSTPARTUM AND DOCUMENTATION THAT CURRENT DEPRESSIVE EPISODE IS MODERATE TO SEVERE BASED ON A STANDARDIZED AND VALIDATED QUESTIONNAIRE/SCALE (E.G. A SCORE OF GREATER THAN 10 ON THE PATIENT HEALTH QUESTIONNAIRE (PHQ-9), A SCORE OF GREATER THAN 20 ON THE HAMILTON DEPRESSION RATING SCALE (HAM-D), ETC.)

Pending CMS Approval

AGE RESTRICTION
18 YEARS OF AGE OR OLDER

PRESCRIBER RESTRICTION
BY OR IN CONSULTATION WITH A PSYCHIATRIST OR OBSTETRICIAN

COVERAGE DURATION
ONE-TIME COURSE OF THERAPY OF 14 DAYS

OTHER CRITERIA
ADDITIONAL COURSE(S) OF ZURANOLONE FOR FUTURE CASES OF PPD ASSOCIATED WITH ADDITIONAL PREGNANCIES WILL BE REVIEWED FOR MEDICAL NECESSITY BASED ON THE ABOVE CRITERIA. MORE THAN ONE ADMINISTRATION OF ZURANOLONE PER PREGNANCY/BIRTH IS CONSIDERED INVESTIGATIONAL AND NOT COVERED.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

Pending CMS Approval

ZYCUBO(GHP2027)

MEDICATION(S)
ZYCUBO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Menkes disease

AGE RESTRICTION
17 YEARS OF AGE OR LESS

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 MONTHS

OTHER CRITERIA
Documentation of a dose and administration that is consistent with FDA approved packaged labeling, nationally recognized compendia, or peer-reviewed medical literature. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZYKADIA(GHP2027)

MEDICATION(S)
ZYKADIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Documentation of ALK Gene rearrangement. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZYNLONTA(GHP2027)

MEDICATION(S)
ZYNLONTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZYNYZ(GHP2027)

MEDICATION(S)
ZYNYZ

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist. Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Pertinent Diagnostic Test Results (if applicable). Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

ZYPITAMAG(GHP2027)

MEDICATION(S)
ZYPITAMAG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
Documentation of intolerance to, contraindication to, or failure (including up-to-date laboratory values) to reach goal LDL (per NCEP guidelines) after titration to tolerated doses of atorvastatin and rosuvastatin.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

Pending CMS Approval

ZYTIGA(GHP2027)

MEDICATION(S)
ABIRATERONE ACETATE, ABIRTEGA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
As limited by FDA labeling.

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
Consistent with FDA approval or medically accepted indication for stated diagnosis.

PRESCRIBER RESTRICTION
Cancer Dx: Oncologist or Hematologist, or Urologist (if Prostate Cancer). Non-Cancer Dx: Appropriate Specialist.

COVERAGE DURATION
6 MONTHS

OTHER CRITERIA
Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

Pending CMS Approval

NON-FORMULARY ONCOLOGY EXCEPTIONS

MEDICATION(S)
NON-FORMULARY ONCOLOGY MEDICATIONS

PA INDICATION INDICATOR
N/A

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
DOCUMENTATION OF USE FOR AN FDA-APPROVED INDICATION OR USE FOR A MEDICALLY ACCEPTED INDICATION ACCORDING TO MEDICARE RECOGNIZED COMPENDIA.

AGE RESTRICTION
PER FDA LABELING

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
REMAINDER OF CONTRACT YEAR

OTHER CRITERIA
DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES FOR THE DIAGNOSIS SUBMITTED.

PART B PREREQUISITE
N/A

Pending CMS Approval