Geisinger Medicare 2023 Prior Authorization Criteria

GHP Medicare Formulary - Prior Authorization Criteria

Page 1 of 591

Table of Contents

ABILIFY ASIMTUFII	20
ABILIFY MYCITE	21
ABRAXANE	22
ACTEMRA	23
ACTEMRA SUBQ	24
ACTIQ	25
ADAKVEO	26
ADASUVE	27
ADBRY	28
ADCETRIS	29
ADCIRCA	30
ADEMPAS	31
AFINITOR	32
AFINITOR DISPERZ	33
AIMOVIG	34
AJOVY	35
AKYNZEO	36
ALDURAZYME	37
ALECENSA	
ALINIA	
ALIQOPA	40
ALKINDI	41
ALOXI	42
ALUNBRIG	43
AMONDYS	44
AMVUTTRA	45
ANTIPARKINSON AGENT HRM	46
APTIOM	47
ARALAST	48

GHP Medicare Formulary - Prior Authorization Criteria

ARANESP	49
ARAZLO	50
ARCALYST	51
ARISTADA INITIO	52
ARRANON	53
ARZERRA	54
ASPARAGINASE	55
ASTAGRAF	56
AUSTEDO	57
AUVELITY	58
AVSOLA	59
ΑΥVΑΚΙΤ	61
BALVERSA	62
BANZEL	63
BAVENCIO	64
BAXDELA	65
BECONASE AQ	66
BELEODAQ	67
BEMPEDOIC ACID	68
BENLYSTA	70
BESPONSA	71
BESREMI	72
BETHKIS	73
BEXAROTENE GEL	74
BEYFORTUS	75
BLINCYTO	76
BONIVA IV	77
BONJESTA	78
BOSULIF	79
BRAFTOVI	

Page 3 of 591

BRINTELLIX	81
BRIUMVI	82
BRIVIACT	83
BROVANA	84
BRUKINSA	85
BUDESONIDE ER	86
BYLVAY	87
CABLIVI	88
САВОМЕТҮХ	89
CALQUENCE	90
CAMZYOS	91
CAPLYTA	92
CARBAGLU	93
CAYSTON	94
CEREZYME	95
CHOLBAM	96
CHORIONIC GONADOTROPIN	97
CIALIS	98
CIBINQO	
CIMZIA	100
CINRYZE	102
CLOLAR	103
CLOMIPRAMINE HRM	104
COLUMVI	105
COMETRIQ	106
COPIKTRA	107
CORLANOR	
COSELA	109
COSENTYX	110
COTELLIC	112

Page 4 of 591

CRINONE	113
CRIZOTINIB	114
CRYSVITA	115
CUVRIOR	116
CYCLOSET	117
CYPROHEPTADINE HRM	118
CYRAMZA	119
DALIRESP	120
DANYELZA	121
DARAPRIM	122
DARZALEX	123
DARZALEX FASPRO	125
DAURISMO	127
DAYBUE	128
DEMSER	129
DIACOMIT	130
DICLEGIS	131
DIFICID	132
DOJOLVI	133
DOPTELET	134
DRIZALMA	135
DRONABINOL	136
DUAVEE	137
DUPIXENT	138
ELAPRASE	140
ELELYSO	141
ELFABRIO	142
ELIDEL	143
ELITEK	144
ELREXFIO	145

Page 5 of 591

EMEND	146
EMFLAZA	147
EMGALITY	148
EMPAVELI	150
EMPLICITI	151
ENBREL	152
ENDARI	154
ENHERTU	155
ENSPRYNG	156
EPCLUSA	157
EPIDIOLEX	158
EPKINLY	159
EPOETIN	160
EPOPROSTENOL	162
EPRONTIA	163
ERAXIS	164
ERIVEDGE	165
ERLEADA	
ESBRIET	167
EUCRISA	168
EVENITY	169
EVKEEZA	170
EVRYSDI	171
EXJADE	172
EXKIVITY	173
EXONDYS	174
EXSERVAN	175
EYSUVIS	176
FABIOR	177
FABRAZYME	178

Page 6 of 591

FARYDAK	179
FASENRA	
FENSOLVI	
FERRIC CITRATE	
FERRIPROX	
FETROJA	
FETZIMA	
FILSPARI	
FINTEPLA	
FIRAZYR	
FIRDAPSE	
FLECTOR	
FORTEO	191
FOTIVDA	
FYARRO	
FYCOMPA	194
FYLNETRA	195
GALAFOLD	196
GAMIFANT	197
GATTEX	198
GAVRETO	199
GAZYVA	
GILOTRIF	201
GIVLAARI	
GLEOSTINE	203
GROWTH HORMONE	204
HAEGARDA	205
HALAVEN	
HARVONI	207
HETLIOZ	208

Page 7 of 591

HUMIRA	
HYFTOR	211
IBRANCE	212
ICLUSIG	213
IDHIFA	214
IGALMI	215
ILARIS	216
IMBRUVICA	218
IMFINZI	219
IMJUDO	
IMLYGIC	221
INFLIXIMAB	222
INGREZZA	224
INJECTABLE ANTIPSYCHOTICS	225
INLYTA	
INQOVI	
INQOVI INREBIC	
	228
INREBIC	228
INREBIC	
INREBIC INSULIN CONCENTRATE INTUNIV	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA. ISTODAX	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA ISTODAX ITRACONAZOLE	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA ISTODAX ITRACONAZOLE IVERMECTIN	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA ISTODAX ITRACONAZOLE IVERMECTIN IVIG	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA IRESSA ISTODAX ISTODAX ITRACONAZOLE IVERMECTIN IVIG IXEMPRA	
INREBIC INSULIN CONCENTRATE INTUNIV INVEGA HAFYERA INVEGA HAFYERA IRESSA ISTODAX ISTODAX ITRACONAZOLE IVERMECTIN IVIG IXEMPRA JADENU	

Page 8 of 591

JEVTANA
JOENJA
JUXTAPID
JYNARQUE
KADCYLA
KALYDECO
KERENDIA
KEVZARA
KEYTRUDA
KIMMTRAK
KINERET
KISQALI
KORLYM
KOSELUGO
KRAZATI
KRYSTEXXA
KUVAN
KYPROLIS
LAMZEDE
LAZANDA
LENVIMA
LEQVIO
LETAIRIS
LEUKINE
LIBTAYO
LIDODERM
LIQREV
LIVMARLI
LIVTENCITY
LOKELMA

LONSURF	276
LORBRENA	277
LUCEMYRA	278
LUMAKRAS	279
	280
LUMOXITI	281
LUNSUMIO	282
LUPKYNIS	283
LYBALVI	284
	285
	287
LYTGOBI	288
MARGENZA	289
MARQIBO	290
MAVENCLAD	291
MAVYRET	292
MEBENDAZOLE	293
MEKINIST	294
MEKTOVI	295
MEPROBAMATE HRM	296
MEPSEVII	297
MONJUVI	298
MOUNJARO	299
MULPLETA	300
MYFEMBREE	301
MYLOTARG	302
MYRBETRIQ SUSPENSION	303
NAGLAZYME	304
NATPARA	305
NERLYNX	306

Page 10 of 591

NEULASTA	
NEXAVAR	
NEXIUM IV	
NEXVIAZYME	
NINLARO	
NITYR	
NIVESTYM	
NOCDURNA	315
NORTHERA	
NOURIANZ	
NOXAFIL	
NPLATE	
NUBEQA	
NUCALA	321
NUEDEXTA	
NULIBRY	
NULOJIX	
NUPLAZID	
NURTEC	
NUVIGIL	
NUZYRA	
NYVEPRIA	
OCREVUS	
ODOMZO	
OFEV	
OLUMIANT	
ONIVYDE	
ONPATTRO	
ONUREG	
OPDIVO	

Page 11 of 591

OPDUALAG	341
OPSUMIT	342
OPZELURA	343
ORENCIA	344
ORGOVYX	345
ORIAHNN	346
ORILISSA	347
ORKAMBI	348
ORLADEYO	349
ORSERDU	350
OTEZLA	351
OXBRYTA	352
OXERVATE	353
OXLUMO	354
PADCEV	355
PALYNZIQ	356
PANRETIN	357
PEMAZYRE	358
PEPAXTO	359
PERFOROMIST	360
PERSERIS	361
PIQRAY	362
POLIVY	363
POMALYST	364
PORTRAZZA	365
PRALUENT	366
PRETOMANID	368
PREVYMIS	369
PROCYSBI	370
PROLIA	371

Page 12 of 591

PROMACTA	372
PROMETHAZINE HRM	373
PROVIGIL	374
PULMOZYME	375
PYRUKYND	376
QALSODY	377
QINLOCK	378
QUDEXY	379
QUININE	380
QULIPTA	381
RADICAVA	382
RADICAVA IV	383
RAVICTI	384
REBLOZYL	385
REBYOTA	386
RECARBRIO	387
REGRANEX	388
RELEUKO	389
RELISTOR	391
RELYVRIO	392
REPATHA	393
RETEVMO	395
REVATIO	396
REVCOVI	397
REVLIMID	398
REXULTI	399
REZLIDHIA	400
REZUROCK	401
RINVOQ	402
RITUXAN	404

Page 13 of 591

RITUXAN HYCELA	
ROLVEDON	407
ROZLYTREK	408
RUBRACA	
RUXOLITINIB	410
RYBREVANT	412
RYDAPT	413
RYLAZE	414
SABRIL	415
SANTYL	416
SAPHNELO	417
SAPHRIS	418
SARCLISA	419
SCEMBLIX	
SECUADO	421
SEROSTIM	
SIGNIFOR	
SIGNIFOR LAR	
SIKLOS	
SIMPONI	
SIRTURO	427
SIVEXTRO	
SKYCLARYS	
SKYRIZI	430
SLEEPERS HRM	431
SORIATANE	432
SPEVIGO	433
SPRAVATO	435
SPRYCEL	437
STELARA	438

Page 14 of 591

STIMUFEND
STIVARGA
STRATTERA
STRENSIQ
SULFONYLUREAS HRM
SUNOSI
SUPPRELIN LA
SUTENT
SYLVANT
SYMDEKO
SYMLIN
SYMPAZAN
SYNAGIS
SYNERCID
SYNRIBO
SYPRINE
TABRECTA
TAFAMIDIS MEGLUMINE
TAFINLAR
TAGRISSO
TAKHZYRO
TALVEY
TALZENNA
TARCEVA
TARPEYO
TASIGNA
TAVALISSE
TAVNEOS
TAZORAC

Page 15 of 591

TCA HRM
TECENTRIQ
TECVAYLI
TEGSEDI
TEPEZZA
TEPMETKO
TEZSPIRE
THIORIDAZINE HRM
TIBSOVO
TIGLUTIK
TIVDAK
TLANDO
TOBI
TOBRAMYCIN NEB
TORISEL
TRACLEER
TREMFYA
TRETINOIN
TRIKAFTA
TRIPTODUR
TRODELVY
TROKENDI XR
TRUSELTIQ
TUKYSA
TURALIO
TYKERB
TYMLOS
TYSABRI
TYVASO
TYVASO DPI

Page 16 of 591

TZIELD	
UBRELVY	
UDENYCA	502
UNITUXIN	
UPTRAVI	504
UPTRAVI IV	505
UZEDY	
VALCHLOR	
	508
VANFLYTA	
VARUBI	510
VECTIBIX	511
VELCADE	512
VELTASSA	513
VEMURAFENIB	514
VENCLEXTA	515
VENCLEXTA VENTAVIS	
	516
VENTAVIS	516
VENTAVIS VERQUVO	516 517 518
VENTAVIS VERQUVO VERZENIO	
VENTAVIS VERQUVO VERZENIO VIIBRYD	
VENTAVIS VERQUVO VERZENIO VIIBRYD VIJOICE	
VENTAVIS VERQUVO VERZENIO VIIBRYD VIJOICE VILTEPSO	
VENTAVIS VERQUVO VERZENIO VIIBRYD VIJOICE VILTEPSO VIMPAT	
VENTAVIS VERQUVO VERZENIO VIBRYD VIJOICE VIJOICE VILTEPSO VIMPAT VIRAZOLE	
VENTAVIS VERQUVO VERZENIO VIBRYD VIJOICE VILTEPSO VIMPAT VIRAZOLE VITRAKVI	
VENTAVIS VERQUVO VERZENIO VIBRYD VIJOICE VIJOICE VILTEPSO VIMPAT VIRAZOLE VITRAKVI	
VENTAVIS VERQUVO VERZENIO VIBRYD VIJOICE VILTEPSO VIMPAT VIRAZOLE VITRAKVI VIVJOA	

VOWST	531
VPRIV	532
VRAYLAR	533
VUITY	534
VYEPTI	535
VYONDYS	537
VYXEOS	538
WELIREG	539
ХАТМЕР	540
XCOPRI	541
XELJANZ	542
XENLETA	544
XENPOZYME	545
XERMELO	546
XGEVA	547
XIFAXAN	548
XOLAIR	549
XOSPATA	550
ΧΡΟΥΙΟ	551
XTANDI	552
XYREM	553
XYWAV	554
YERVOY	555
YONDELIS	557
YONSA	558
ZALTRAP	559
ZARXIO	
ZAVESCA	
ZEJULA	
ZEPOSIA	

Page 18 of 591

ZEPZELCA	.565
ZERBAXA	.566
ZIEXTENZO	.567
ZINPLAVA	.568
ΖΟΚΙΝΥΥ	.569
ΖΟΝΤΙVΙΤΥ	.570
ZORBTIVE	.571
ZORTRESS	.572
ZORYVE	.573
ZTALMY	.574
ZULRESSO	
ZYDELIG	.576
ZYKADIA	.577
	.578
ZYNYZ	.579
ZYTIGA	.580

ABILIFY ASIMTUFII

Affected Drugs: Abilify Asimtufii

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF SCHIZOPHRENIA or BIPOLAR I DISORDER AS MONOTHERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY.

ABILIFY MYCITE

Affected Drugs:

Abilify MyCite Abilify MyCite Maintenance Kit Abilify MyCite Starter Kit

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of schizophrenia OR diagnosis of acute treatment of mania and mixed episodes or maintenance treatment of Bipolar I disorder as either monotherapy or as adjunct to lithium or valproate OR diagnosis of use as adjunctive treatment of major depressive disorder.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: DOCUMENTATION OF THE NEED TO MONITOR DRUG INGESTION AND DOCUMENTATION OF ACCESS TO A COMPATIBLE SMART PHONE. FOR SCHIZOPHRENIA AND BIPOLAR I DISORDER: DOCUMENTATION OF REASON WHY ARIPIPRAZOLE ORAL TABLETS CANNOT BE USED. FOR ADJUNCTIVE TREATMENT OF MAJOR DEPRESSIVE DISORDER: DOCUMENTATION OF USE AS ADJUNCTIVE THERAPY AND DOCUMENTATION OF REASON WHY ARIPIPRAZOLE ORAL TABLETS CANNOT BE USED.

ABRAXANE

Affected Drugs:

Abraxane PACLitaxel Protein-Bound Part

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF BREAST CANCER OR DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) OR DIAGNOSIS OF METASTATIC ADENOCARCINOMA OF THE PANCREAS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: FOR BREAST CANCER: DOCUMENTATION OF FAILURE ON COMBINATION CHEMOTHERAPY FOR METASTATIC DISEASE OR RELAPSE WITHIN 6 MONTHS OF ADJUVANT CHEMOTHERAPY AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ANTHRACYCLINE AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO STANDARD PACLITAXEL THERAPY. FOR NSCLC: DOCUMENTATION OF ABRAXANE USED AS FIRST-LINE TREATMENT IN COMBINATION WITH CARBOPLATIN WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION THERAPY. FOR ADENOCARCINOMA OF PANCREAS: DOCUMENTATION OF USE IN COMBINATION WITH GEMCITABINE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ACTEMRA

Affected Drugs:

Actemra

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.

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

Prescription Order Restrictions: 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 (HUMIRA, ENBREL, RINVOQ, XELJANZ). FOR PJIA: FAILURE ON, CONTRAINDICATION TO OR INTOLERANCE TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. FOR GCA: DOCUMENTATION OF USE IN COMBINATION WITH ORAL GLUCOCORTICOIDS. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

ACTEMRA SUBQ

Affected Drugs:

Actemra Actemra ACTPen

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 Restrictions: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.

Prescription Order Restrictions: 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 (HUMIRA, ENBREL, RINVOQ, XELJANZ). FOR GIANT CELL ARTERITIS, DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH ORAL GLUCOCORTICOIDS. FOR PJIA: FAILURE ON, CONTRAINDICATION TO OR INTOLERANCE TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. 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.

ACTIQ

Affected Drugs:

fentaNYL Citrate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE TO MANAGE BREAKTHROUGH CANCER PAIN IN PATIENTS WITH CANCER

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:CONCOMITANT MORPHINE 60 MG/DAY OR MORE, TRANSDERMAL FENTANYL 25 MCG/H, OXYCODONE 30 MG/DAY, ORAL HYDROMORPHONE 8 MG/DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID FOR 1 WEEK OR LONGER.

ADAKVEO

Affected Drugs:

Adakveo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTATION OF DIAGNOSIS OF SICKLE CELL DISEASE.

Age Restrictions: MUST BE 16 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 ENDARI. 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).

ADASUVE

Affected Drugs:

Adasuve

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 Restrictions:N/A

Prescription Order Restrictions: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.

ADBRY

Affected Drugs:

Adbry

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

ADCETRIS

Affected Drugs:

Adcetris

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.

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

Prescription Order Restrictions: 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.

GHP Medicare Formulary - Prior Authorization Criteria

Page 29 of 591

ADCIRCA

Affected Drugs:

Alyq Tadalafil (PAH)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF ONE OF THE FOLLOWING: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND LETAIRIS OR DOCUMENTATION OF USE AS FIRST LINE THERAPY IN COMBINATION WITH LETAIRIS IN PATIENTS WITH WHO GROUP 1 PAH

ADEMPAS

Affected Drugs:

Adempas

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 Restrictions:N/A

Prescription Order Restrictions: 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 OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS.

AFINITOR

Affected Drugs:

Everolimus

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF RENAL CELL CARCINOMA. DX OF HORMONE-RECEPTOR POSITIVE, HER-2 NEGATIVE ADVANCED BREAST CANCER. DX OF PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (PNET) THAT IS UNRESCTABLE, LOCALLY ADVANCED OR METASTATIC. DX OF PROGRESSIVE, WELL DIFFERENTIATED, NON-FUNCTIONAL NEUROENDOCRINE TUMORS OF GASTROINTESTINAL (GI) ORIGIN OR LUNG ORIGIN THAT ARE UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC. DX OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) ASSOCIATED WITH TUBEROUS SCLEROSIS (TS) WHO REQUIRE THERAPEUTIC INTERVENTION BUT ARE NOT CANDIDATES FOR CURATIVE SURGICAL RESECTION. DX OF RENAL ANGIOMYOLIPOMA AND TUBUEROUS SCLEROSIS COMPLEX/SPORADIC LYMPHANGIOLEIOMYMATOSIS NOT REQUIRING IMMEDIATE SURGERY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST, NEPHROLOGIST, UROLOGIST, or NEUROLOGIST

Coverage Duration:12 MONTHS

Other Criteria: FOR RENAL CELL CARCINOMA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO sunitinib (SUTENT) or sorafenib (NEXAVAR). FOR BREAST CANCER: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PREVIOUS ENDOCRINE THERAPY TREATMENT AND EVEROLIMUS MUST BE USED IN COMBINATION WITH AN AROMATASE INHIBITOR. FOR RENAL ANGIOMYOLIPOMA AND TUBUEROUS SCLEROSIS COMPLEX/SPORADIC LYMPHANGIOLEIOMYMATOSIS: AT LEAST ONE ANGIOMYOLIPOMA OF GREATER THAN OR EQUAL TO 3CM IN LONGEST DIAMETER ON CT/MRI BASED ON LOCAL RADIOLOGY ASSESSMENT. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

AFINITOR DISPERZ

Affected Drugs:

Everolimus

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 treatement of of Tuberous Sclerosis Complex (TSC) associated partial-onset seizures

Age Restrictions:N/A

Prescription Order Restrictions: 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.

AIMOVIG

Affected Drugs:

Aimovig

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria: Provider attestation of a therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta blocker (i.e., metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine. Attestation that medication is not being used concurrently with botulinum toxin OR if being used in combination attestation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Attestation that medication will not be used concomitantly with another CGRP receptor antagonist indicated for the preventive 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 either attestation that the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox attestation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist AND Attestation that medication will not be used concomitantly with another CGRP receptor antagonist indicated for the preventive treatment of migraine.

AJOVY

Affected Drugs:

Ajovy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria: Documentation of a therapeutic failure on, intolerance to, or contraindication to Emgality and Aimovig. Documentation that medication is not being used concurrently with botulinum toxin OR if being used in combination documentation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Documentation that medication will not be used concomitantly with another CGRP receptor antagonist indicated for the preventive treatment of migraine. Reauthorization will require documentation of continued or sustained reduction in migraine or headache frequency or a decrease in severity or duration of migraine AND either documentation use with Botox documentation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist AND documentation that medication will not be used concomitant use of a CGRP antagonist AND documentation that medication will not be used concomitant use of a CGRP receptor antagonist AND documentation that medication will not be used concomitant use of a CGRP receptor antagonist indicated for the preventive treatment of migraine.

AKYNZEO

Affected Drugs:

Akynzeo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE FOR THE PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING IN PATIENTS WHO ARE RECEIVING MODERATELY TO HIGHLY EMETOGENIC CHEMOTHERAPY, INCLUDING, BUT ARE NOT LIMITED TO REGIMENS CONTAINING BENDAMUSTINE, CARBOPLATIN, CISPLATIN, CYCLOPHOSPHAMIDE, DACARBAZINE, DOXORUBICIN, IFOSFAMIDE, IRINOTECAN, OXALIPLATIN, AND TEMOZOLOMIDE

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

ALDURAZYME

Affected Drugs:

Aldurazyme

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 Restrictions:N/A

Prescription Order Restrictions:METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MUCOPOLYSACCHARIDOSIS

Coverage Duration:12 MONTHS

Other Criteria:N/A

ALECENSA

Affected Drugs:

Alecensa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ALINIA

Affected Drugs:

Nitazoxanide

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF DIARRHEA CAUSED BY GIARDIA LAMBLIA OR CRYPTOSPORIDIUM PARVUM

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

ALIQOPA

Affected Drugs:

Aliqopa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELPASED FOLLICULAR LYMPHOMA (FL) WITH DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO PRIOR SYSTEMIC THERAPIES

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ALKINDI

Affected Drugs:

Alkindi Sprinkle

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF ADRENOCORTICAL INSUFFICIENCY.

Age Restrictions: MUST BE 17 YEARS OF AGE OR YOUNGER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF DIFFICULTY SWALLOWING OR THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO GENERIC FORMULARY CORTICOSTEROIDS, ONE OF WHICH MUST BE HYDROCORTISONE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AGE APPROPRIATENESS AND NEED FOR SPRINKLE FORMULATION.

ALOXI

Affected Drugs:

Palonosetron HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE FOR PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA OR VOMITING FROM LOW OR MINIMALLY EMETOGENIC CHEMOTHERAPY OR DOCUMENTATION OF USE FOR PREVENTION OF ACUTE OR DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF MODERATELY OR HIGHLY EMETOGENIC CHEMOTHERAPY

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:FOR LOW OR MINIMALLY EMETOGENIC CHEMOTHERAPY: TREATMENT FAILURE OR CONTRAINDICATION TO GRANISETRON OR ONDANSETRON. TREATMENT FAILURE IS DEFINED AS AN ALLERGY, INTOLERABLE SIDE EFFECTS, SIGNIFICANT DRUG-DRUG INTERACTION, OR LACK OF EFFICACY

ALUNBRIG

Affected Drugs:

Alunbrig

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of ALK-positive, metastatic non-small cell lung cancer

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

AMONDYS

Affected Drugs:

Amondys 45

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 Restrictions:N/A

Prescription Order Restrictions: 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 BY DOCUMENTATION OF A FOLLOW UP 6 MINUTE WALK TEST DISTANCE WITHIN THE PAST 6 MONTHS

AMVUTTRA

Affected Drugs:

Amvuttra

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:By or in consultation with neurologist, board certified medical geneticist, or specialist with experience treating hATTR

Coverage Duration:12 MONTHS

Other Criteria:Documentation of a dose and duration of therapy that is consistent with FDAapproved 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.

ANTIPARKINSON AGENT HRM

Affected Drugs:

Trihexyphenidyl HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF EXTRAPYRAMIDAL SIDE EFFECTS (EPS) OR PARKINSON'S DISEASE

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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. DIAGNOSIS OF EPS WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AMANTADINE. DIAGNOSIS OF PARKINSON'S WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CARBIDOPA/LEVODOPA, PRAMIPEXOLE, ROPINIROLE.

APTIOM

Affected Drugs:

Aptiom

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF PARTIAL ONSET SEIZURES

Age Restrictions: MUST BE 4 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES ONE OF WHICH MUST BE OXCARBAZEPINE.

ARALAST

Affected Drugs:

Aralast NP Prolastin-C

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF PANACINAR EMPHYSEMA

Age Restrictions:N/A

Prescription Order Restrictions: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).

ARANESP

Affected Drugs: Aranesp (Albumin Free)

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.

Age Restrictions:N/A

Prescription Order Restrictions: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.

ARAZLO

Affected Drugs:

Arazlo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ACNE, ACNE VULGARIS, OR ADULT-ONSET ACNE.

Age Restrictions: MUST BE 9 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR MEMBERS 12 YEARS OF AGE AND OLDER: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL RETINOIDS, SUCH AS BUT NOT LIMITED TO ADAPALENE AND TRETINOIN.

ARCALYST

Affected Drugs:

Arcalyst

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.

Age Restrictions: FOR RECURRENT PERICARDITIS: 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions:IMMUNOLOGIST, RHEUMATOLOGIST, PEDIATRICIAN, ALLERGIST OR CARDIOLOGIST

Coverage Duration: 3 MONTHS INITIAL, 12 MONTHS CONTINUATION

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.

ARISTADA INITIO

Affected Drugs:

Aristada Initio

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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. Documentation of a therapeutic failure on or intolerance to the oral equivalent form of the medication.

ARRANON

Affected Drugs:

Arranon Nelarabine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA OR T-CELL LYMPHOBLASTIC LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF FAILURE TO RESPOND TO, OR RELAPSE FOLLOWING TREATMENT WITH A MINIMUM OF 2 CHEMOTHERAPY REGIMENS. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ARZERRA

Affected Drugs:

Arzerra

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION THAT CLL IS REFRACTORY TO BOTH FLUDARABINE AND ALEMTUZUMAB OR FOR PREVIOUSLY UNTREATED: DOCUMENTATION OF USE IN COMBINATION WITH CHLORAMBUCIL AND DOCUMENTATION OF INABILITY TO USE FLUDARABINE OR FOR RELAPSE: DOCUMENTATION OF USE IN COMBINATION WITH FLUDARABINE AND CYCLOPHOSPHAMIDE OR FOR EXTENDED TREATMENT: DOCUMENTATION OF COMPLETE OR PARTIAL RESPONSE AFTER AT LEAST TWO LINES OF THERAPY FOR RECURRENT OR PROGRESSIVE DISEASE. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ASPARAGINASE

Affected Drugs:

Erwinase Erwinaze

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF TREATMENT OF PATIENT WITH ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) WHO HAS DEVELOPED A HYPERSENSITIVITY TO E.COLI DERIVED ASPARAGINASE (PEGASPARGASE)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

ASTAGRAF

Affected Drugs:

Astagraf XL

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of kidney transplant.

Age Restrictions: Must be 4 years of age or older

Prescription Order Restrictions: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.

AUSTEDO

Affected Drugs: Austedo Austedo Patient Titration Kit

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 the symptoms are related to use of a first-generation antipsychotic, documentation that a switch to a second generation antipsychotic has been attempted and did not resolve symptoms OR provider rationale as to why a switch to a second generation antipsychotic would not be appropriate.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH PSYCHIATRIST, NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST

Coverage Duration:12 MONTHS

Other Criteria:For Huntingtons: therapeutic failure on, intolerance to or contraindication to tetrabenazine. For tardive dykinesia: therapeutic failure on, intolerance to, or contraindication to valbenazine. Reauthorization for huntingtons will require documentation of an improvement in chorea as evidenced by a 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 for tardive dyskinesia will require documentation of an improvement in symptoms as evidenced by a reduction from baseline AIMS score.

AUVELITY

Affected Drugs:

Auvelity

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF THERAPEUTIC FAILURE ON OR INTOLERANCE TO TWO ANTIDEPRESSANT CLASSES.

GHP Medicare Formulary - Prior Authorization Criteria

AVSOLA

Affected Drugs:

Avsola

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 HUMIRA 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

Age Restrictions: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.

Prescription Order Restrictions: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, HUMIRA, RINVOQ, XELJANZ). FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR UC (HUMIRA, 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 (COSENTYX, HUMIRA, RINVOQ, XELJANZ). FOR PP: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR

GHP Medicare Formulary - Prior Authorization Criteria

Page 59 of 591

CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (COSENTYX, ENBREL, HUMIRA, 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 (COSENTYX, HUMIRA, RINVOQ, XELJANZ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

AYVAKIT

Affected Drugs:

Ayvakit

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE OR METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST) AND DOCUMENTATION OF A PLATELET-DERIVED GROWTH FACTOR RECEPTOR ALPHA (PDGFRA) EXON 18 MUTATION. DIAGNOSIS OF ADVANCED SYSTEMIC MASTOCYTOSIS (ADVSM), INCLUDING: AGGRESSIVE SYSEMIC MASTOCYTOSIS (ASM), SYSTEMIC MASTOCYTOSIS WITH AN ASSOCIATED HEMATOLOGICAL NEOPLASM (SM-AHN), OR MAST CELL LEUKEMIA (MCL).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST, HEMATOLOGIST, ALLERGIST OR IMMUNOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR AdvSM: DOCUMENTATION OF A PLATELET COUNT GREATER THAN OR EQUAL TO 50 X 109/L. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

BALVERSA

Affected Drugs:

Balversa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Dx of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following at least one prior line of platinum-based chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-based chemotherapy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

BANZEL

Affected Drugs:

Rufinamide

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 Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

BAVENCIO

Affected Drugs:

Bavencio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF METASTATIC MERKEL CELL CARCINOMA (MCC). DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WITH ONE OF THE FOLLOWING: DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM-CONTAINING CHEMOTHERAPY OR DISEASE PROGRESSION WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT TREATMENT WITH PLATINUM-CONTAINING CHEMOTHERAPY OR FOR USE AS MAINTENANCE TREATMENT WITH NO PROGRESSION FOLLOWING FIRST-LINE PLATINUM CONTAINING CHEMOTHERAPY. DIAGNOSIS OF ADVANCED RENAL CELL CARCINOMA AND DOCUMENTATION OF USE AS FIRST LINE TREATMENT IN COMBINATION WITH AXITINIB.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS RENEWAL

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

BAXDELA

Affected Drugs:

Baxdela

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of either a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following: Staphylococcus aureus (including methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa OR Documentation of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococccus aureus (MSSA isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila, or Mycloplasma pneumoniae AND documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration:2 WEEKS

Other Criteria:For Baxdela injection formulation: documentation of reason why the oral formulation cannot be tried or is not appropriate.

BECONASE AQ

Affected Drugs:

Beconase AQ

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of allergic or vasomotor rhinitis OR documentation of use for the prevention of nasal polyps.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:For rhinitis: documentation of failure on, intolerance to, or contraindication to two formulary agents (flunisolide, fluticasone propionate, mometasone, budesonide). For prevention of nasal polyps: documentation of failure on, intolerance to, or contraindication to mometasone.

BELEODAQ

Affected Drugs:

Beleodaq

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

BEMPEDOIC ACID

Affected Drugs:

Nexletol Nexlizet

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF EITHER 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 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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 Praluent as

GHP Medicare Formulary - Prior Authorization Criteria

Page 68 of 591

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.

BENLYSTA

Affected Drugs:

Benlysta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS AND DOCUMENTATION OF A POSITIVE ANA/ANTI-DSDNA ANTIBODY AND DOCUMENTATION OF BEING ON A STABLE TREATMENT REGIMEN WITH PREDNISONE, NSAID, ANTI-MALARIAL OR IMMUNOSUPPRESSANT AND NO DOCUMENTATION OF CNS INVOLVEMENT. DOCUMENTATION OF A DIAGNOSIS OF ACTIVE LUPUS NEPHRITIS, CLASS III, IV, V ALONE OR IN COMBINATION, CONFIRMED BY A KIDNEY BIOPSY.

Age Restrictions:N/A

Prescription Order Restrictions: 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

BESPONSA

Affected Drugs:

Besponsa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:3 MONTHS

Other Criteria:ONE TIME REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF THE FOLLOWING: PATIENT IS NOT RECEIVING HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) AND HAS ACHIEVED COMPLETE REMISSION OR COMPLETE REMISSION WITH INCOMPLETE HEMATOLOGIC RECOVERY AND MINIMAL RESIDUAL DISEASE (MRD) AND IS NOT EXPERIENCING TOXICITY OR WORSENING OF DISEASE.

BESREMI

Affected Drugs:

Besremi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTATION OF A DIAGNOSIS OF POLYCYTHEMIA VERA

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF AN INADEQUATE RESPONSE OR INTOLERANCE TO HYDROXYUREA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

BETHKIS

Affected Drugs: Tobramycin Off-Label Uses:N/A Exclusion Criteria:N/A

Required Medical Information:DX OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Effective 12/2023

BEXAROTENE GEL

Affected Drugs:

Bexarotene

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of cutaneous lesions of stage IA or IB Cutaneous Tcell lymphoma (CTCL) in patients who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Prescribed by or in consultation with oncologist or dermatologist.

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION and DOCUMENTATION THAT MEMBER CONTINUES TO BE FOLLOWED BY AN ONCOLOGIST OR DERMATOLOGIST.

BEYFORTUS

Affected Drugs:

Beyfortus

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:5 MONTHS

Other Criteria:DOCUMENTATION THAT MEMBER HAS NOT RECEIVED SYNAGIS DURING THE CURRENT RSV SEASON.

BLINCYTO

Affected Drugs:

Blincyto

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY CD19-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) OR DIAGNOSIS OF CD19-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN FIRST OR SECOND REMISSION WITH MINIMAL RESIDUAL DISEASE (MRD) GREATER THAN OR EQUAL TO 0.1%

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:RELAPSED OR REFRACTORY DISEASE: 20 MONTHS, MRD B CELL ALL: 6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF WELL-CONTROLLED PEER-REVIEWED LITERATURE WITH EVIDENCE SUPPORTING THE REQUEST.

BONIVA IV

Affected Drugs:

Ibandronate Sodium

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:INTOLERANCE TO ORAL BIPHOSPHONATES OR INABILITY TO REMAIN IN AN UPRIGHT POSITION FOR A MINIMUM OF 30-60 MINUTES AFTER INGESTION OR DISRUPTION OF THE ALIMENTARY TRACT DUE TO ANY OF THE FOLLOWING REASONS WHICH PRECLUDES THE USE OF ORAL BISPHOSPHONATES: OBSTRUCTING STRICTURE OR NEOPLASM OF THE ESOPHAGUS, STOMACH OR INTESTINE OR SHORT BOWEL SYNDROME SECONDARY TO EXTENSIVE SMALL BOWEL RESECTION OR MOTILITY DISORDER OR MALABSORPTION SECONDARY TO ENTEROVESICAL, ENTEROCUTANEOUS OR ENTEROCOLIC FISTULAS OR PROLONGED PARALYTIC ILEUS FOLLOWING SURGERY OR INJURY AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ZOLEDRONIC ACID. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B, BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES (PART B) OR COVERED UNDER MEDICARE PART D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

GHP Medicare Formulary - Prior Authorization Criteria

Effective 12/2023

BONJESTA

Affected Drugs:

Bonjesta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF NAUSEA AND VOMITING OF PREGNANCY IN ADULT WOMEN

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:9 MONTHS

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

BOSULIF

Affected Drugs:

Bosulif

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF CHRONIC, ACCELERATED, OR BLAST PHASE PH POSITIVE CHRONIC MYELOGENOUS LEUKEMIA (CML) or DOCUMENTATION OF NEWLY DIAGNOSED CHRONIC PHASE PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR ALL INDICATIONS EXCEPT NEWLY DIAGNOSED CHRONIC PHASE PHILADELPHIA CHROMOSOME POSITIVE CML: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING PRIOR THERAPIES IMATINIB, SPRYCEL, OR TASIGNA. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

BRAFTOVI

Affected Drugs:

Braftovi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of unresectable or metastatic melanoma AND documentation that medication is being prescribed in combination with Mektovi AND documentation of BRAF V600E OR V600K mutation as detected by an FDA approved test. Documentation of metastatic colorectal cancer with progression on at least one prior therapy AND documentation that medication is being prescribed in combination with cetuximab AND documentation of a BRAF V600E mutation as detected by an FDA approved test.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

BRINTELLIX

Affected Drugs:

Trintellix

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

GHP Medicare Formulary - Prior Authorization Criteria

BRIUMVI

Affected Drugs:

Briumvi

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 Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

BRIVIACT

Affected Drugs:

Briviact

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:1 WEEK

Other Criteria:DOCUMENTATION OF INABILITY TO USE ORAL FORMULATION OF MEDICATION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 83 of 591

Effective 12/2023

BROVANA

Affected Drugs: Arformoterol Tartrate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF COPD

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

GHP Medicare Formulary - Prior Authorization Criteria

BRUKINSA

Affected Drugs:

Brukinsa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MANTLE CELL LYMPHOMA (MCL) AND DOCUMENTATION OF THERAPEUTIC FAILURE ON OR INTOLERANCE TO ONE PRIOR THERAPY. DIAGNOSIS OF WALDENSTROM'S MACROGLOBULINEMIA. DIAGNOSIS OF RELAPSED OR REFRACTORY MARGINAL ZONE LYMPHOMA (MZL) AND DOCUMENTATION OF THERAPEUTIC FAILURE ON OR INTOLERANCE TO ONE PRIOR ANTI-CD20 BASED REGIMEN. DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LYMPHOMA (SLL).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

BUDESONIDE ER

Affected Drugs:

Budesonide ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of ulcerative colitis

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:8 WEEKS

Other Criteria:Documentation of failure on, intolerance to, or contraindication to sulfasalazine, balsalazide, or an oral mesalamine product

GHP Medicare Formulary - Prior Authorization Criteria

BYLVAY

Affected Drugs:

Bylvay Bylvay (Pellets)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC) AND DOCUMENTATION OF THE PRESENCE OF MODERATE TO SEVERE PRURITIS. DOCUMENTATION OF A DIAGNOSIS ALAGILLE SYNDROME (ALGS) AND DOCUMENTATION OF THE PRESENCE OF MODERATE TO SEVERE PRURITUS.

Age Restrictions: PFIC: 3 MONTHS OF AGE OR OLDER, ALGS: 12 MONTHS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH A HEPATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF AN APPROPRIATE DOSE BASED ON PATIENTS WEIGHT. FOR PFIC: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO URSODIOL. FOR ALGS: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO URSODIOL AND ONE OF THE FOLLOWING: CHOLESTYRAMINE, RIFAMPIN, OR NALTREXONE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF 1) IMPROVEMENT IN PRURITIS AND/OR REDUCTION IN SERUM BILE ACID AND 2) DOCUMENTATION OF AN APPROPRIATE DOSE BASED ON THE PATIENTS WEIGHT.

CABLIVI

Affected Drugs:

Cablivi

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, immunosuppresive 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).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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).

CABOMETYX

Affected Drugs:

Cabometyx

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE IN COMBINATION WITH NIVOLUMAB FOR PREVIOUSLY UNTREATED ADVANCED RENAL CELL CARCINOMA OR DOCUMENTATION OF USE AS A SINGLE AGENT FOR RELAPSE OR FOR SURGICALLY UNRESECTABLE ADVANCED OR METASTATIC RENAL CELL CARCINOMA AND IF THE REQUESTED DOSE IS 80 MG DAILY, DOCUMENTATION THAT THE PATIENT IS USING IN COMBINATION WITH A STRONG CYP3A4 INDUCER, INCLUDING BUT NOT LIMITED TO, RIFAMPIN, PHENYTOIN, CARBAMAZEPINE, PHENOBARBITAL, RIFABUTIN, RIFAPENTINE, OR ST. JOHN'S WORT. DOCUMENTATION OF HEPATOCELLULAR CARCINOMA AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO SORAFENIB. DOCUMENTATION OF LOCALLY ADVANCED OR METASTATIC DIFFERENTIATED THYROID CANCER (DTC) AND DOCUMENTATION OF PROGRESSION FOLLOWING PRIOR VEGFR-TARGETED THERAPY AND DOCUMENTATION THAT MEMBER IS RADIOACTIVE IODINE-REFRACTORY OR INELIGIBLE.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Effective 12/2023

CALQUENCE

Affected Drugs:

Calquence

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy OR diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). If the requested dose is 400 mg daily, need documentation that the patient is using in combination with a strong CYP3A inducer, including but not limited to carbamazepine, enzalutamide, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, or St. John's Wort.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

CAMZYOS

Affected Drugs:

Camzyos

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

CAPLYTA

Affected Drugs:

Caplyta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF SCHIZOPHRENIA OR DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR DISORDER (BIPOLAR DEPRESSION).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 LATUDA.

CARBAGLU

Affected Drugs:

Carbaglu Carglumic Acid

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 Restrictions:N/A

Prescription Order Restrictions: 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 PROGRESSION

CAYSTON

Affected Drugs:

Cayston

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 Restrictions: MUST BE 7 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TOBRAMYCIN INHALATION SOLUTION

CEREZYME

Affected Drugs:

Cerezyme

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF TYPE 1 GAUCHER DISEASE ALONG WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS: ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

Age Restrictions:N/A

Prescription Order Restrictions:METABOLIC SPECIALIST, GENETICIST, OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

Coverage Duration:6 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ELELYSO FOR THOSE 4 YEARS OF AGE AND OLDER. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

CHOLBAM

Affected Drugs:

Cholbam

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF BILE ACID SYNTHESIS DISORDERS DUE TO SINGLE ENZYME DEFECTS (SEDS) OR PEROXISOMAL DISORDERS (PDS) INCLUDING ZELLWEGER SPECTRUM DISORDERS IN PATIENTS WHO EXHIBIT MANIFESTATIONS OF LIVER DISEASE, STEATORRHEA, OR COMPLICATIONS FROM DECREASED FAT SOLUBLE VITAMIN ABSORPTION AND DOCUMENTATION THAT DIAGNOSIS HAS BEEN CONFIRMED WITH AN ABNORMAL URINARY BILE ACID FAST ATOM BOMBARDMENT IONIZATION MASS SPECTROMETRY (FAB-MS) ANALYSIS AND FOR THE TREATMENT OF PEROXISOMAL DISORDERS, DOCUMENTATION THAT MEDICATION WILL BE USED AS ADJUNCTIVE THERAPY AND DOCUMENTATION OF BASELINE ALT, AST, TOTAL BILIRUBIN, AND BODY WEIGHT.

Age Restrictions:N/A

Prescription Order Restrictions:GASTROENTEROLOGIST, HEPATOLOGIST, OR METABOLIC SPECIALIST WITH EXPERIENCE IN THE DIAGNOSIS AND TREATMENT OF BILE ACID SYNTHESIS AND PEROXISOMAL DISORDERS

Coverage Duration: 3 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION SUPPORTING IMPROVEMENT IN TWO LABORATORY CRITERION (ALT OR AST VALUES REDUCED TO LESS THAN 50 U/L OR BASELINE LEVELS REDUCED BY 80%, TOTAL BILIRUBIN VALUES REDUCED TO LESS THAN OR EQUAL TO 1 MG/DL, NO EVIDENCE OF CHOLESTASIS ON LIVER BIOPSY) OR ONE OF THE PRIOR LABORATORY CRITERIA IMPROVEMENTS IN ADDITION TO A BODY WEIGHT INCREASE OF 10% OR BODY WEIGHT STABLE AT GREATER THAN THE 50TH PERCENTILE.

CHORIONIC GONADOTROPIN

Affected Drugs:

Chorionic Gonadotropin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PREPUBERTAL CRYPTORCHIDISM NOT CAUSED BY ANATOMICAL OBSTRUCTION IN MALE INFANTS AND CHILDREN OR DIAGNOSIS OF HYPOGONADOTROPIC HYPOGONADISM

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR HYPOGONADISM: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TRANSDERMAL TESTOSTERONE

GHP Medicare Formulary - Prior Authorization Criteria

CIALIS

Affected Drugs:

Tadalafil

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH)

Age Restrictions:N/A

Prescription Order Restrictions: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)

CIBINQO

Affected Drugs:

Cibinqo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MODERATE TO SEVERE ATOPIC DERMATITIS.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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: 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 DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO DUPIXENT. REAUTHORIZATION WILL REQUIRE DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

CIMZIA

Affected Drugs:

Cimzia Cimzia Starter Kit

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 5% OF BODY SURFACE AREA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. Diagnosis of non-radiographic axial spondylarthritis with documentation of either Creactive protein (CRP) level above the upper limit of normal or Sacroiliitis on magnetic resonance imaging (MRI).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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, HUMIRA, RINVOQ, XELJANZ). FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, TREMFYA). FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (COSENTYX, ENBREL, HUMIRA, 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 (COSENTYX, ENBREL,

GHP Medicare Formulary - Prior Authorization Criteria

Page 100 of 591

Effective 12/2023

HUMIRA, XELJANZ, RINVOQ). FOR CROHN'S: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO HUMIRA. 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.

CINRYZE

Affected Drugs:

Cinryze

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

CLOLAR

Affected Drugs:

Clofarabine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF RELAPSED OR REFRACTORY ACUTE LYMPHOBLASTIC LEUKEMIA

Age Restrictions:1 TO 21 YEARS OF AGE

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO PRIOR TREATMENT REGIMENS. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

CLOMIPRAMINE HRM

Affected Drugs:

clomiPRAMINE HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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 AND WILL FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: FLUOXETINE, FLUVOXAMINE, SERTRALINE

COLUMVI

Affected Drugs:

Columvi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, OR LARGE B-CELL LYMPHOMA (LBCL) ARISING FROM FOLLICULAR LYMPHOMA AND DOCUMENTATION OF PRIOR THERAPY WITH AT LEAST TWO LINES OF SYSTEMIC THERAPY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 6 MONTHS CONTINUATION

Other Criteria:ONE TIME REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. TREATMENT WITH COLUMVI SHOULD NOT EXCEED THE FDA-APPROVED TREATMENT DURATION OF 12 MONTHS. REQUESTS EXCEEDING 12 MONTHS WILL REQUIRE DOCUMENTATION OF PEER REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

COMETRIQ

Affected Drugs:

Cometriq (100 MG Daily Dose) Cometriq (140 MG Daily Dose) Cometriq (60 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PROGRESSIVE METASTATIC MEDULLARY THYROID CANCER

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

COPIKTRA

Affected Drugs:

Copiktra

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of one of the following: Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior therapies. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

CORLANOR

Affected Drugs:

Corlanor

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 AND DOCUMENTATION OF HOSPITALIZATION FOR WORSENING HEART FAILURE WITHIN THE PREVIOUS 12 MONTHS. 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

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

Prescription Order Restrictions: 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

COSELA

Affected Drugs:

Cosela

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF EXTENSIVE-STAGE SMALL CELL LUNG CANCER (ES-SCLC) AND DOCUMENTATION THAT MEMBER IS CURRENTLY TAKING A PLATINUM/ETOPOSIDE-CONTAINING REGIMEN OR TOPOTECAN-CONTAINING REGIMEN.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

COSENTYX

Affected Drugs:

Cosentyx Cosentyx (300 MG Dose) Cosentyx Sensoready (300 MG) Cosentyx Sensoready Pen

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 GREATER THAN 5% OF BSA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, OR GENITALS. 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). DIAGNOSIS OF ENTHESITIS-RELATED ARTHRITIS.

Age Restrictions:N/A

Prescription Order Restrictions: 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 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 PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE 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 NR-AXSPA: 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 NR-AXSPA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR ENTHESITIS RELATED ARTHIRITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR

GHP Medicare Formulary - Prior Authorization Criteria

Page 110 of 591

CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO FORMULARY NSAIDS. FOR PSORIASIS, PSORIATIC ARTHRITIS, AND ENTHESITIS RELATED ARTHRITIS: DOCUMENTATION THAT THE PRESCRIBED DOSE IS APPROPRIATE FOR PATIENTS WEIGHT. DOCUMENTATION OF FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

COTELLIC

Affected Drugs:

Cotellic

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:1)DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA AND DOCUMENTATION OF BRAF V600E OR V600K MUTATION AS DETECTED BY AN FDA APPROVED TEST. DOCUMENTATION OF CONCOMITANT USE WITH VEMURAFENIB. 2)Diagnosis of histiocytic neoplasm (Langerhans Cell Histiocytosis, Rosai-Dorfman Disease, Erdheim-Chester Disease, Xanthogranuloma, Mixed Histiocytosis).

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST, or DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

CRINONE

Affected Drugs: Crinone Off-Label Uses:N/A Exclusion Criteria:N/A Required Medical Information:Diagnosis of secondary amenorrhea Age Restrictions:N/A Prescription Order Restrictions:N/A Coverage Duration:REMAINDER OF CONTRACT YEAR

Other Criteria: Failure on, intolerance to, or contraindication to medroxyprogesterone

CRIZOTINIB

Affected Drugs:

Xalkori

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK) POSITIVE AS DETECTED BY AN FDA APPROVED TEST or DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ROS 1-POSITIVE. Diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK) positive AND documentation of at least one prior systemic treatment. DIAGNOSIS OF UNRESECTABLE, RECURRENT, OR REFRACTORY INFLAMMATORY MYOFIBROBLASTIC TUMOR (IMT) THAT IS ALK POSITIVE.

Age Restrictions: FOR IMT ONLY: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER: DOCUMENTATION OF RATIONALE FOR NOT TREATING WITH ALECENSA IF CLINICALLY APPROPRIATE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

CRYSVITA

Affected Drugs:

Crysvita

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.

Age Restrictions: TIO:2 YEARS OR OLDER. X-LINKED:6 MONTHS OR OLDER

Prescription Order Restrictions: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

CUVRIOR

Affected Drugs:

Cuvrior

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF WILSON'S DISEASE AND DOCUMENTATION OF CONTROLLED WILSON'S DISEASE AS EVIDENT BY SERUM NON-CERULOPLASMIN COPPER (NCC) LEVEL BETWEEN 25 AND 150 MCG/L AND DOCUMENTATION THAT MEMBER IS TOLERANT TO PENICILLAMINE AND THAT PENICILLAMINE WILL BE DISCONTINUED PRIOR TO THERAPY WITH WITH CUVRIOR.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GENERIC TRIENTINE.

CYCLOSET

Affected Drugs:

Cycloset

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF TYPE 2 DIABETES MELLITUS.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO ORAL FORMULARY ANTIDIABETIC AGENTS.

GHP Medicare Formulary - Prior Authorization Criteria

CYPROHEPTADINE HRM

Affected Drugs:

Cyproheptadine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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. DIAGNOSIS OF ALLERGIC CONDITIONS PRURITUS, URTICARIA, SEASONAL OR PERENNIAL ALLERGIES) WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DESLORATADINE AND LEVOCETIRIZINE.

CYRAMZA

Affected Drugs:

Cyramza

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF ADVANCED OR METASTATIC, GASTRIC, OR GASTRO-ESOPHAGEAL JUNCTION ADENOCARCINOMA WITH DISEASE PROGRESSION ON OR AFTER PRIOR FLUOROPYRIMIDINE OR PLATINUM CONTAINING CHEMOTHERAPY. DOCUMENTATION OF USE IN COMBINATION WITH PACLITAXEL OR CLINICAL JUSTIFICATION FOR USE AS MONOTHERAPY. DIAGNOSIS OF METASTATIC NON SMALL CELL LUNG CANCER WITH EITHER 1)IN COMBINATION WITH DOCETAXEL IN THOSE WITH DISEASE PROGRESSION ON OR AFTER PLATINUM BASED CHEMOTHERAPY AND PATIENTS WITH EGFR OR ALK GENOMIC TUMOR ABERRATIONS MUST PROVIDE DOCUMENTATION OF DISEASE PROGRESSION ON FDA APPROVED THERAPIES FOR THESE ABERRATIONS PRIOR TO RECEIVING CYRAMZA OR 2) USED IN COMBINATION WITH ERLOTINIB AS FIRST LINE TREATMENT WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) MUTATIONS. DOCUMENTATION OF METASTATIC COLON OR RECTAL CANCER WITH DISEASE PROGRESSION ON OR AFTER FOLFOX, CAPEOX OR A REGIMEN NOT PREVIOUSLY CONTAINING IRINOTECAN AND DOCUMENTATION OF USE IN COMBINATION WITH IRINOTECAN OR FOLFIRI (FLUOROURACIL, LEUCOVORIN, AND IRINOTECAN). DOCUMENTATION OF HEPATOCELLULAR CARCINOMA AND DOCUMENTATION OF AN ALPHA FETOPROTEIN (AFP) LEVEL OF 400 NG/ML OR GREATER AND DOCUMENTATION OF DISEASE PROGRESSION ON OR AFTER TREATMENT WITH SORAFENIB OR AN INTOLERANCE TO SORAFENIB.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

Page 119 of 591

DALIRESP

Affected Drugs:

Daliresp Roflumilast

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF COPD ASSOCIATED WITH CHRONIC BRONCHITIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:CONCOMITANT USE OF, FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 1) SPIRIVA or INCRUSE ELLIPTA AND 2) ONE LONG ACTING BETA AGONISTS.

DANYELZA

Affected Drugs:

Danyelza

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 Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

DARAPRIM

Affected Drugs:

Pyrimethamine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of toxoplasmosis

Age Restrictions:N/A

Prescription Order Restrictions: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.

DARZALEX

Affected Drugs:

Darzalex

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MULTIPLE MYELOMA (MM). FOR NEWLY DIAGNOSED MM: DOCUMENTATION OF EITHER 1)NOT BEING ELIGIBLE FOR STEM CELL TRANSPLANTATION (I.E. COEXISTING CONDITIONS, AGE GREATER THAN 65, ETC) AND DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBINATION WITH ONE OF THE FOLLOWING: BORTEZOMIB, MELPHALAN AND PREDNISONE (VMP) OR LENALIDOMIDE AND DEXAMETHASONE OR 2) DOCUMENTATION THAT MEMBER IS ELIGIBLE FOR STEM-CELL TRANSPLANTATION AND DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBINATION WITH BORTEZOMIB, THALIDOMIDE, AND DEXAMETHASONE (DVTD). FOR RELAPSED OR REFRACTORY MM: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST THREE PRIOR LINES OF THERAPY INCLUDING A PROTEASOME INHIBITOR (INCLUDING BUT NOT LIMITED TO VELCADE, KYPROLIS OR NINLARO) AND AN IMMUNOMODULATORY AGENT (INCLUDING BUT NOT LIMITED TO POMALYST, REVLIMID OR THALOMID) OR DOCUMENTATION THAT THE MEMBER IS DOUBLE-REFRACTORY TO A PROTEASOME INHIBITOR AND AN IMMUNOMODULATORY AGENT OR DOCUMENTATION OF USE IN COMBINATION WITH POMALIDOMIDE AND DEXAMETHASONE FOLLOWING A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST 2 PRIOR LINES OF THERAPY INCLUDING LENALIDOMIDE AND A PROTEASOME INHIBITOR OR DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST 1 PRIOR THERAPY INCLUDING A PROTEASOME INHIBITOR OR AN IMMUNOMODULATORY AGENT AND ONE OF THE FOLLOWING: DOCUMENTATION OF USE IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE, OR IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE OR IN COMBINATION WITH CARFILZOMIB AND DEXAMETHASONE.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

GHP Medicare Formulary - Prior Authorization Criteria

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

GHP Medicare Formulary - Prior Authorization Criteria

Affected Drugs:

Darzalex Faspro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MULTIPLE MYELOMA (MM). FOR NEWLY DIAGNOSED MM: DOCUMENTATION OF EITHER 1)NOT BEING ELIGIBLE FOR STEM CELL TRANSPLANTATION (I.E. COEXISTING CONDITIONS, AGE GREATER THAN 65, ETC) AND DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBINATION WITH ONE OF THE FOLLOWING: BORTEZOMIB, MELPHALAN AND PREDNISONE (VMP) OR LENALIDOMIDE AND DEXAMETHASONE OR 2) DOCUMENTATION THAT MEMBER IS ELIGIBLE FOR STEM-CELL TRANSPLANTATION AND DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBINATION WITH BORTEZOMIB, THALIDOMIDE, AND DEXAMETHASONE (DVTD). FOR RELAPSED OR REFRACTORY MM: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST THREE PRIOR LINES OF THERAPY INCLUDING A PROTEASOME INHIBITOR (INCLUDING BUT NOT LIMITED TO VELCADE, KYPROLIS OR NINLARO) AND AN IMMUNOMODULATORY AGENT (INCLUDING BUT NOT LIMITED TO POMALYST, REVLIMID OR THALOMID) OR DOCUMENTATION THAT THE MEMBER IS DOUBLE-REFRACTORY TO A PROTEASOME INHIBITOR AND AN IMMUNOMODULATORY AGENT OR DOCUMENTATION OF USE IN COMBINATION WITH POMALIDOMIDE AND DEXAMETHASONE WITH DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST ONE PRIOR LINE OF THERAPY INCLUDING LENALIDOMIDE AND A PROTEOSOME INHIBITOR OR DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST 1 PRIOR THERAPY INCLUDING A PROTEASOME INHIBITOR OR AN IMMUNOMODULATORY AGENT AND ONE OF THE FOLLOWING: DOCUMENTATION OF USE IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE, OR IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE OR IN COMBINATION WITH CARFILZOMIB AND DEXAMETHASONE. DOCUMENTATION OF LIGHT-CHAIN AMYLOIDOSIS USED IN COMBINATION WITH BORTEZOMIB, CYCLOPHOSPHAMIDE AND DEXAMETHASONE.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

GHP Medicare Formulary - Prior Authorization Criteria

Other Criteria: FOR LIGHT-CHAIN AMYLOIDOSIS: DOCUMENTATION THAT MEMBER DOES NOT HAVE NEW YORK HEART ASSOCIATION (NYHA) CLASS IIIB OR CLASS IV HEART FAILURE OR MAYO CARDIAC STAGE IIIB. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

DAURISMO

Affected Drugs:

Daurismo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of newly diagnosed acute myeloid leukemia (AML) AND documentation of age greater than or equal to 75 years or documentation of a comorbidity that precludes use of intensive induction chemotherapy AND documentation of use in combination with low-dose cytarabine.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

DAYBUE

Affected Drugs:

Daybue

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 Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: 3 MONTHS INITIAL, 12 MONTHS CONTINUATION

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).

DEMSER

Affected Drugs:

metyroSINE

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

DIACOMIT

Affected Drugs:

Diacomit

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 Restrictions: MUST BE 6 MONTHS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation wih a neurologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

DICLEGIS

Affected Drugs: Doxylamine-Pyridoxine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF NAUSEA AND VOMITING OF PREGNANCY IN ADULT WOMEN

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:9 MONTHS

DIFICID

Affected Drugs:

Dificid

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTED DIAGNOSIS OF C. DIFFICILE INFECTION (CDI).

Age Restrictions:6 MONTHS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:10 DAYS

Other Criteria:DOCUMENTATION OF AN APPROPIATE DOSE AND DURATION OF THERAPY. DOCUMENTATION OF ONE OF THE FOLLOWING: 1) THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO VANCOMYCIN, OR 2) DOCUMENTATION THAT MEMBER IS AT HIGH RISK FOR TREATMENT FAILURE WITH VANCOMYCIN (I.E., DUE TO A MEDICAL CONDITION SUCH AS COMPROMISED IMMUNITY), OR 3) DOCUMENTATION OF CONTINUED THERAPY UPON INPATIENT DISCHARGE, OR 4) DOCUMENTATION OF BEING USED FOR TREATMENT OF A RECURRENT C. DIFFICILE INFECTION.

DOJOLVI

Affected Drugs:

Dojolvi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following, (1) Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma, (2) Low enzyme activity in cultured fibroblasts, (3) One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g., CPT2, ACADVL, HADHA, or HADHB)

Age Restrictions:N/A

Prescription Order Restrictions:by or in consultation with a metabolic specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

DOPTELET

Affected Drugs:

Doptelet

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 100000000 (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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 100000000 (10 TO THE 9TH POWER)/L: 40 mg once daily for 5 consecutive days, platelet count less than 40 x 100000000 (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.

DRIZALMA

Affected Drugs:

Drizalma Sprinkle

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

Prescription Order Restrictions: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 THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DULOXETINE CAPSULES.

DRONABINOL

Affected Drugs:

droNABinol

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

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.

DUAVEE

Affected Drugs:

Duavee

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF AN INTACT UTERUS. DOCUMENTATION OF USE FOR ABNORMAL VASOMOTOR FUNCTION OR PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR ABNORMAL VASOMOTOR FUNCTION: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FEMRING. FOR PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: ALENDRONATE, IBANDRONATE, RALOXIFENE, RISEDRONATE.

DUPIXENT

Affected Drugs:

Dupixent

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.

Age Restrictions: ATOPIC DERMATITIS: 6 MONTHS OR OLDER. ASTHMA: 6 YRS OR OLDER. CRwNP and EOSINOPHILLIC ESOPHAGITIS: 12 YRS OR OLDER. PRURIGO NODULARIS: 18 YRS OR OLDER

Prescription Order Restrictions: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 ATOPIC DERMATITIS: 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. FOR ASTHMA, DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH BENRALIZUMAB, MEPOLIZUMAB, OMALIZUMAB, RESLIZUMAB, OR TEZEPELUMAB AND DOCUMENTATION OF ONE OF THE FOLLOWING: A CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST A 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. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO INTRANASAL CORTICOSTEROIDS. DOCUMENTATION

GHP Medicare Formulary - Prior Authorization Criteria

Page 138 of 591

THAT MEDICATION WILL BE USED AS ADD ON THERAPY (I.E. WITH INTRANASAL CORTICOSTEROIDS OR OTHER THERAPY). FOR EOSINOPHILLIC ESOPHAGITIS: DOCUMENTATION OF MEMBER WEIGHT GREATER THAN OR EQUAL TO 40 KG. DOCUMENTATION OF 15 OR MORE INTRAEPITHELIAL EOSINOPHILS PER HIGH POWER FIELD (eos/hpf). DOCUMENTATION OF 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 PRURIGO NODULARIS: DOCUMENTATION OF FAILURE ON AT LEAST A VERY HIGH-POTENCY TOPICAL CORTICOSTEROID (such as but not limited to betamethasone diproprionate, clobetasol or halobetasol) OR CALCINEURIN INHIBITOR (i.e., tacrolimus) IF TOPICAL CORTICOSTEROIDS ARE NOT ADVISABLE. 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.

ELAPRASE

Affected Drugs:

Elaprase

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF HUNTER'S SYNDROME (MPS II)

Age Restrictions:N/A

Prescription Order Restrictions:METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MPS II

Coverage Duration: REMAINDER OF CONTRACT YEAR

ELELYSO

Affected Drugs:

Elelyso

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 Restrictions:N/A

Prescription Order Restrictions: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.

ELFABRIO

Affected Drugs:

Elfabrio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF FABRY DISEASE.

Age Restrictions:N/A

Prescription Order Restrictions: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.

ELIDEL

Affected Drugs:

Pimecrolimus

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF ATOPIC DERMATITIS

Age Restrictions:N/A

Prescription Order Restrictions: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))

ELITEK

Affected Drugs:

Elitek

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 Restrictions:N/A

Prescription Order Restrictions: 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

ELREXFIO

Affected Drugs:

Elrexfio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND DOCUMENTATION OF TREATMENT WITH AT LEAST 4 PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT, AND AN ANTI-CD38 MONOCLONAL ANTIBODY.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

EMEND

Affected Drugs:

Aprepitant

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:CHEMOTHERAPY REGIMEN WITH MODERATE TO HIGH EMETOGENIC POTENTIAL OR INDICATION OF POSTOPERATIVE NAUSEA/VOMITING.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST, SURGEON

Coverage Duration:12 MONTHS

Other Criteria:MUST BE USED IN COMBINATION WITH OTHER ORAL ANTIEMETIC AGENTS WHEN USED FOR THE PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA

EMFLAZA

Affected Drugs:

Emflaza

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF DUCHENNE MUSCULAR DYSTROPHY CONFIRMED BY GENETIC TESTING

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: NEUROLOGIST OR PEDIATRIC NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PREDNISONE

EMGALITY

Affected Drugs:

Emgality Emgality (300 MG Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month. Diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline cluster headache attack frequency AND documentation that member is currently experiencing a cluster headache period (period of recurrent attacks).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:MIGRAINE:6 MONTHS INITIAL, 1 YEAR CONTINUATION. CLUSTER HA:6 MONTHS

Other Criteria: Migraine: provider attestation of a therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta blocker (i.e., metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine. Attestation that medication is not being used concurrently with botulinum toxin OR if being used in combination, attestation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Attestation that medication will not be used concomitantly with another CGRP receptor antagonist indicated for the preventive 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 either attestation that the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox attestation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist AND Attestation that medication will not be used concomitantly with another CGRP receptor antagonist indicated for the preventive treatment of migraine. Cluster HA: Documentation of a therapeutic failure on, intolerance to, or contraindication to verapamil. Reauthorization for use for cluster headaches will require a diagnosis of episodic cluster

GHP Medicare Formulary - Prior Authorization Criteria

Page 148 of 591

Effective 12/2023

headache, based on the ICHD-III diagnostic criteria AND documentation that the member is currently experiencing a cluster headache period (period of recurrent attacks) AND documentation of continued or sustained reduction in cluster headache attack frequency.

GHP Medicare Formulary - Prior Authorization Criteria

Effective 12/2023

EMPAVELI

Affected Drugs:

Empaveli

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF DIAGNOSIS CONFIRMED BY FLOW CYTOMETRY. DOCUMENTATION THAT MEMBER HAS RECEIVED VACCINATIONS AGAINST ENCAPSULATED BACTERIA, INCLUDING STREPTOCOCCUS PNEUMONIAE, NEISSERIA MENINGITIDIS, AND HAEMOPHILUS INFLUENZA TYPE B. DOCUMENTATION OF ONE OF THE FOLLOWING:1)MEMBER IS TRANSFUSION-DEPEDENT 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 IMPACT ON MEMBERS HEALTH SUCH AS END ORGAN DAMAGE OR THROMBOSIS WITHOUT OTHER CAUSE. REAUTHORIZATION 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.

EMPLICITI

Affected Drugs:

Empliciti

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF ONE OF THE FOLLOWING: 1) DOCUMENTATION THAT MEMBER HAS PREVIOUSLY BEEN TREATED WITH AT LEAST ONE PRIOR THERAPY FOR MULTIPLE MYELOMA AND THAT THE MEDICATION IS BEING USED IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE OR 2) DOCUMENTATION THAT THE MEMBER HAS PREVIOUSLY BEEN TREATED WITH AT LEAST TWO PRIOR THERAPIES FOR MULTIPLE MYELOMA AND THAT MEDICATION IS BEING USED IN COMBINATION WITH POMALIDOMIDE AND DEXAMETHASONE.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ENBREL

Affected Drugs:

Enbrel Enbrel Mini Enbrel SureClick

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. DIAGNOSIS OF PERIPHERAL PSA OR DIAGNOSIS OF AXIAL PSA. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF MODERATE TO SEVERE ADULT OR PEDIATRIC PLAQUE PSORIASIS WITH GREATER THAN OR EQUAL TO 5% OF BSA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE OR GENITALS.

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE UNLESS TREATING JIA, THEN PATIENT MUST BE AT LEAST 2 YEARS OF AGE, OR IF TREATING PLAQUE PSORIASIS MUST BE AT LEAST 4 YEARS OF AGE.

Prescription Order Restrictions: 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 JIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE FORMULARY NSAID AND ONE OF THE FOLLOWING DMARDS: LEFLUNOMIDE OR METHOTREXATE. FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE FORMULARY NSAID AND METHOTREXATE. FOR AXIAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE FORMULARY NSAID AND

GHP Medicare Formulary - Prior Authorization Criteria

Page 152 of 591

Effective 12/2023

THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 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.

ENDARI

Affected Drugs:

Endari

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 Restrictions: MUST BE 5 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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)

ENHERTU

Affected Drugs:

Enhertu

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER AND DOCUMENTATION OF ONE OF THE FOLLOWING: 1) DOCUMENTATION OF PRIOR ANTI-HER2 BASED THERAPY IN THE METASTATIC SETTING OR 2) DOCUMENTATION OF PRIOR ANTI-HER2 BASED THERAPY IN THE NEOADJUVANT SETTING AND DOCUMENTATION OF DISEASE RECURRENCE DURING OR WIHTIN 6 MONTHS OF COMPLETING THERAPY. DIAGNOSIS OF UNRESECTABLE OR METASTATIC HER2-LOW (IHC 1+ OR IHC2+/ISH-) BREAST CANCER, AS DETECTED BY AN FDA APPROVED TEST, USED AS A SINGLE AGENT AND DOCUMENTATION OF ONE OF THE FOLLOWING 1) DOCUMENTATION OF PRIOR CHEMOTHERAPY IN THE METASTATIC SETTING OR 2) DOCUMENTATION OF DISEASE RECURRENCE DURING OR WITHIN 6 MONTHS OF COMPLETING ADJUVANT CHEMOTHERAPY. DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC HER2-POSITIVE GASTRIC OR GASTROESOPHAGEAL JUNCTION (GEJ) ADENOCARCINOMA AND DOCUMENTATION OF ONE OR MORE PRIOR TRASTUZUMAB BASED THERAPIES. DOCUMENTATION OF USE AS A SINGLE AGENT FOR UNRESECTABLE OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND DOCUMENTATION OF TUMORS THAT HAVE ACTIVATING HER2 (ERBB2) MUTATIONS AS DETECTED BY AN FDA APPROVED TEST AND DOCUMENTATION OF TREATMENT WITH PRIOR SYSTEMIC THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ENSPRYNG

Affected Drugs:

Enspryng

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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

EPCLUSA

Affected Drugs: Sofosbuvir-Velpatasvir

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. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Age Restrictions: MUST BE 3 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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). 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 hepatits 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.

EPIDIOLEX

Affected Drugs:

Epidiolex

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 Restrictions:N/A

Prescription Order Restrictions: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 alternatives.

EPKINLY

Affected Drugs:

Epkinly

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM INDOLENT LYMPHOMA AND DOCUMENTATION OF PRIOR THERAPY WITH AT LEAST TWO LINES OF SYSTEMIC THERAPY.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

EPOETIN

Affected Drugs:

Epogen Procrit Retacrit

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: HGB MUST BE LESS THAN 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.

Age Restrictions:N/A

Prescription Order Restrictions: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

GHP Medicare Formulary - Prior Authorization Criteria

Page 160 of 591

Effective 12/2023

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.

EPOPROSTENOL

Affected Drugs:

Epoprostenol Sodium

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF CLASS II OR HIGHER PULMONARY ARTERIAL HYPERTENSION

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR CLASS 2 OR 3 PAH: MEDICAL RECORD DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL

EPRONTIA

Affected Drugs:

Eprontia

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

Prescription Order Restrictions: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, ONE OF WHICH MUST BE TOPIRAMATE IR TABLETS OR TOPIRAMATE IR SPRINKLE CAPSULE OR DOCUMENTATION OF DIFFICULTY SWALLOWING TABLETS AND THERAPEUTIC FAILURE ON OR INTOLERANCE TO TWO FORMULARY ALTERNATIVES USED FOR THE TREATMENT OF ASSOCIATED DIAGNOSIS, ONE OF WHICH MUST BE TOPIRAMATE IR SPRINKLE CAPSULES

ERAXIS

Affected Drugs:

Eraxis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:NON-NEUTROPENIC PATIENT WITH DX OF CANDIDEMIA OR OTHER CANDIDA INFECTION (OTHER THAN ENDOCARDITIS, OSTEOMYELITIS OR MENINGITIS).

Age Restrictions:1 MONTH OF AGE OR OLDER

Prescription Order Restrictions: INFECTIOUS DISEASE SPECIALIST

Coverage Duration:8 WEEKS (TWO COURSES OF THERAPY)

Other Criteria:FOR A DIAGNOSIS OF ESOPHAGEAL CANDIDIASIS - FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FLUCONAZOLE THERAPY

ERIVEDGE

Affected Drugs:

Erivedge

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF METASTATIC BASAL CELL CARCINOMA, OR LOCALLY ADVANCED BASAL CELL CARCINOMA THAT HAS RECURRED FOLLOWING SURGERY OR FOR PATIENTS WHO ARE NOT CANDIDATES FOR SURGERY, AND WHO ARE NOT CANDIDATES FOR RADIATION.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: PER NCCN GUIDELINES, TREATMENT SUPPORTED BY MULTIDISCIPLINARY BOARD CONSULTATION OR A SECOND DERMATOLOGIST OR ONCOLOGIST. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ERLEADA

Affected Drugs:

Erleada

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of prostate cancer with evidence of metastatic castrationsensitive disease OR diagnosis of non-metastatic prostate cancer AND documentation that member is no longer responding to castration or is hormone resistant

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Documentation that medication will be used concurrently with a gonadotropinreleasing hormone (GnRH) analog OR documentation of bilateral orchiectomy. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.n.

ESBRIET

Affected Drugs:

Esbriet Pirfenidone

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 AND DOCUMENTATION THAT THE PATIENT WAS TAUGHT PULMONARY REHABILITATION TECHNIQUES

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

EUCRISA

Affected Drugs:

Eucrisa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of mild to moderate atopic dermatitis

Age Restrictions:N/A

Prescription Order Restrictions: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).

EVENITY

Affected Drugs:

Evenity

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of postmenopausal osteoporosis AND documentation that member has not previously received greater than or equal to 12 monthly doses of Evenity. Documentation that the patient is at high-risk of a fracture, determined by the presence of one or more of the following: 1) previous osteoporotic fracture, 2)spine or hip DXA T-Score of -2.5 or below, 3)FRAX calculation of the 10-year hip fracture risk of 3% or greater, 4)FRAX calculation of the 10-year risk of major osteoporotic fractures of 20% or greater or 5) documentation that the patient has failed or is intolerant to at least one prior osteoporosis therapy.

Age Restrictions:N/A

Prescription Order Restrictions:RHEUMATOLOGIST, ENDOCRINOLOGIST, INTERNIST AND ORTHOPEDIST

Coverage Duration:12 MONTHS

Other Criteria:Documentation that the patient has not had a myocardial infarction or stroke within the past 12 months.

EVKEEZA

Affected Drugs:

Evkeeza

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 PARETNS.

Age Restrictions: MUST BE AT LEAST 5 YEARS OF AGE

Prescription Order Restrictions: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 5 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.

EVRYSDI

Affected Drugs:

Evrysdi

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 Restrictions:N/A

Prescription Order Restrictions: 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 memer will not receive routine concomitant SMN modifying therapy.

EXJADE

Affected Drugs:

Deferasirox

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

Prescription Order Restrictions: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 greater than 300 MCG/L.

EXKIVITY

Affected Drugs:

Exkivity

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND DOCUMENTATION OF DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY AND DOCUMENTATION OF EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 20 INSERTION MUTATION, AS DETECTED BY AN FDA APPROVED TEST.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

EXONDYS

Affected Drugs:

Exondys 51

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 Restrictions:N/A

Prescription Order Restrictions: 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

EXSERVAN

Affected Drugs:

Exservan

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of ALS (amyotrophic lateral sclerosis)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 riluzole tablets OR documentation that the patient has dysphagia or is unable to swallow tablets.

GHP Medicare Formulary - Prior Authorization Criteria

Page 175 of 591

Effective 12/2023

EYSUVIS

Affected Drugs:

Eysuvis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation that the medication is being used for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

Age Restrictions:N/A

Prescription Order Restrictions: OPTOMETRIST OR OPHTHALMOLOGIST

Coverage Duration:14 DAYS

Other Criteria:Documentation that medication will be prescribed according to the FDA approved dose.

FABIOR

Affected Drugs:

Fabior

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF ACNE, ACNE VULGARIS, OR ADULT ONSET ACNE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL RETINOIDS, INCLUDING BUT NOT LIMITED TO ADAPALENE AND TRETINOIN.

FABRAZYME

Affected Drugs:

Fabrazyme

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF FABRY DISEASE

Age Restrictions:N/A

Prescription Order Restrictions: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.

FARYDAK

Affected Drugs:

Farydak

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF BEING USED IN COMBINATION WITH VELCADE AND DEXAMETHASONE

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND CONTINUATION. MAXIMUM OF 12 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BORTEZOMIB AND AN IMMUNOMODULATORY AGENT (INCLUDING, BUT NOT LIMITED TO POMALYST, REVLIMID, THALOMID)

FASENRA

Affected Drugs:

Fasenra Fasenra Pen

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.

Age Restrictions: Must be 12 years of age or older

Prescription Order Restrictions: ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: 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 AND DOCUMENTATION THAT FASENRA IS NOT BEING USED IN COMBINATION WITH DUPILUMAB, OMALIZUMAB, MEPOLIZUMAB, TEZEPELUMAB OR RESLIZUMAB. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO NUCALA. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

FENSOLVI

Affected Drugs:

Fensolvi (6 Month)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF CENTRAL PRECOCIOUS PUBERTY

Age Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PEDIATRIC ENDOCRINOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO , OR CONTRAINDICATION TO TWO OF THE FOLLOWING: LUPRON DEPOT-PED, TRIPTODUR, OR SUPPRELIN LA.

FERRIC CITRATE

Affected Drugs:

Auryxia

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: This medication requires payment determination

FERRIPROX

Affected Drugs:

Deferiprone Ferriprox Ferriprox Twice-A-Day

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 Restrictions:N/A

Prescription Order Restrictions: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.

FETROJA

Affected Drugs:

Fetroja

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

FETZIMA

Affected Drugs:

Fetzima Fetzima Titration

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

FILSPARI

Affected Drugs:

Filspari

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF PRIMARY IMMUNOGLOBULIN 1 NEPHROPATHY (IgAN) VERIFIED BY BIOPSY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEPHROLOGIST

Coverage Duration:9 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:DOCUMENTATION THAT MEMBER IS AT HIGH RISK OF DISEASE PROGRESSION AND DOCUMENTATION OF EGFR GREATER THAN OR EQUAL TO 30 ML/MIN/1.73M2 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 INHIBITORS, ENDOTHELIN RECEPTOR ANTAGONISTS, OR

FINTEPLA

Affected Drugs:

Fintepla

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF DRAVET SYNDROME OR A DIAGNOSIS OF LENNOX-GASTAUT SYNDROME

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

FIRAZYR

Affected Drugs:

Icatibant Acetate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HEREDITARY ANGIOEDEMA AND DOCUMENATION OF THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDEMA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF TWO OR MORE SETS OF COMPLEMENT STUDIES, SEPARATED BY ONE MONTH OR MORE SHOWING LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS.

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

Prescription Order Restrictions: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 disease improvement or lack of disease progression.

FIRDAPSE

Affected Drugs:

Firdapse

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 Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

FLECTOR

Affected Drugs:

Diclofenac Epolamine

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 WEEKS

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 190 of 591

Effective 12/2023

FORTEO

Affected Drugs: Teriparatide (Recombinant)

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

FOTIVDA

Affected Drugs:

Fotivda

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of relapsed or refractory advanced renal cell cancer following two or more prior systemic therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

FYARRO

Affected Drugs:

Fyarro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED UNRESECTABLE OR METASTATIC MALIGNANT PERIVASCULAR EPITHELIOID CELL TUMOR (PEComa).

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

FYCOMPA

Affected Drugs:

Fycompa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PARTIAL ONSET SEIZURES OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES.

Age Restrictions:N/A

Prescription Order Restrictions: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, Lyrica, Sabril, Aptiom, Vimpat

FYLNETRA

Affected Drugs:

Fylnetra

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

GALAFOLD

Affected Drugs:

Galafold

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of Fabry disease as confirmed by one of the following: Enzyme assay indicating deficiency of Alpha Gal-A (if male) OR genetic test documenting galactosidase alpha gene mutation. Documentation of in vitro assay data confirming the presence of an amenable galactosidase alpha gene (GLA) variant, in accordance with the FDA-approved prescribing information.

Age Restrictions: MUST BE 16 YEARS OF AGE OR OLDER

Prescription Order Restrictions:By or in consultation with a geneticist, nephrologist, cardiologist or a specialist with experience treating Fabry disease

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:Documentation that medication is not being used concurrently with enzyme replacement therapy intended for the treatment of Fabry disease, such as agalsidase beta. Reauthorization will require medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease while on therapy.

GAMIFANT

Affected Drugs:

Gamifant

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, 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.

Age Restrictions:N/A

Prescription Order Restrictions: 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.

Effective 12/2023

GATTEX

Affected Drugs:

Gattex

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF SHORT BOWEL SYNDROME

Age Restrictions: MUST BE AT LEAST 1 YEAR OF AGE

Prescription Order Restrictions: GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:FOR PATIENTS 1 THROUGH 17 YEARS OF AGE: DOCUMENTATION THAT THE MEMBER IS DEPENDENT ON PARENTERAL NUTRITION/INTRAVENOUS SUPPORT. FOR PATIENTS 18 YEARS AND OLDER: DOCUMENTATION THAT THE MEMBER HAS BEEN DEPENDENT ON PARENTERAL NUTRITION/INTRAVENOUS SUPPORT FOR A MINIMUM OF 12 MONTHS CONTINUOUSLY AND THAT THE MEMBER REQUIRES PARENTERAL NUTRITION AT LEAST 3 TIMES PER WEEK. 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.

GAVRETO

Affected Drugs:

Gavreto

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of metastatic non-small cell lung cancer (NSCLC) AND documentation of a rearranged during transfection (RET)-fusion positive tumor as detected by an FDA approved test. Documentation of either 1)advanced metastatic RET-mutant medullary thyroid cancer (MTC) AND documentation that systemic therapy is required OR 2)documentation of advanced metastatic RET fusion-positive thryoid cancer AND documentation that systemic therapy is required AND documentation that patient is radioactive-iodine refractory when radioactive iodine is appropriate.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GAZYVA

Affected Drugs:

Gazyva

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA WHICH IS PREVIOUSLY UNTREATED OR DIAGNOSIS OF FOLLICULAR LYMPHOMA.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:CLL: 12 MONTHS. FOLLICULAR LYMPHOMA: 6 MONTHS INITIAL, 24 MONTHS REAUTH

Other Criteria:FOR CLL: DOCUMENTATION OF BEING USED IN COMBINATION WITH CHLORAMBUCIL. FOR FOLLICULAR LYMPHOMA: DOCUMENTATION OF PREVIOUSLY UNTREATED STAGE II BULKY, III OR IV DISEASE USED IN COMBINATION WITH CHEMOTHERAPY, OR AS MONOTHERAPY FOLLOWING AT LEAST A PARTIAL REMISSION IF PREVIOUSLY TREATED WITH AT LEAST 6 CYCLES OF GAZYVA IN COMBINATION WITH CHEMOTHERAPY. FOR SECOND LINE FOLLICULAR LYMPHOMA: DOCUMENTATION OF BEING USED IN COMBINATION WITH BENDAMUSTINE, OR AS MONOTHERAPY IF PREVIOUSLY TREATED WITH 6 CYCLES IN COMBINATION WITH BENDAMUSTINE AND DOCUMENTATION THAT PATIENT RELAPSED AFTER, OR IS REFRACTORY TO A RITUXIMAB CONTAINING REGIMEN. REAUTH FOR FOLLICULAR LYMPHOMA AFTER INITIAL 6 MONTHS WILL REQUIRE DOCUMENTATION OF A COMPLETE RESPONSE, PARTIAL RESPONSE, OR HAS STABLE DISEASE AND THAT MEDICATION IS BEING USED AS MONOTHERAPY. SUBSEQUENT APPROVAL FOR CLL WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

GILOTRIF

Affected Drugs:

Gilotrif

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF FIRST LINE TREATMENT FOR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE NON-RESISTANT EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST or DOCUMENTATION OF A DIAGNOSIS OF METASTATIC, SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) WHICH HAS PROGRESSED AFTER PLATINUM BASED CHEMOTHERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GIVLAARI

Affected Drugs:

Givlaari

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 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).

GLEOSTINE

Affected Drugs:

Gleostine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of primary or metastatic brain tumors, following appropriate surgical or radiotherapeutic procedures. Diagnosis of Hodgkin lymphoma in patients who have progressive disease following initial chemotherapy, used in combination with other chemotherapy agents.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GROWTH HORMONE

Affected Drugs:

Norditropin FlexPro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST OR NEPHROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 204 of 591

Effective 12/2023

HAEGARDA

Affected Drugs:

Haegarda

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

HALAVEN

Affected Drugs:

Halaven

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF METASTATIC BREAST CANCER OR DIAGNOSIS OF UNRESECTABLE OR METASTATIC LIPOSARCOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR BREAST CA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST 2 PRIOR CHEMOTHERAPEUTIC REGIMENS. PRIOR THERAPY SHOULD HAVE INCLUDED AN ANTHRACYCLINE AND A TAXANE IN THE ADJUVANT OR METASTATIC SETTING. FOR LIPOSARCOMA: DOCUMENTATION OF A PREVIOUS TRIAL OF AN ANTHRACYCLINE CONTAINING REGIMEN. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

HARVONI

Affected Drugs:

Ledipasvir-Sofosbuvir

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. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Age Restrictions: MUST BE 3 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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). 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 hepatits 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

HETLIOZ

Affected Drugs:

Hetlioz Hetlioz LQ Tasimelteon

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 Restrictions: SLEEP WAKE DISORDER: 18 YRS OF AGE OR OLDER. SMS: 3 YRS OF AGE OR OLDER

Prescription Order Restrictions: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.

HUMIRA

Affected Drugs:

Humira Humira Pediatric Crohns Start Humira Pen Humira Pen-CD/UC/HS Starter Humira Pen-Pediatric UC Start Humira Pen-Ps/UV/Adol HS Start Humira Pen-Psor/Uveit Starter

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 MODERATE TO SEVERE PSA AND ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. DIAGNOSIS OF PERIPHERAL PSA. DIAGNOSIS OF AXIAL PSA. PLAQUE PSORIASIS - DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. CROHN'S -DOCUMENTATION OF MODERATE OR HIGH RISK PATIENT OR A DX OF CROHNS DISEASE WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING CONVENTIONAL THERAPIES: 6-MERCAPTOPURINE, AZATHIOPRINE, CORTICOSTEROIDS OR METHOTREXATE. 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 WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING CONVENTIONAL THERAPIES: 6-MERCAPTOPURINE, AZATHIOPRINE, CORTICOSTEROIDS OR AMINOSALICYLATES (SUCH AS BUT NOT LIMITED TO MESALAMINE, OLSALAZINE, OR SULFASALAZINE). 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.

Age Restrictions:MUST BE AT LEAST 18 YEARS FOR: PSORIASIS, PSA, RA, AND ANKYLOSING SPONDYLITIS. MUST BE AT LEAST 2 YEARS OF AGE FOR PJIA OR UVEITIS. MUST BE AT LEAST 5 YEARS OF AGE FOR UC. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS. MUST BE AT LEAST 12 YEARS OF AGE FOR HS.

Prescription Order Restrictions:RHEUMATOLOGIST, GASTROENTEROLOGIST, DERMATOLOGIST OR OPHTHALMOLOGIST

GHP Medicare Formulary - Prior Authorization Criteria

Page 209 of 591

Effective 12/2023

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 ONE DISEASE MODIFYING ANTI-RHEUMATIC DRUG (DMARD), SUCH AS BUT NOT LIMITED TO METHOTREXATE, LEFLUNOMIDE OR SULFASALAZINE. FOR JIA: THERAPEUTIC FALIURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY NSAID AND ONE OF THE FOLLOWING DMARDS: LEFLUNOMIDE OR METHOTREXATE. FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY NSAID AND METHOTREXATE. FOR AXIAL PSA: THERAPEUTIC FAILURE ON. INTOLERANCE TO OR CONTRAINDICATION TO 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 UVEITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE LOCAL OR SYSTEMIC CORTICOSTEROID AND EITHER ONE IMMUNOSUPPRESSANT OR IF UNDER 18 YEARS OF AGE, METHOTRAXATE. 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.

HYFTOR

Affected Drugs:

Hyftor

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF DIAGNOSIS OF FACIAL ANGIOFIBROMA ASSOCIATED WITH TUBEROUS SCLEROSIS.

Age Restrictions:6 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 3 MONTHS INITIAL, 6 MONTHS CONTINUATION

Other Criteria:DOCUMENTATION OF AGE APPROPRIATE DOSING (LESS THAN OR EQUAL TO 600 MG PER DAY FOR THOSE 6 TO 11 YEARS OF AGE OR LESS THEN OR EQUAL TO 800 MG PER DAY FOR THOSE 12 YEARS OF AGE OR OLDER). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN SYMPTOMS OF FACIAL ANGIOFIBROMA.

IBRANCE

Affected Drugs:

Ibrance

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HORMONE RECEPTOR POSITIVE, HER2 NEGATIVE ADVANCED OR METASTATIC BREAST CANCER and ONE OF THE FOLLOWING: PRESCRIBED FOR INITIAL ENDOCRINE BASED THERAPY IN COMBINATION WITH AN AROMATASE INHIBITOR (i.e. LETROZOLE) or AFTER DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY, USED IN COMBINATION WITH FULVESTRANT.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ICLUSIG

Affected Drugs:

Iclusig

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF CHRONIC PHASE, ACCELERATED PHASE, OR BLAST PHASE CHRONIC MYELOID LEUKEMIA (CML) OR PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL).

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:For chronic phase (CP) chronic myeloid leukemia: documentation of resistance or intolerance to at least two prior kinase inhibitors. For accelerated phase of blase phase CML or Philadelphis chromosome positive acute lymphoblastic leukemia: DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR TYROSINE KINASE INHIBITOR THERAPY OR DOCUMENTATION OF CELL MUTATION T3151. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

IDHIFA

Affected Drugs:

IDHIFA

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of relapsed or refractory acute myeloid leukemia AND documentation of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by and FDA approved test

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression

IGALMI

Affected Drugs:

Igalmi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF SCHIZOPHRENIA OR BIPOLAR I OR II DISORDER. DOCUMENTATION THAT IGALMI WILL BE USED FOR THE ACUTE TREATMENT OF AGITATION. DOCUMENTATION THAT IGALMI WILL BE ADMINISTERED UNDER THE SUPERVISION OF A HEALTHCARE PROVIDER.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:7 DAYS

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THE ACUTE USE OF AN ANTIPSYCHOTIC AND A BENZODIAZEPINE FOR THE MANAGEMENT OF AGITATION.

ILARIS

Affected Drugs:

llaris

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.

Age Restrictions:FOR CAPS: MUST BE 4 YEARS OF AGE OR OLDER. FOR SJIA: MUST BE 2 YEARS OF AGE OR OLDER

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

Coverage Duration:FOR CAPS: 12 WEEKS THEN 1 YEAR. FOR ALL OTHER INDICATIONS: 6 MONTHS THEN 1 YEAR.

GHP Medicare Formulary - Prior Authorization Criteria

Effective 12/2023

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. REAUTHORIZATION WITH REQUIRE CONTINUED IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF THE DISEASE.

GHP Medicare Formulary - Prior Authorization Criteria

IMBRUVICA

Affected Drugs:

Imbruvica

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY. DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LEUKEMIA (SLL) or CLL/SLL WITH 17P DELETION. DIAGNOSIS OF WALDENSTROM MACROGLOBULINEMIA. DIAGNOSIS OF MARGINAL ZONE LYMPHOMA. DIAGNOSIS OF CHRONIC GRAFT VERSUS HOST DISEASE AFTER FAILURE OF ONE OR MORE LINES OF SYSTEMIC THERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:HEMATOLOGIST, ONCOLOGIST OR TRANSPLANT SPECIALIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

IMFINZI

Affected Drugs:

Imfinzi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER (NSCLC) WITH DOCUMENTATION THAT PATIENT HAS RECEIVED AND HAS NOT PROGRESSED FOLLOWING A MINIMUM OF TWO CYCLES OF CONCURRENT PLATINUM-BASED CHEMOTHERAPY AND RADIATION THERAPY. DIAGNOSIS OF METASTATIC NSCLC AND NO SENSITIZING EPIDERMAL GROWTH FACTOR (EGFR) MUTATION OR ANAPLASTIC LYMPHOMA KINASE (ALK) GENOMIC TUMOR ABERRATIONS AND DOCUMENTATION OF USE IN COMBINATION WITH TREMELIMUMAB-ACTL AND PLATINUM-BASED CHEMOTHERAPY. DIAGNOSIS OF EXTENSIVE-STAGE SMALL CELL LUNG CANCER USED IN COMBINATION WITH ETOPOSIDE AND EITHER CARBOPLATIN OR CISPLATIN. DIAGNOSIS OF UNRESECTABLE HEPATOCELLULAR CARCINOMA (uHCC) AND DOCUMENTATION OF USE IN COMBINATION WITH TREMELIMUMAB-ACTL. DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC BILIARY TRACT CANCER (BTC) AND DOCUMENTATION OF USE IN COMBINATION WITH GEMCITABINE AND CISPLATIN.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:STAGE III NSCLC: 12 MONTHS. ALL OTHER INDICATIONS: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION FOR STAGE III NSCLC BEYOND 1 YEAR 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.

IMJUDO

Affected Drugs:

Imjudo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE HEPATOCELLULAR CARCINOMA AND DOCUMENTATION OF USE IN COMBINATION WITH DURVALUMAB. DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER AND NO SENSITIZING EPIDERMAL GROWTH FACTOR (EGFR) MUTATION OR ANAPLASTIC LYMPHOMA KINASE (ALK) GENOMIC TUMOR ABERRATIONS AND DOCUMENTATION OF USE IN COMBINATION WITH DURVALUMAB.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:FOR REQUESTS EXCEEDING THE FDA-APPROVED TREATMENT DURATION OF 16 WEEKS, DOCUMENTATION OF PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

IMLYGIC

Affected Drugs:

Imlygic

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE CUTANEOUS, SUBCUTANEOUS OR NODAL MELANOMA LESIONS AND DOCUMENTATION OF MELANOMA RECURRENCE AFTER INTIAL SURGERY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

Page 221 of 591

INFLIXIMAB

Affected Drugs:

Inflectra Renflexis

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). 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

Age Restrictions: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.

Prescription Order Restrictions: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). FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA) OR DOCUMENTATION THAT INFLIXIMAB IS BEING PRESCRIBED TO INDUCE DISEASE REMISSION. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA). FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO INFLIXIMAB-AXXQ (AVSOLA). FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO

GHP Medicare Formulary - Prior Authorization Criteria

Page 222 of 591

INFLIXIMAB-AXXQ (AVSOLA). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 223 of 591

INGREZZA

Affected Drugs:

Ingrezza

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 the symptoms are related to use of a first-generation antipsychotic, documentation that a switch to a second generation antipsychotic has been attempted and did not resolve symptoms OR provider rationale as to why a switch to a second generation antipsychotic would not be appropriate.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH PSYCHIATRIST OR NEUROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorization will require documentation of improvement in condition as evidenced by a reduction from baseline AIMS score.

INJECTABLE ANTIPSYCHOTICS

Affected Drugs:

Abilify Maintena Aristada Invega Sustenna Invega Trinza RisperDAL Consta ZyPREXA Relprevv

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, INVEGA TRINZA AND ZYPREXA RELPREVV - DIAGNOSIS OF SCHIZOPHRENIA. FOR INVEGA SUSTENNA - DIAGNOSIS OF SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDERS AS MONOTHERAPY OR AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS. FOR RISPERDAL CONSTA -SCHIZOPHRENIA OR BIPOLAR I DISORDER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY. FOR INVEGA TRINZA -DOCUMENTATION THAT THE PATIENT HAS BEEN ADEQUATELY TREATED WITH INVEGA SUSTENNA FOR AT LEAST 4 MONTHS.

INLYTA

Affected Drugs:

Inlyta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF ADVANCED RENAL CELL CARCINOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:For advanced RCC: documentation of failure on one prior systemic therapy OR use as first line treatment in combination with either pembrolizumab or avelumab. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

INQOVI

Affected Drugs:

Inqovi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

INREBIC

Affected Drugs:

Inrebic

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of intermediate (INT-2) or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis AND documentation of platelet count greater than or equal to 50 X 10(9)/L AND documentation of splenomegaly (as measured by CT, MRI or ultrasound) AND documentation of a baseline total symptom score measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:6 MONTHS

Other Criteria: Documentation that member is ineligible for allogeneic hematopoietic cell transplantation. Documentation that medication will not be used in combination with another Janus kinase inhibitor (i.e. ruxolitinib). Reauthorization will require documentation of platelet count greater than or equal to $50 \times 10(9)/L$ AND either a reduction of at least 35% in spleen volume from pretreatment baseline OR achievement of a 50% or greater reduction in Total Symptom Score from baseline as measured by the MFSAF.

INSULIN CONCENTRATE

Affected Drugs:

HumuLIN R U-500 (CONCENTRATED) HumuLIN R U-500 KwikPen

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of type 1 or type 2 diabetes mellitus

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:Documentation that patient requires a total dose of at least 200 units of insulin per day. Documentation that member has been instructed on the appropriate dosing of the medication, including the differences between this and u-100 insulin.

INTUNIV

Affected Drugs:

guanFACINE HCI ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

Age Restrictions: MUST BE BETWEEN 6 TO 17 YEARS OF AGE.

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY STIMULANTS

INVEGA HAFYERA

Affected Drugs:

Invega Hafyera

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF SCHIZOPHRENIA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

GHP Medicare Formulary - Prior Authorization Criteria

IRESSA

Affected Drugs:

Gefitinib Iressa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETIONS OR EXON (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA APPROVED TEST

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ISTODAX

Affected Drugs:

romiDEPsin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF CUTANEOUS T-CELL LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF DISEASE PROGRESSION WHILE ON AT LEAST ONE PRIOR SYSTEMIC THERAPY INCLUDING BUT NOT LIMITED TO CHOP REGIMENS, CHOEP, ICE, IVE, EPOCH, HYPERCVAD.

ITRACONAZOLE

Affected Drugs:

Itraconazole

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: POSITIVE CULTURE SUBSTANTIATING DIAGNOSIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR ONYCHOMYCOSIS: FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO TERBINAFINE

IVERMECTIN

Affected Drugs:

Ivermectin

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:3 MONTHS

Other Criteria:N/A

IVIG

Affected Drugs: Asceniv Bivigam Cutaquig Cuvitru Flebogamma DIF Gammagard Gammagard S/D Less IgA Gammaplex Gamunex-C Hizentra Hyqvia Panzyga Privigen Xembify

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.

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) DOCUMENTATION OF PRIOR

GHP Medicare Formulary - Prior Authorization Criteria

Page 236 of 591

TREATMENT WITH A LONG COURSE OF HIGH DOSE CORTICOSTEROIDS AND A SPLENECTOMY IF OVER 12 MONTHS HAVE ELAPSED FROM DATE OF INITIAL DIAGNOSIS OR (4) 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 Restrictions:N/A

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

Coverage Duration:CDIP AND MULTIFOCAL MOTOR NEUROPATHY: 12 WEEKS. ALL OTHERS: 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.

IXEMPRA

Affected Drugs:

Ixempra Kit

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF METASTATIC OR LOCALLY ADVANCED BREAST CANCER

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION OF USE IN COMBO WITH CAPECITABINE FOR THE TREATMENT OF METASTATIC OR LOCALLY ADVANCED BREAST CANCER WITH RESISTANCE TO AN ANTHRACYCLINE AND A TAXANE OR CANCER THAT IS TAXANE RESISTANT AND FURTHER ANTHRACYCLINE THERAPY IS CONTRAINDICATED OR DOCUMENTATION OF USE AS A MONOTHERAPY WITH TUMORS RESISTANT OR REFRACTORY TO ANTHRACYCLINES, TAXANES AND CAPECITABINE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

JADENU

Affected Drugs:

Deferasirox Deferasirox Granules

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

Prescription Order Restrictions: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 greater than 300 MCG/L.

JATENZO

Affected Drugs:

Jatenzo

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: PRIMARY HYPOGONADISM (CONGENITAL OR ACQUIRED) OR HYPOGONADOTROPIC HYPOGONADISM (CONGENITAL OR ACQUIRED).

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ANDROGEN ALTERNATIVES.

JAYPIRCA

Affected Drugs:

Jaypirca

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MANTLE CELL LYMPHOMA AND DOCUMENTATION OF AT LEAST TWO LINES OF SYSTEMIC THERAPY, INCLUDING A BTK INHIBITOR.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

JEMPERLI

Affected Drugs:

Jemperli

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF RECURRENT OR ADVANCED ENDOMETRIAL CANCER WITH DOCUMENTATION OF DISEASE PROGRESSION ON OR FOLLOWING PRIOR TREATMENT WITH A PLATINUM CONTAINING REGIMEN AND DOCUMENTATION OF MISMATCH REPAIR DEFICIENT (DMMR) AS DETERMINED BY AN FDA APPROVED TEST AND DOCUMENTATION THAT MEMBER IS NOT A CANDIDATE FOR CURATIVE SURGERY OR RADIATION. DIAGNOSIS OF RECURRENT OR ADVANCED SOLID TUMORS FOLLOWING AT LEAST ONE PRIOR TREATMENT WITH NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS AND DOCUMENTATION OF MISMATCH REPAIR DEFICIENT (DMMR) AS DETERMINED BY AN FDA APPROVED TEST.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

JEVTANA

Affected Drugs:

Jevtana

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HORMONE-REFRACTORY METASTATIC PROSTATE CANCER USED IN COMBINATION WITH PREDNISONE

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF NEUTROPHIL COUNT GREATER THAN 1500 CELLS/MM(3) AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A DOCETAXEL-BASED REGIMEN. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

JOENJA

Affected Drugs:

Joenja

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ACTIVATED PHOPHOINOSITIDE 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 Restrictions:12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

JUXTAPID

Affected Drugs:

Juxtapid

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AND ONE OF THE FOLLOWING (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 TPE 9 (PCSK9) GENE, OR LDL PROTEIN RECEPTOR 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 WITH EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) IN BOTH PARENTS. DOCUMENTATION OF FAILURE TO ADEQUATELY CONTROL LDL LEVELS WITH MAXIMUM TOLERATED STATIN THERAPY (IF STATIN TOLERANT) DEFINED AS LESS THAN OR EQUAL TO 100 MG/DL IN PATIENTS WITHOUT CVD OR LESS THAN OR EQUAL TO 70 MG/DL IN PATIENTS WITH ESTABLISHED CVD AND DOCUMENTATION OF MEDICATION BEING USED IN ADJUNCT WITH OTHER LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) LOWERING THERAPIES.

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

Prescription Order Restrictions:HEPATOLOGIST, LIDIPOLOGIST, ENDOCRINOLOGIST OR CARDIOLOGIST REGISTERED WITH THE JUXTAPID REMS PROGRAM

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO REPATHA OR PRALUENT. IF THE REQUEST IS FOR USE IN COMBINATION WITH EVKEEZA: DOCUMENTATION OF FAILURE TO ADEQUATELY CONTROL LDL LEVELS WITH A MINIMUM 3-MONTH TRIAL OF EVKEEZA WITHOUT THE CONCOMITANT USE OF JUXTAPID.

JYNARQUE

Affected Drugs:

Jynarque

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Nephrologist

Coverage Duration:12 MONTHS

Other Criteria: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)

KADCYLA

Affected Drugs:

Kadcyla

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HER2-POSITIVE, METASTATIC BREAST CANCER. DIAGNOSIS OF HER2- POSITIVE EARLY BREAST CANCER.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:METASTATIC BREAST CA: DOCUMENTATION OF PREVIOUS TREATMENT WITH TRASTUZUMAB (HERCEPTIN) AND A TAXANE (PACLITAXEL OR DOCETAXEL), SEPARATELY OR IN COMBINATION. MUST HAVE EITHER RECEIVED PRIOR THERAPY FOR METASTATIC DISEASE OR DEVELOPED DISEASE RECURRENCE DURING OR WITHIN SIX MONTHS OF COMPLETING ADJUVANT THERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. EARLY BREAST CA: DOCUMENTATION OF NEOADJUVANT TREATMENT WITH TRASTUZUMAB AND A TAXANE AND DOCUMENTATION OF RESIDUAL INVASIVE DISEASE DETECTED IN THE SURGICAL SPECIMEN OF THE BREAST OR AXILLARY NODES AFTER COMPLETION OF NEOADJUVANT THERAPY. REAUTHORIZATION FOR EARLY BREAST CANCER SHOULD NOT EXCEED THE FDA APPROVED TREATMENT DURATION OF 14 CYCLES OR WILL REQUIRE DOCUMENTATION OF PEER REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS INDICATING THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

KALYDECO

Affected Drugs:

Kalydeco

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 Restrictions: MUST BE 4 MONTHS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

KERENDIA

Affected Drugs:

Kerendia

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.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

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. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO DAPAGLIFLOZIN.

KEVZARA

Affected Drugs:

Kevzara

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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, HUMIRA, 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 CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

KEYTRUDA

Affected Drugs:

Keytruda

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:UNRESEC/METASTAT MELANOMA. COMPLETELY RESECTED STAGE IIB, IIC OR III MM & MEDICATION USED AS SINGLE AGENT IN ADJ SETTING. METASTAT NSCLC OR METASTAT NONSQUAMOUS NSCLC.

RECURRENT/METASTAT/UNRESEC HEAD/NECK SQUAMOUS CELL CA. CLASSICAL HODGKIN LYMPHOMA & 1 OF: REFRACTORY DISEASE OR AGE GREATER THAN 18 YRS W/RELAPSE FOLLOWING 1 OR MORE PRIOR TX OR AGE LESS THAN 18 YRS W/RELAPSE FOLLOWING 2 OR MORE PRIOR TXS. UNRESEC/METASTAT MSI-H OR dMMR SOLID TUMORS W/PROGRESSION FOLLOWING PRIOR TX OR NO ALTER. TX OPTIONS. FIRST LINE MSI-H or dMMR COLORECTAL CANCER. LOCALLY ADVANCED/METASTAT UROTHELIAL CA & 1 OF: 1) PROGRESSION AFTER PLATINUM CHEMO OR 2) PROGRESSION W/IN 12 MOS OF (NEO) ADJ PLATINUM CHEMO OR 3) NOT ELIGIBLE FOR PLATINUM CHEMO OR 4) DX OF HIGH RISK, NON-MUSCLE INVASIVE BLADDER CA & IS UNRESPONSIVE TO TRIAL OF BCG AND INELIGIBLE FOR CYSTECTOMY OR 5) NOT ELIGIBLE FOR CISPLATIN CHEMO AND USED IN COMBO W/ PADCEV. LOCALLY ADVANCED UNRESECTABLE/METASTATIC HER-2+ GASTRIC OR GEJ ADENOCA. LOCALLY ADVANCED/METAST SQUAMOUS CELL CA OF THE ESOPHAGUS OR GEJ WHOSE TUMORS EXPRESS PDL1 (CPS GREATER THAN OR EQUAL TO 10), W/PROGRESSION ON 1 OR MORE PRIOR LINES OF SYSTEMIC TX OR IN COMBO W/ PLATINUM AND FLUOROPYRIMIDINE BASED CHEMO FOR DISEASE NOT AMENABLE TO SURGICAL RESECTION OR CHEMORADIATION. RECURRENT/METASTAT CERVICAL CA & TUMORS EXPRESS PDL1 (CPS GREATER THAN 1) & 1) DISEASE PROGRESSION AFTER AT LEAST 1 PRIOR TX OR 2) USED IN COMBO W/ CHEMO W/ OR W/O BEVACIZUMAB. REFRACTORY PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA OR RELAPSE FOLLOWING 2 OR MORE TXS. HEPATOCELLULAR CA. METASTAT/RECURRENT MERKEL CELL CA. ADVANCED RENAL CELL CA. ADVANCED ENDOMETRIAL CA. RECURRENT/METASTAT OR LOCALLY ADVANCED CUTANEOUS SQUAMOUS CELL CA NOT CURABLE BY SURGERY/RADIATION. UNRESEC/METASTAT TUMOR MUTATIONAL BURDEN HIGH SOLID TUMORS W/ PROGRESSION FOLLOWING PRIOR TX & NO ALTER. TX OPTIONS. LOCALLY RECURRENT UNRESEC/METASTAT TRIPLE-NEGATIVE BREAST CA.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

GHP Medicare Formulary - Prior Authorization Criteria

Page 251 of 591

Coverage Duration:ADJUVANT TX OF MM/RCC/NSCLC/EARLY STAGE TNBC: 6 MONTHS. ALL OTHERS: 6 MONTHS, 12 MONTHS REAUTH

Other Criteria: STAGE IB, II, OR IIIA NSCLC: USED AS SINGLE AGENT IN ADJUVANT SETTING AFTER RESECTION & PLATINUM BASED CHEMOTX. BREAST CA:(1)DX THAT TUMORS EXPRESS PD-L1 (CPS MORE THAN OR EQUAL TO 10) AS DETERMINED BY AN FDA APPROVED TEST & DOC. OF USE IN COMBO W/ CHEMOTX, OR 2)HIGH-RISK EARLY STAGE TNBC IN COMBO W/ CHEMOTX AS NEOADJUVANT TX & THEN CONTINUED AS SINGLE AGENT ADJUVANT TX AFTER SURGERY. TMB-H DEFINED AS MORE THAN OR EQUAL TO 10 MUTATIONS/MEGABASE DETERMINED BY AN FDA APPROVED TEST. GASTRIC CA: USED AS 1ST LINE TX IN COMBO W/TRASTUZUMAB, FLUOROPYRIMIDINE & PLATINUM CONTAINING CHEMOTX. HEAD/NECK SQUAMOUS CELL CARCINOMA: EITHER 1) USED AS SINGLE AGENT FOR DX PROGRESSION ON/AFTER PLATINUM TX, 2) USED AS SINGLE AGENT FOR 1ST LINE TX & TUMORS EXPRESS PD-L1 (CPS) AT LEAST 1%, 3) USE AS 1ST LINE TX IN COMBO W/ PLATINUM CHEMOTX & FLUOROURACIL. METASTATIC NSCLC: 1)AS 1ST LINE, MONOTHERAPY FOR STAGE III, METASTATIC DISEASE, OR WHEN NOT ELIGIBLE FOR SURGICAL RESECTION OR CHEMORADIATION & THAT TUMORS EXPRESS PD-L1 (TPS) AT LEAST 1% & THAT TUMORS DO NOT HAVE EGFR OR ALK GENOMIC ABERRATIONS OR 2)MONOTHERAPY FOR TPS MORE THAN 1% W/DISEASE PROGRESSION ON/AFTER PLATINUM BASED TX & IF EGFR OR ALK ABERRATIONS ARE PRESENT, DOC. OF DISEASE PROGRESSION ON ONE FDA APPROVED TX FOR THESE ABERRATIONS OR 3) IN COMBO W/ CARBO/(NAB)PACLITAXEL AS 1ST LINE TX. NONSQUAMOUS NSCLC: USED IN COMBO W/ PEMETREXED & EITHER CARBO/CISPLATIN & DOC. THAT TUMORS DO NOT HAVE EGFR OR ALK TUMOR ABERRATIONS. METASTATIC MELANOMA: DOC. THAT KEYTRUDA IS NOT BEING USED IN COMBO W/ ANY OTHER AGENTS & IF BEING USED FOR THE ADJUVANT TX OF MM: EVIDENCE OF PRIOR LYMPH NODE INVOLVEMENT WHICH HAS BEEN COMPLETELY RESECTED. HCC: DOC. OF THERAPEUTIC FAILURE OR INTOLERANCE TO SORAFENIB. ADVANCED RCC: DOC. OF USE IN COMBO W/ AXITINIB OR LENVATINIB & OF BEING USE FOR 1ST LINE TX OF ADVANCED DISEASE. ADJUVANT TREATMENT OF RCC: DOC. OF INTERMEDIATE-HIGH OR HIGH RISK OF RECURRENCE FOLLOWING NEPHRECTOMY/RESECTION OF METASTATIC LESIONS & BEING USED AS SINGLE AGENT IN ADJUVANT SETTING. ENDOMETRIAL CARCINOMA: 1)DISEASE PROGRESSION FOLLOWING AT LEAST 1 PRIOR SYSTEMIC TX & 2)NOT A CANDIDATE FOR CURATIVE SURGERY OR RADIATION& ONE OF THE FOLLOWING 1)TUMORS ARE NOT MSI-H OR MISMATCH REPAIR DEFICIENT (DMMR) & 4)WILL BE USED IN COMBO W/ LENVATINIB OR 2) USE AS A SINGLE AGENT FOR TUMORS THAT ARE MSI-H OR MISMATCH REPAIR DEFICIENT (DMMR). SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. USE BEYOND 12 TOTAL MOS FOR THE ADJUVANT TREATMENT OF MM/RCC OR BEYOND 24 WKS NEOADJ OR 27 WKS FOR ADJUV EARLY STAGE TNBC WILL REQUIRE DOCUMENTATION OF CLINICAL TRIALS TO

INDICATE THAT THE HEALTHCARE OUTCOME WILL BE IMPROVED BEYOND THE FDA APPROVED TREATMENT DURATION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 253 of 591

Effective 12/2023

KIMMTRAK

Affected Drugs:

Kimmtrak

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF UNRESECTABLE OR METASTATIC UVEAL MELANOMA AND DOCUMENTATION OF HLA-A*02:01–POSITIVE DISEASE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION THAT KIMMTRAK IS NOT BEING USED IN COMBINATION WITH ANY OTHER AGENTS FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC UVEAL MELANOMA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

KINERET

Affected Drugs:

Kineret

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).

Age Restrictions: FOR RA - MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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, HUMIRA, RINVOQ, XELJANZ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

KISQALI

Affected Drugs:

Kisqali (200 MG Dose) Kisqali (400 MG Dose) Kisqali (600 MG Dose) Kisqali Femara (400 MG Dose) Kisqali Femara (600 MG Dose) Kisqali Femara(200 MG Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HORMONE RECEPTOR POSITIVE, HER2 NEGATIVE METASTATIC BREAST CANCER. FOR FIRST LINE INITIAL ENDOCRINE THERAPY, ONE OF THE FOLLOWING FOR KISQALI: 1) DOCUMENTATION OF USE IN POSTMENOPAUSAL FEMALES IN COMBINATION WITH EITHER AN AROMATASE INHIBITOR OR FULVESTRANT 2)FOR PRE/PERIMENOPAUSAL FEMALES IN COMBINATION WITH A LUTEINIZING HORMONE-RELEASING HORMONE (LHRH) AGONIST AND AN AROMATASE INHITOR 3) DOCUMENTATION OF USE IN MALES WITH A LUTEINIZING HORMONE-RELEASING HORMONE (LHRH) AGONIST AND EITHER AN AROMATASE INHITOR OR FULVESTRANT. FOR FIRST LINE INITIAL ENDOCRINE THERAPY WITH KISQALI FEMARA CO-PACK: DOCUMENTATION OF USE IN MALES OR PRE/PERIMENOPAUSAL FEMALES IN COMBINATION WITH A LHRH AGONIST OR IN POSTMENOPAUSAL FEMALES. FOR DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY, FOR KISQALI: DOCUMENTATION OF USE IN COMBINATION WITH FULVESTRANT IN POSTMENOPAUSAL FEMALES OR IN MALES UTILIZING AN LHRH AGONIST.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Effective 12/2023

KORLYM

Affected Drugs:

Korlym

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 Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

KOSELUGO

Affected Drugs:

Koselugo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of Neurofibromatosis type 1 as defined by a positive NF1 mutation OR documentation of two 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 glioma (tumor of nerve to eye), 5) two or more Lisch nodules (iris hamartomas), 6) a distinctive osseous lesion (sphenoid dysplasia or tibial pseudarthrosis), or 7) a first degree relative with NF1. Documentation of symptomatic, inoperable plexiform neurofibromas.

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions:WRITTEN BY OR IN CONSULTATION WITH AN ONCOLOGIST, NEUROLOGIST OR GENETICIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

KRAZATI

Affected Drugs:

Krazati

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER AND DOCUMENTATION OF A KRAS-G12C MUTATION, AS DETERMINED BY AN FDA APPROVED TEST AND DOCUMENTATION OF AT LEAST ONE PRIOR SYSTEMIC THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

KRYSTEXXA

Affected Drugs:

Krystexxa

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 Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 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.

KUVAN

Affected Drugs:

Sapropterin Dihydrochloride

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 Restrictions:N/A

Prescription Order Restrictions: 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.

KYPROLIS

Affected Drugs:

Kyprolis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST ONE PRIOR THERAPY. DOCUMENTATION THAT MEDICATION WILL BE USED 1)AS MONOTHERAPY OR 2)IN COMBINATION WITH DEXAMETHASONE OR 3)IN COMBINATION WITH DEXAMETHASONE AND LENALIDOMIDE OR 4)IN COMBINATION WITH DARATUMUMAB AND DEXAMETHASONE OR 5)IN COMBINATION WITH DARATUMUMAB AND HYALURONIDASE-FIHJ AND DEXAMETHASONE OR 6)IN COMBINATION WITH ISATUXIMAB AND DEXAMETHASONE. REAUTHORIZATION WILL REQUIRED DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

LAMZEDE

Affected Drugs:

Lamzede

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 Restrictions:N/A

Prescription Order Restrictions: 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 INFECTIONS, ETC.).

LAZANDA

Affected Drugs:

Lazanda

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF CANCER AND OF USE TO MANAGE BREAKTHROUGH CANCER PAIN

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:MEDICAL RECORD DOCUMENTATION OF CONCOMITANT MORPHINE 60 MG/DAY OR MORE, TRANSDERMAL FENTANYL 25 MCG/H, OXYCODONE 30 MG/DAY, ORAL HYDROMORPHONE 8 MG/DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID FOR 1 WEEK OR LONGER AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GENERIC FENTANYL LOZENGES.

LENVIMA

Affected Drugs:

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)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. Diagnosis of use in combination with Afinitor (everolimus) for surgically unresectable advanced or metastatic renal cell carcinoma following a therapeutic failure on or intolerance to one prior anti-angiogenic therapy OR documentation of use in combination with pembrolizumab for first line treatment of advanced renal cell carcinoma. Diagnosis of unresectable hepatocellular carcinoma (HCC) in those who have not received prior therapy AND documentation of Child-Pugh Class A liver disease. Diagnosis of advanced endometrial carcinoma with disease progression following at least one prior systemic therapy in patients not candidates for curative surgery or radiation AND documentation that tumors are NOT microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND documentation of use in combination with pembrolizumab.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

LEQVIO

Affected Drugs:

Leqvio

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 HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA. DOCUMENTATION OF A BASELINE LDL DRAWN WITHIN 3 MONTHS OF THE START OF THERAPY SHOWING AN LDL GREATER THAN 100 IF USING FOR PRIMARY PREVENTION OR AN LDL GREATER THAN 70 IF USING FOR SECONDARY PREVENTION. DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR. 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 LEQVIO IS STARTED. FOR STATIN INTOLERANT PATIENTS, DOCUMENTATION OF REASON FOR STATIN INTOLERANCE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: CARDIOLOGIST, ENDOCRINOLOGIST OR LIPIDOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO REPATHA OR PRALUENT. FOR HEFH DOCUMENTATION OF EITHER GENETIC TESTING TO CONFIRM MUTATION IN THE LDL RECEPTOR, PCSK9, OR APOB GENE OR MEDICAL RECORD DOCUMENTATION OF DEFINITE HEFH (SCORE GREATER THAN 8) ON THE DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. 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

GHP Medicare Formulary - Prior Authorization Criteria

Page 266 of 591

Effective 12/2023

FOR PATIENTS WITH HEFH USING LEQVIO 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. RENEWAL CRITERIA: DOCUMENTATION OF AN UP TO DATE LDL CHOLESTEROL LEVEL SINCE THE PREVIOUS REVIEW SHOWING A CLINICALLY SIGNIFICANT RESPONSE TO TREATMENT AND DOCUMENTATION OF NO SIGNIFICANT ADVERSE EVENTS RELATED TO THERAPY AND DOCUMENTATION OF STILL TAKING STATIN (IF STATIN TOLERANT) AND DOCUMENTATION THAT LEQVIO CONTINUES TO NOT BE USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR.

LETAIRIS

Affected Drugs:

Ambrisentan

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 Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

LEUKINE

Affected Drugs:

Leukine

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:N/A

LIBTAYO

Affected Drugs:

Libtayo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC) OR LOCALLY ADVANCED CSCC AND DOCUMENATION THAT THE PATIENT IS NOT A CANDIDATE FOR CURATIVE SURGERY OR CURATIVE RADIATION. DOCUMENTATION OF LOCALLY ADVANCED BASAL CELL CARCINOMA (LABCC) OR METASTATIC BCC (MBCC) AND DOCUMENTATION OF PREVIOUS TREATMENT WITH A HEDGEHOG PATHWAY INHIBITOR OR DOCUMENTATION THAT A HEDGEHOG PATHWAY INHIBITOR IS INAPPROPRIATE. DOCUMENTATION OF NON-SMALL CELL LUNG CANCER (NSCLC) AND 1) DOCUMENTATION OF ONE OF THE FOLLOWING: METASTATIC DISEASE OR LOCALLY ADVANCED DISEASE AND THE PATIENT IS NOT A CANDIDATE FOR SURGICAL RESECTION OR DEFINITIVE CHEMORADIATION AND 2) DOCUMENTATION OF NO EGFR, ALK OR ROS1 GENOMIC TUMOR ABERRATIONS AND 4) DOCUMENTATION OF THAT MEDICATION IS BEING USED AS FIRST LINE TREATMENT AND 5) DOCUMENTATION OF ONE OF THE FOLLOWING: THAT MEDICATION IS BEING USED AS A SINGLE AGENT AND DOCUMENTATION OF HIGH PD-L1 EXPRESSION (TUMOR PROPORTION SCORE (TPS) OF 50% OR GREATER AS DETERMINED BY AN FDA APPROVED TEST OR MEDICATION IS BEING USED IN COMBINATION WITH PLATINUM-BASED CHEMOTHERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

LIDODERM

Affected Drugs:

Lidocaine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF POST-HERPETIC NEURALGIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Effective 12/2023

LIQREV

Affected Drugs:

Liqrev

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION WITHOUT CONCOMITANT USE OF ORGANIC NITRATES.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

LIVMARLI

Affected Drugs:

Livmarli

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF DIAGNOSIS OF ALAGILLE SYNDROME (ALGS).

Age Restrictions:N/A

Prescription Order Restrictions: HEPATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION THAT THE MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON THE PATIENT WEIGHT. DOCUMENTATION OF THE PRESENCE OF MODERATE TO SEVERE PRURITUS AND DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CHOLESTYRAMINE, RIFAMPIN, OR NALTREXONE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN PRURITUS FROM BASELINE AND DOCUMENTATION THAT THE MEMBER IS RECEIVING AN APPROPRIATE DOSE BASED ON THE PATIENT WEIGHT.

LIVTENCITY

Affected Drugs:

Livtencity

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 Restrictions:12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 PHENOBARBITAL.

LOKELMA

Affected Drugs:

Lokelma

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of mild to moderate hyperkalemia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: DOCUMENTATION THAT ATTEMPT HAS BEEN MADE TO IDENTIFY AND CORRECT THE UNDERLYING CAUSE OF THE HYPERKALEMIA OR RATIONALE AS TO WHY THE UNDERLYING CAUSE CANNOT BE CORRECTED.

LONSURF

Affected Drugs:

Lonsurf

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of metastatic colorectal cancer AND documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type,an anti-EGFR therapy. Diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma AND documentation of previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum agent, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

LORBRENA

Affected Drugs:

Lorbrena

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of ALK-positive metastatic non-small cell lung cancer (NSCLC)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorization will require documentation of continued disease improvement or lack of disease progression

LUCEMYRA

Affected Drugs:

Lucemyra

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:2 WEEKS

Other Criteria:Documentation of a therapeutic failure on, intolerance to, or contraindication to clonidine.

LUMAKRAS

Affected Drugs:

Lumakras

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND DOCUMENTATION OF A KRAS G12C MUTATION AS DETECTED BY AN FDA APPROVED TEST AND DOCUMENTATION OF TREATEMENT WITH A LEAST ONE PRIOR SYSTEMIC THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

LUMIZYME

Affected Drugs:

Lumizyme

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.

Age Restrictions:N/A

Prescription Order Restrictions: 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).

LUMOXITI

Affected Drugs:

Lumoxiti

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF RELAPSED OR REFRACTORY HAIRY-CELL LEUKEMIA AND DOCUMENTATION OF TRIAL OF AT LEAST 2 PRIOR SYSTEMIC THERAPIES, ONE OF WHICH MUST BE A PURINE NUCLEOSIDE ANALOG.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REUTHORIZATION WILL REQUIRE DOCUMENTATION OF MEDICAL OR SCIENTIFIC LITERATURE TO SUPPORT THE USE OF THIS AGENT BEYOND THE FDA APPROVED TREATMENT DURATION

LUNSUMIO

Affected Drugs:

Lunsumio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA AND DOCUMENTATION OF PRIOR TREATMENT WITH TWO OR MORE LINES OF THERAPY.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTH INITIAL, 12 MONTH CONTINUATION

Other Criteria: AUTHORIZATION OF LUNSUMIO FOR THE TX OF RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA SHOULD NOT EXCEED THE FDA-APPROVED TREATMENT DURATION OF 8 TOTAL CYCLES FOR PATIENTS WHO ARE IN COMPLETE REMISSION FOLLOWING 8 CYCLES OF LUNSUMIO TREATMENT. AUTHORIZATION OF LUNSUMIO FOR THE TX OF RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA SHOULD NOT EXCEED THE FDA-APPROVED TREATMENT DURATION OF 17 TOTAL CYCLES FOR PATIENTS WHO ARE IN PARTIAL REMISSION OR STABLE DISEASE FOLLOWING 8 CYCLES OF LUNSUMIO TREATMENT. FOR REQUESTS EXCEEDING THE FDA-APPROVED TREATMENT DURATION, DOCUMENTATION OF THE FOLLOWING IS REQUIRED: PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

LUPKYNIS

Affected Drugs:

Lupkynis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ACTIVE LUPUS NEPHRITIS, CLASS III, IV, V ALONE OR IN COMBINATION, CONFIRMED BY A KIDNEY BIOPSY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST OR NEPHROLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH A BACKGROUND IMMUNOSUPPRESSIVE THERAPY REGIMEN (E.G. MYCOPHENOLATE MOFETIL (MMF) AND CORTICOSTEROIDS) AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BENLYSTA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF A POSITIVE CLINICAL RESPONSE (E.G. IMPROVEMENT/STABILIZATION IN UPCR, EGFR, RENAL RELATED EVENTS) AND DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH A BACKGROUND IMMUNOSUPPRESSIVE THERAPY REGIMEN (E.G. MYCOPHENOLATE MOFETIL (MMF) AND CORTICOSTEROIDS).

LYBALVI

Affected Drugs:

Lybalvi

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 Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OLANZAPINE AND ONE OTHER FORMULARY ATYPICAL ANTIPSYCHOTICS (I.E., RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE)

Affected Drugs:

Lynparza

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:1)DX OF ADVANCED EPITHELIAL OVARIAN & DELETERIOUS/SUSPECTED DELETERIOUS GERMLINE BRCA-MUTATED ADVANCED OVARIAN CANCER AS VERIFIED BY AN FDA APPROVED TEST & FAILURE ON. INTOLERANCE TO OR CONTRAINDICATION TO 3 OR MORE PRIOR LINES OF CHEMOTX. 2) MAINTENANCE TX AFTER A COMPLETE OR PARTIAL RESPONSE TO PLATINUM BASED CHEMOTX FOR RECURRENT EPITHELIAL OVARIAN, PRIMARY PERITONEAL, OR FALLOPIAN TUBE CANCER. 3)MAINTENANCE THERAPY FOR ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER FOR THOSE IN COMPLETE OR PARTIAL RESPONSE TO FIRST LINE PLATINUM CONTAINING CHEMOTX WHEN ONE OF THE FOLLOWING IS PRESENT I) DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE OR SOMATIC BRCA-MUTATION (GBRCAM OR SBRCAM) OR II) HOMOLOGOUS RECOMBINATION DEFICIENCY (HRD)-POSITIVE STATUS WITH A DELETERIOUS/SUSPECTED DELETERIOUS BRCA MUTATION OR GENOMIC INSTABILITY AND DOC. THAT MEDICATION WILL BE USED IN COMBINATION W/ BEVACIZUMAB. 4)DX OF DELETERIOUS/SUSPECTED DELETERIOUS GBRCAM, HER2-NEGATIVE METASTATIC BREAST CA & DOC. OF BEING PREVIOUSLY TREATED WITH CHEMOTX IN THE NEOADJUVANT, ADJUVANT, OR METASTATIC SETTING & IF HORMONE RECEPTOR (HR)-POSITIVE DOC. THAT PRIOR TX INCLUDED ENDOCRINE THERAPY OR DOC. THAT ENDOCRINE THERAPY WOULD BE CONSIDERED INAPPROPRIATE. 5)DX OF DELETERIOUS/SUSPECTED DELETERIOUS GBRCAM. HER2-NEGATIVE HIGH RISK EARLY BREAST CA & DOC. OF BEING PREVIOUSLY TREATED WITH CHEMOTX IN THE NEOADJUVANT OR ADJUVANT SETTING. 6)DX OF DELETERIOUS/SUSPECTED DELETERIOUS GBRCAM METASTATIC PANCREATIC ADENOCARCINOMA AND DOC. THAT MEMBER HAS NOT PROGRESSED ON AT LEAST 16 WEEKS OF A FIRST-LINE PLATINUM-BASED CHEMOTX REGIMEN. 7) DX OF DELETERIOUS/SUSPECTED GERMLINE OR SOMATIC HOMOLOGOUS RECOMBINATION REPAIR (HRR) GENE-MUTATED METASTATIC CASTRATION RESISTANT PROSTATE CANCER (MCRPC) AND DOC. OF PROGRESSION FOLLOWING TX W/ ENZALUTAMIDE OR ABIRATERONE & THAT A GONADOTROPIN-RELEASING HORMONE (GNRH) ANALOG WILL BE USED CONCURRENTLY OR DOC. OF BILATERAL ORCHIECTOMY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

GHP Medicare Formulary - Prior Authorization Criteria

Page 285 of 591

Effective 12/2023

Coverage Duration:12 MONTHS

Other Criteria:8) DX OF DELETERIOUS/SUSPECTED DELETERIOUS BRCA-MUTATED (BRCAm) METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (mCRPC) AND DOC. THAT LYNPARZA WILL BE USED IN COMBINATION WITH ABIRATERONE AND PREDNISONE OR PREDNISOLONE. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. FOR ADJUVANT TREATMENT OF HIGH-RISK EARLY BREAST CANCER: REQUESTS FOR TREATMENT BEYOND 1 YEAR WILL REQUIRE PEER-REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION. FOR FIRST-LINE MAINTENANCE OF BRCA-MUTATED ADVANCED OR HRD-POSITIVE ADVANCED OVARIAN CANCER: REQUESTS FOR TREATMENT BEYOND 2 YEARS WILL REQUIRE PEER-REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

Effective 12/2023

LYRICA CR

Affected Drugs:

Pregabalin ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Medical record documentation of one of the following: postherpetic neuralgia OR neuropathic pain associated with diabetic peripheral neuropathy

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:For postherpetic neuralgia: documentation of a therapeutic failure on, intolerance to, or contraindication to gabapentin and pregabalin. For neuropathic pain associated with diabetic peripheral neuropathy: documentation of a therapeutic failure on, intolerance to, or contraindication to duloxetine and pregabalin

LYTGOBI

Affected Drugs:

Lytgobi (12 MG Daily Dose) Lytgobi (16 MG Daily Dose) Lytgobi (20 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA AND FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) FUSION OR OTHER REARRANGEMENT AS VERIFIED BY AN FDA-APPROVED TEST AND ONE PRIOR LINE OF THERAPY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

MARGENZA

Affected Drugs:

Margenza

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HER2-POSITIVE BREAST CANCER AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH CHEMOTHERAPY AND DOCUMENTATION OF TWO OR MORE PRIOR ANTI-HER2 REGIMENS, AT LEAST ONE OF WHICH WAS FOR METASTATIC DISEASE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

MARQIBO

Affected Drugs:

Marqibo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF PHILADELPHIA CHROMOSOME-NEGATIVE (PH-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND OR GREATER RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR MORE ANTI-LEUKEMIA THERAPIES.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO VINCRISTINE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

MAVENCLAD

Affected Drugs:

Mavenclad (10 Tabs) Mavenclad (4 Tabs) Mavenclad (5 Tabs) Mavenclad (6 Tabs) Mavenclad (7 Tabs) Mavenclad (8 Tabs) Mavenclad (9 Tabs)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of relapsing form of multiple sclerosis including relapsingremitting disease and active secondary progressive disease.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration:48 WEEKS

Other Criteria: Documentation that medication will be used as monotherapy, that requested dose is appropriate for the patient's weight, that patient has not been treated with more than three previous treatment cycles AND documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives for the treatment of MS. Reauthorization will require documentation that patient has not received more than three previous cycles of Mavenclad for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting disease and active secondary progressive disease) AND that member is not experiencing unacceptable toxicity or worsening of disease while on therapy.

MAVYRET

Affected Drugs:

Mavyret

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. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

Age Restrictions: MUST BE 3 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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). 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 HEPATITS 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.

MEBENDAZOLE

Affected Drugs:

Emverm

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworms), Enterobius vermicularis (pinworms), or Trichuris trichiura (whipworms)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:1 MONTH

Other Criteria:N/A

MEKINIST

Affected Drugs:

Mekinist

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of unresectable or metastatic melanoma with one of the following: documentation of concurrent use with Tafinlar (dabrafenib) OR if being used as a single agent, documentation of no prior therapeutic failure with a BRAF inhibitor therapy (such as vemurafenib, dabrafenib, or encorafenib). Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test. Diagnosis of metastatic non-small cell lung cancer with concomitant use of Tafinlar AND documentation of BRAF V600E mutation as detected by an FDA approved test. Diagnosis of use for adjuvant treatment of melanoma with involvement of lymph nodes following complete resection AND documentation. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND documentation of concurrent use of Tafinlar (dabrafenib) AND documentation of BRAF V600E mutation of BRAF V600E mutations AND documentation of unresectable or metastatic solid tumors AND documentation of BRAF V600E mutation. Documentation of low-grade glioma (LGG) AND documentation of BRAF V600E mutation. AND documentation of low-grade glioma (LGG) AND documentation of BRAF V600E mutation AND documentation of concurrent use of Tafinlar (dabrafenib).

Age Restrictions: For LGG: age greater than or equal to one year and less than 18 years.

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: FOR UNRESECTABLE OR SOLID TUMORS, DOCUMENTATION OF PREVIOUS TREATMENT RESULTING IN DISEASE PROGRESSION AND DOCUMENTATION OF USE IN COMBINATION WITH TAFINLAR. REAUTHORIZATION BEYOND 12 MONTHS FOR ADJUVANT TREATMENT OF MELANOMA WILL REQUIRE LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND TEH FDA APPROVED TREATMENT DURATION. ALL OTHER REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

MEKTOVI

Affected Drugs:

Mektovi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of unresectable or metastatic melanoma AND documentation that medication is being prescribed in combination with Braftovi. Documentation of BRAF V600E OR V600K mutation as detected by an FDA approved test.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

MEPROBAMATE HRM

Affected Drugs:

Meprobamate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF ANXIETY

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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 AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: BUSPIRONE, ESCITALOPRAM, OR VENLAFAXINE XR.

MEPSEVII

Affected Drugs:

Mepsevii

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 Restrictions:N/A

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

MONJUVI

Affected Drugs:

Monjuvi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, INCLUDING DLBCL ARISING FROM LOW GRADE LYMPHOMA AND DOCUMENTATION THAT MEMBER IS NOT ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT (ASCT) AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH LENALIDOMIDE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

MOUNJARO

Affected Drugs:

Mounjaro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of Type 2 diabetes mellitus

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

MULPLETA

Affected Drugs:

Mulpleta

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 8 to 14 days after initiation of treatment.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, endocrinologist, or surgeon

Coverage Duration:30 DAYS

Other Criteria:Documentation that the member is not receiving other TPO-Ras (i.e. romiplostin, eltrombopag). Documentation that the correct dose of medication is being used (3 mg orally once daily for 7 days). Documentation of a therapeutic failure on, intolerance to, or contraindication to Doptelet.

MYFEMBREE

Affected Drugs:

Myfembree

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS (FIBROIDS) OR DIAGNOSIS OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: GYNECOLOGIST

Coverage Duration:24 MONTHS

Other Criteria: DOCUMENTATION OF PREMENOPAUSAL STATUS. FOR UTERINE LEIOMYOMAS: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST ONE PRIOR TREATMENT TO REDUCE MENSTRUAL BLEEDING, INCLUDING BUT NOT LIMITED TO: ORAL CONTRACEPTIVES OR ORAL PROGESTERONE OR TRANEXAMIC ACID OR GONADOTROPIN-RELEASING HORMONE (GNRH) AGONISTS. FOR ENDOMETRIOSIS: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE EXTENDED CYCLE CONTRACEPTIVE AND ONE FORMULARY NSAID. REQUESTS FOR REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT PATIENT HAS NOT BEEN TREATED FOR MORE THAN A TOTAL OF 24 MONTHS WITH A GNRH RECEPTOR ANTAGONIST (SUCH AS RELUGOLIX OR ELAGOLIX) OR DOCUMENTATION OF MEDICAL OR SCIENTIFIC LITERATURE TO SUPPORT THE USE OF THIS AGENT BEYOND THE FDA-APPROVED TREATMENT DURATION.

MYLOTARG

Affected Drugs:

Mylotarg

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:NEWLY DIAGNOSED CD33-POSITIVE ACUTE MYELOID LEUKEMIA OR RELAPSED OR REFRACTORY CD33-POSITIVE ACUTE MYELOID LEUKEMIA

Age Restrictions: RELAPSED OR REFRACTORY DX: 2 YEARS OF AGE OR OLDER. NEWLY DIAGNOSED: 1 MONTH OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: NEWLY DIAGNOSED PEDS: 6 MONTHS. ALL OTHERS: 12 MONTHS

Other Criteria: FOR NEWLY DIAGNOSED CD33-POSITIVE AML, AND AGE LESS THAN 18 YEARS OF AGE: DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH STANDARD CHEMOTHERAPY. REQUESTS FOR REAUTHORIZATION WILL BE BASED ON MEDICAL NECESSITY AND WILL REQUIRE DOCUMENTATION THAT MAXIMUM TREATMENT DURATION HAS NOT BEEN EXCEEDED OR 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.

MYRBETRIQ SUSPENSION

Affected Drugs:

Myrbetriq

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF NEUROGENIC DETRUSOR OVERACTIVITY (NEUROGENIC BLADDER).

Age Restrictions:MUST BE GREATER THAN OR EQUAL TO 3 YEARS AND LESS THAN 18 YEARS OF AGE.

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

NAGLAZYME

Affected Drugs:

Naglazyme

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF MUCOPOLYSACCHARIDOSIS VI (MAROTEAUX-LAMY DISEASE)

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 304 of 591

Effective 12/2023

NATPARA

Affected Drugs:

Natpara

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM AND DOCUMENTATION OF NO INCREASED BASELINE RISK FOR OSTEOSARCOMA

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION SUPPORTING THE CONTINUED USE OF THE LOWEST DOSE THAT ACHIEVES A TOTAL SERUM CALCIUM (ALBUMIN CORRECTED) WITHIN THE LOWER HALF OF THE NORMAL TOTAL SERUM CALCIUM RANGE

NERLYNX

Affected Drugs:

Nerlynx

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of early stage (Stages 1-3A) breast cancer AND documentation of HER-2 overexpression or amplification AND documentation of prior treatment with trastuzumab based therapy. Diagnosis of advanced or metastatic HER2-positive breast cancer used in combination with capecitabine AND documentation of trial of two or more prior anti-HER2 based regimens given in the metastatic setting.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorization for advanced or metastatic breast cancer will require documentation of continued disease improvement or lack of disease progression

NEULASTA

Affected Drugs:

Neulasta Onpro

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

NEXAVAR

Affected Drugs:

SORAfenib Tosylate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

NEXIUM IV

Affected Drugs: Esomeprazole Sodium

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PANTOPRAZOLE IV.

GHP Medicare Formulary - Prior Authorization Criteria

NEXVIAZYME

Affected Drugs:

Nexviazyme

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 Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions: 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 COMBINATION WITH OTHER ENZYME REPLACEMENT THERAPY (I.E. LUMIZYME).

NINLARO

Affected Drugs:

Ninlaro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF MEDICATION BEING USED IN COMBINATION WITH REVLIMID AND DEXAMETHASONE. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST ONE PRIOR THERAPY

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

NITYR

Affected Drugs:

Nityr

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HEREDITARY TYROSINEMIA TYPE 1 (HT-1). DOCUMENTATION OF ELEVATED PLASMA OR URINE SUCCINYLACETONE (SA) LEVELS

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC SPECIALIST OR GENETICIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs:

Nivestym

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. 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. FOR NEUPOGEN ONLY: HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

Age Restrictions:N/A

Prescription Order Restrictions: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

GHP Medicare Formulary - Prior Authorization Criteria

Page 313 of 591

Effective 12/2023

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).

NOCDURNA

Affected Drugs:

Nocdurna

Off-Label Uses:N/A

Exclusion Criteria:History of hyponatremia or serum sodium less than 135 mEq/L. GFR less than 50 ml/min. Diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH), New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension.

Required Medical Information:Documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart AND documentation of waking at least two times per night to void.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:Documentation that medication is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoid. Reauthorization will require documentation of clinical benefit AND documentation of none of the following: hyponatremia, GFR less than 50 ml/min, SIADH, class II-IV NYHA CHF, uncontrolled hypertension or use of loop diuretics or systemic or inhaled glucocorticoids.

NORTHERA

Affected Drugs:

Droxidopa

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: CARDIOLOGIST OR NEUROLOGIST

Coverage Duration: 4 WEEKS INITIAL AND 3 MONTHS CONTINUATION

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MIDODRINE

NOURIANZ

Affected Drugs:

Nourianz

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of Parkinson's disease with 'OFF' episodes or motor fluctuations AND documentation that medication will be used as adjunctive treatment to carbidopa-levodopa

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: By or in consultation with a neurologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES FOR THE TREATMENT OF PARKINSONS DISEASE (INCLUDING BUT NOT LIMITED TO ORAL DOPAMINE AGONISTS, CATECHOL-O-METHYLTRANSFERASE (COMT) INHIBITORS, AND MONOAMINE OXIDASE TYPE B (MAO-B) INHIBITORS).

NOXAFIL

Affected Drugs:

Noxafil Posaconazole

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.

Age Restrictions:N/A

Prescription Order Restrictions: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.

NPLATE

Affected Drugs:

Nplate

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 Restrictions:N/A

Prescription Order Restrictions: 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.

NUBEQA

Affected Drugs:

Nubeqa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of non-metastatic, castration-resistant prostate cancer AND documentation of concurrent use with a GnRH analog or that patient has had a bilateral orchiectomy. Diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) AND documenation of use in combination with docetaxel.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

NUCALA

Affected Drugs:

Nucala

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 DOCUMENTAION 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 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.

Age Restrictions:ASTHMA:6 YEARS OF AGE OR OLDER. EGPA OR CRSwNP:18 YEARS OR OLDER. HES:12 YEARS OR OLDER

Prescription Order Restrictions:FOR ASTHMA OR EGPA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST, RHEUMATOLOGIST. FOR CRSWNP: BY OR IN CONSULTATION WITH ALLERGIST, PULMONOLOGIST OR OTOLARYNGOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION THAT NUCALA IS NOT BEING USED IN COMBINATION WITH DUPILUMAB, OMALIZUMAB, BENRALIZUMAB, TEZEPELUMAB OR RESLIZUMAB. FOR EOSINOPHILIC ASTHMA: DOCUMENTATION OF CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST A 30 DAY TRIAL OF MAXIMALLY TOLERATED INHALED CORTICOSTEROIDS AND/OR ORAL SYSTEMIC CORTICOSTEROIDS

GHP Medicare Formulary - Prior Authorization Criteria

Page 321 of 591

Effective 12/2023

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 AND AT LEAST ONE IMMUNOSUPPRESSANT THRAPY (I.E. CYCLOPHOSPHAMIDE, AZATHIOPRINE, METHOTREXATE). 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. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

NUEDEXTA

Affected Drugs:

Nuedexta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF PSEUDOBULBAR AFFECT

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

NULIBRY

Affected Drugs:

Nulibry

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.

Age Restrictions:N/A

Prescription Order Restrictions: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.

NULOJIX

Affected Drugs:

Nulojix

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTATION OF RENAL TRANSPLANT

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION OF EPSTEIN-BARR VIRUS (EBV) SEROPOSITIVITY

NUPLAZID

Affected Drugs:

Nuplazid

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 3 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN SIGNS AND SYMPTOMS OF PARKINSON'S DISEASE PSYCHOSIS.

NURTEC

Affected Drugs:

Nurtec

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA. DOCUMENTATION OF USE FOR THE ACUTE TREATMENT OF MIGRAINE OR DOCUMENTATION OF USE FOR THE PREVENTION OF EPISODIC MIGRAINE (DEFINED AS NO MORE THAN 14 HEADACHE DAYS PER MONTH).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:Acute treatment: remainder of contract year: Migraine prevention: 6 month initial, 12 month reauth

Other Criteria: FOR MIGRAINE TREATMENT: DOCUMENTATION OF A THERAPEUTIC FAILURE ON. INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TRIPTANS (E.G., ALMOTRIPTAN, NARATRIPTAN, RIZATRIPTAN, SUMATRIPTAN, ZOLMITRIPTAN). DOCUMENTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP ANTAGONIST INDICATED FOR THE ACUTE TREATMENT OF MIGRAINE. FOR MIGRAINE PREVENTION: DOCUMENTATION OF THE NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AIMOVIG AND EMGALITY. DOCUMENTATION OR ATTESTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF BEING USED IN COMBINATION ATTESTATION OF THE FOLLOWING: THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF A THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTIVE TREATMENT OF MIGRAINE. REAUTHORIZATION FOR MIGRAINE PREVENTION WILL REQUIRE ATTESTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND EITHER ATTESTATION THAT THE MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF THE REQUEST IS FOR COMBINATION USE

GHP Medicare Formulary - Prior Authorization Criteria

Page 327 of 591

Effective 12/2023

WITH BOTOX ATTESTATION OF THE FOLLOWING: PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF A PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST AND ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTIVE TREATMENT OF MIGRAINE.

Effective 12/2023

NUVIGIL

Affected Drugs:

Armodafinil

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

NUZYRA

Affected Drugs:

Nuzyra

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following: Staphylococcus aureus (including methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus Group (including S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae and Klebsiella pneumoniae OR Diagnosis of community acquired bacterial pneumonia caused by susceptible isolates of the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible (MSSA) isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophilia, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration:2 WEEKS

Other Criteria:Documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to two other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

NYVEPRIA

Affected Drugs:

Nyvepria

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

OCREVUS

Affected Drugs:

Ocrevus

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

ODOMZO

Affected Drugs:

Odomzo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED BASAL CELL CARCINOMA (BCC) THAT HAS RECURRED FOLLOWING SURGERY OR RADIATION THERAPY OR THOSE WHO ARE NOT CANDIDATES FOR SURGERY OR RADIATION THERAPY. DOCUMENTATION THAT TREATMENT IS SUPPORTED BY MULTIDISCIPLINARY BOARD CONSULTATION PER NCCN GUIDELINES.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

OFEV

Affected Drugs:

Ofev

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 AND DOCUMENTATION THAT THE PATIENT WAS TAUGHT PULMONARY REHABILITATION TECHNIQUES. 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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

OLUMIANT

Affected Drugs:

Olumiant

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

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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, HUMIRA, RINVOQ, XELJANZ). 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.

ONIVYDE

Affected Drugs:

Onivyde

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF METASTATIC ADENOCARCINOMA OF THE PANCREAS AND DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH FLUOROURACIL AND LEUCOVORIN AND MEDICAL RECORD DOCUMENTATION OF DISEASE PROGRESSION FOLLOWING GEMCITABINE BASED THERAPY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ONPATTRO

Affected Drugs:

Onpattro

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 ONE OF THE FOLLOWING: 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 (PND) INDICATING THE PATIENT IS NOT WHEELCHAIR BOUND OR BEDRIDDEN.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH A NEUROLOGIST, GENETICIST, OR SPECIALIST WITH EXPERIENCE TREATING HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS

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 PROGRESSION TO FAP STAGE 3 AND NO DOCUMENTATION OF A POLYNEUROPATHY DISABILITY SCORE INDICATING THE PATIENT IS WHEELCHAIR BOUND OR BEDRIDDEN.

ONUREG

Affected Drugs:

Onureg

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of acute myeloid leukemia AND documentation that patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy AND documentation that patient is not able to complete intensive curative therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

OPDIVO

Affected Drugs:

Opdivo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: UNRESECTABLE/MET MELANOMA OR AS SINGLE AGENT IN ADJUVANT SETTING FOR COMPLETELY RESECTED MET MELANOMA. MET NSCLC AND 1)PROGRESSION ON/AFTER PLATINUM-BASED TX OR 2)PD-L1 OF AT LEAST 1% AND NO EGFR OR ALK GENOMIC TUMOR ABERRATIONS USED W/ YERVOY OR 3)NO EGFR OR ALK GENOMIC TUMOR ABERRATIONS USED FOR FIRST LINE TX W/ YERVOY AND 2 CYCLES OF PLATINUM-DOUBLET CHEMOTX. RESECTABLE NSCLC & MED WILL BE USED FOR NEOADJUVANT TX IN COMBO W/ PLATINUM-DOUBLET CHEMOTX. AS SINGLE AGENT FOR RELAPSED/SURGICALLY UNRESECT ADVANCED/METASTATIC RENAL CELL CARCINOMA (RCC) OR DX OF PREVIOUSLY UNTREATED ADVANCED RCC W/ ONE OF THE FOLLOWING: USED IN COMBO WITH IPILIMUMAB W/ INTERMEDIATE-POOR RISK (1 OR MORE PROGNOSTIC RISK FACTORS AS PER THE IMDC CRITERIA) OR USE IN COMBO W/ CABOZANTINIB. CLASSICAL HODGKIN LYMPHOMA (CHL) THAT HAS RELAPSED/PROGRESSED AFTER AUTOLOGOUS HSCT AND POST-TRANSPLANT BRENTUXIMAB OR AFTER 3 OR MORE LINES OF SYSTEMIC CHEMOTX THAT INCLUDES AUTOLOGOUS HSCT. RECURRENT METASTAT SQUAMOUS CELL CARCINOMA OF THE HEAD & NECK W/ PROGRESSION ON/AFTER RECEIVING A PLATINUM-BASED TX. LOCALLY ADVANCED/METASTATIC UROTHELIAL CARCINOMA (UC) W/ EITHER PROGRESSION FOLLOWING PLATINUM TX OR WITHIN 12 MONTHS OF NEOADJUVANT/ADJUVANT TX W/ PLATINUM THERAPY OR FOR USE IN THE ADJUVANT SETTING WITH BOTH OF THE FOLLOWING: 1) RADIAL RESECTION OF UC AND 2) HIGH RISK OF RECURRENCE. METASTATIC COLORECTAL CANCER WITH MICROSATELLITE INSTABILITY HIGH (MSI-H) OR MISMATCH REPAIR AND PROGRESSION FOLLOWING TX W/ A FLUOROPYRIMIDINE, OXALIPLATIN. OR IRINOTECAN-BASED THERAPY AND USED AS MONOTHERAPY OR IN COMBO W/ IPILIMUMAB. HEPATOCELLULAR CARCINOMA USED ALONE OR IN COMBO WITH IPILIMUMAB. UNRESECTABLE ADVANCED, RECURRENT, OR METASTATIC ESOPHAGEAL SQUAMOUS CELL CARCINOMA (ESCC). ADJUVANT TREATMENT OF RESECTED ESOPHAGEAL OR GASTROESOPHAGEAL JUNCTION (GEJ) CANCER. GASTRIC CANCER, GEJ CANCER OR ESOPHAGEAL ADENOCARCINOMA. UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA WITH DOCUMENTATION OF USE IN COMBO W/ IPILIMUMAB.

Age Restrictions:FOR MCRC AND UNRESECT/MET MELANOMA MUST BE AT LEAST 12 YEARS OF AGE. ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

GHP Medicare Formulary - Prior Authorization Criteria

Page 339 of 591

Effective 12/2023

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:6 M, 12 M REAUTH.ADJ MELAN,GEJ,UC,RES NSCLC:6 M.1ST LINE NSCLC/MESOTH/ESOPH ADENOCA.6 M.18 M REAUTH

Other Criteria: FOR THE TREATMENT OF HCC: DOCUMENTATION OF A THERAPEUTIC FAILURE ON OR INTOLERANCE TO SORAFENIB. FOR THE TREATMENT OF NSCLC OR UROTHELIAL CARCINOMA, DOCUMENTATION THAT OPDIVO IS NOT BEING USED IN COMBINATION WITH ANY OTHER AGENTS. FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA, DOCUMENTATION THAT OPDIVO IS NOT BEING USED IN COMBINATION WITH ANY OTHER AGENT, EXCEPT IPILIMUMAB. FOR THE TREATMENT OF RENAL CELL CARCINOMA. DOCUMENTATION OF A THERAPEUTIC FAILURE OR INTOLERANCE TO ONE PRIOR ANTI-ANGIOGENIC THERAPY, INCLUDING BUT NOT LIMITED TO SUNITINIB, PAZOPANIB, AXITINIB, SORAFENIB, BEVACIZUMAB, EVEROLIUMS, OR TEMSIROLIMUS. FOR ESCC: 1)FOR UNRESECTABLE ADVANCED, RECURRENT OR METASTATIC DISEASE, DOCUMENTATION OF PREVIOUS TRIAL OF FLUOROPYRIMIDINE AND PLATINUM BASED THERAPY OR 2) DOCUMENTATION OF USE AS FIRST LINE THERAPY IN UNRESECTABLE ADVANCED OR METASTATIC DISEASE GIVEN IN COMBINATION WITH FLUOROPYRIMIDINE AND PLATINUM CONTAINING CHEMOTHERAPY or IN COMBINATION WITH IPILIMUMAB. FOR TREATMENT OF RESECTED ESOPHAGEAL OR GEJ CANCER: DOCUMENTATION OF COMPLETE RESECTION WITH RESIDUAL PATHOLOGIC DISEASE AND DOCUMENTATION THAT MEMBER HAS RECEIVED NEOADJUVANT CHEMORADIOTHERAPY AND DOCUMENATION THAT MEDICATION IS BEING USED AS A SINGLE AGENT IN THE ADJUVANT SETTING. FOR GASTRIC, GEJ AND ESOPHAGEAL ADENOCARCINOMA: DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH FLUOROPYRIMIDINE AND PLATINUM BASED CHEMOTHERAPY. SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REQUESTS BEYOND 12 MONTHS FOR ADJUVANT TREATMENT OF METASTATIC MELANOMA, ADJUVANT TREATMENT OF RESECTED ESOPHAGEAL OR GEJ CANCER, AND ADJUVANT UROTHELIAL CARCINOMA WILL REQUIRE PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

OPDUALAG

Affected Drugs:

Opdualag

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA.

Age Restrictions:12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR PATIENTS GREATER THAN 12 YEARS OF AGE AND LESS THAN 18 YEARS OF AGE: DOCUMENTATION OF WEIGHT GREATER THAN OR EQUAL TO 40 KG. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

OPSUMIT

Affected Drugs:

Opsumit

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 Restrictions:N/A

Prescription Order Restrictions: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

OPZELURA

Affected Drugs:

Opzelura

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF MILD TO MODERATE ATOPIC DERMATITIS (AD). DOCUMENTATION OF DIAGNOSIS OF NONSEGMENTAL VITILIGO.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH DERMATOLOGIST, ALLERGIST, OR IMMUNOLOGIST

Coverage Duration:FOR AD: 3 MONTHS INITIAL, 6 MONTHS CONTINUATION. FOR VITILIGO: 6 MONTHS INITIAL AND CONTINUATION.

Other Criteria: DOCUMENTATION THAT OPZELURA IS NOT BEING USED IN COMBINATION WITH THERAPEUTIC BIOLOGICS, OTHER JAK INHIBITORS OR POTENT IMMUNOSUPPRESSANTS SUCH AS AZATHIOPRINE OR CYCLOSPORINE. FOR AD: DOCUMENTATION THAT MEMBER IS IMMUNOCOMPETENT AND DOCUMENTATION OF BODY SURFACE AREA (BSA) LESS THAN OR EQUAL TO 20%. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO (2) OF THE FOLLOWING: ONE FORMULARY TOPICAL CALCINEURIN INHIBITOR, ONE FORMULARY TOPICAL CORTICOSTEROID UNLESS DEEMED INADVISABLE DUE TO POTENTIAL RISKS SUCH AS USE ON SENSITIVE SKIN AREAS (FACE, AXILLAE, OR GROIN), OR EUCRISA. FOR VITILIGO: DOCUMENTATION OF BODY SURFACE AREA (BSA) LESS THAN OR EQUAL TO 10% AND DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL CORTICOSTEROIDS UNLESS DEEMED INADVISABLE DUE TO POTENTIAL RISKS SUCH AS USE ON SENSITIVE SKIN AREAS (FACE, AXILLAE, OR GROIN). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF TOLERABILITY AND POSITIVE CLINICAL RESPONSE TO OPZELURA AND DOCUMENTATION THAT OPZELURA IS NOT BEING USED IN COMBINATION WITH THERAPEUTIC BIOLOGICS. OTHER JAK INHIBITORS OR POTENT IMMUNOSUPPRESSANTS SUCH AS AZATHIOPRINE OR CYCLOSPORINE AND DOCUMENTATION OF SYMPTOMATIC ATOPIC DERMATITIS THAT REQUIRES ADDITIONAL TREATMENT WITH OPZELURA OR DOCUMENTATION OF SYMPTOMATIC NONSEGMENTAL VITILIGO THAT REQUIRES ADDITIONAL TREATMENT WITH OPZELURA.

ORENCIA

Affected Drugs:

Orencia Orencia ClickJect

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 or DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS or DIAGNOSIS OF PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS.

Age Restrictions:FOR RA AND PSA: MUST BE 18 YEARS OF AGE OR OLDER. FOR PJIA: MUST BE 2 YEARS OF AGE OR OLDER.

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria: DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS INDICATED FOR RA (HUMIRA, ENBREL, RINVOQ, XELJANZ). FOR PJIA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR JIA (HUMIRA, ENBREL, ACTEMRA SC, XELJANZ). FOR PSA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (ENBREL, HUMIRA, OTEZLA, SKYRIZI, TALTZ, TREMFYA). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

ORGOVYX

Affected Drugs:

Orgovyx

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of advanced prostate cancer.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST OR UROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

ORIAHNN

Affected Drugs:

Oriahnn

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HEAVY MENSTRUAL BLEEDING ASSOCIATED WITH UTERINE LEIOMYOMAS (FIBROIDS)

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: GYNECOLOGIST

Coverage Duration:24 MONTHS

Other Criteria:DOCUMENTATION OF PREMENOPAUSAL STATUS. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST ONE PRIOR TREATMENT TO REDUCE MENSTRUAL BLEEDING, INCLUDING BUT NOT LIMITED TO: ORAL CONTRACEPTIVES OR ORAL PROGESTERONE OR TRANEXAMIC ACID OR GONADOTROPIN-RELEASING HORMONE (GNRH) AGONISTS. REQUESTS FOR REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT PATIENT HAS NOT BEEN TREATED FOR MORE THAN A TOTAL OF 24 MONTHS WITH A GNRH RECEPTOR ANTAGONIST (SUCH AS RELUGOLIX OR ELAGOLIX) OR DOCUMENTATION OF MEDICAL OR SCIENTIFIC LITERATURE TO SUPPORT THE USE OF THIS AGENT BEYOND THE FDA-APPROVED TREATMENT DURATION.

ORILISSA

Affected Drugs:

Orilissa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of moderate to severe pain associated with endometriosis, which may include endometriosis-related dyspareunia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: GYNECOLOGIST

Coverage Duration: 150 MG: 24 MONTHS. 200 MG: 6 MONTHS

Other Criteria:Documentation of a therapeutic failure on, intolerance to, or contraindication to one extended cycle contraceptive AND one formulary NSAID. Documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg daily OR more than a total of 6 months with Orilissa 200 mg twice daily OR documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration.

ORKAMBI

Affected Drugs:

Orkambi

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 Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS

ORLADEYO

Affected Drugs:

Orladeyo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1-INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

ORSERDU

Affected Drugs:

Orserdu

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ER-POSITIVE, HER2-NEGATIVE, ESR1-MUTATED ADVANCED OR METASTATIC BREAST CANCER AND DOCUMENTATION THAT ORSERDU IS BEING PRESCRIBED IN POSTMENOPAUSAL WOMEN OR MEN AND DOCUMENTATION OF DISEASE PROGRESSION FOLLOWING AT LEAST ONE PRIOR ENDOCRINE THERAPY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

OTEZLA

Affected Drugs:

Otezla

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. DX OF PERIPHERAL PSA OR AXIAL PSA. DOCUMENTATION OF MILD PLAQUE PSORIASIS CHARACTERIZED BY LESS THAN 5% BODY SURFACE AREA. DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 5% OR GREATER INVOLVEMENT OF BODY SURFACE AREA OR DISEASE INVOVLING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, OR GENITALS. DIAGNOSIS OF ORAL ULCERS ASSOCIATED WITH BEHCET'S DISEASE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE 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 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: 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.

OXBRYTA

Affected Drugs:

Oxbryta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Documentation of diagnosis of sickle cell disease.

Age Restrictions: MUST BE 4 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF BASELINE HEMOGLOBIN. IF 5 YEARS OF AGE OR OLDER: DOCUMENTATION OF INTOLERANCE TO, CONTRAINDICATION OR THERAPEUTIC FAILURE ON 3 MONTH TRIAL OF HYDROXYUREA AND ENDARI. IF LESS THAN 5 YEARS OF AGE: DOCUMENTATION OF INTOLERANCE TO, CONTRAINDICATION OR THERAPEUTIC FAILURE ON 3 MONTH TRIAL OF HYDROXYUREA. IF THE REQUESTED DOSE EXCEEDS 1500 MG DAILY: DOCUMENTATION OF USING IN COMBINATION WITH A STRONG OR MODERATE CYP3A4 INDUCER, INCLUDING BUT NOT LIMITED TO APALUTAMIDE, BOSENTAN, CARBAMAZEPINE, EFAVIRENZ, ETRAVIRINE, ENZALUTAMIDE, NITOTANE, PHENOBARBITAL, PHENYOTIN, PRIMIDONE, RIFAMPIN OR ST. JOHN'S WORT. REAUTHORIZATION WILL REQUIRE AN INCREASE IN HEMOGLOBIN FROM BASELINE OR AN IMPROVEMENT IN COMPLICATIONS OF SICKLE CELL DISEASE (I.E., DECREASE IN VASOOCCLUSIVE CRISIS RELATED EMERGENCIES), AND IF REQUESTING A DOSE OF 2500 MG DAILY, THAT MEDICATION IS BEING USED IN COMBINATION WITH A STRONG OR MODERATE CYP3A4 INDUCER.

OXERVATE

Affected Drugs:

Oxervate

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 Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: OPHTHALMOLOGIST

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.

OXLUMO

Affected Drugs:

Oxlumo

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 Restrictions:N/A

Prescription Order Restrictions: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 OF SUFFICENT KINDEY FUNCTION AS DEFINED BY ONE OF THE FOLLOWING: DOCUMENTATION OF AN EGFR GREATER THAN OR EQUAL TO 30ML/MIN/1.73M2) OR IF EGFR IS NOT CALCULATED DUE TO AGE LIMITATIONS, A SERUM CREATININE WITHIN THE NORMAL AGE-SPECIFIC REFERENCE RANGE. DOCUMENTATION THAT MEMBER DOES NOT HAVE A HISTORY OF LIVER TRANSPLANT. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION, CONTINUED ADEQUATE RENAL FUNCTION (GREATER THAN OR EQUAL TO 30 ML PER MIN) AND DOCUMENTATION OF NOT RECEIVING A LIVER TRANSPLANT.

PADCEV

Affected Drugs:

Padcev

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER AND DOCUMENTATION OF ONE OF THE FOLLOWING: (1) THAT MEMBER HAS RECEIVED A PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH-LIGAND 1 (PD-L1) INHIBITOR, AND A PLATINUM-CONTAINING CHEMOTHERAPY OR (2) THAT MEMBER HAS RECEIVED AT LEAST ONE PRIOR LINE OF THERAPY AND IS INELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY OR (3) THAT MEMBER IS INELIGIBLE FOR CISPLATIN-CONTAINING CHEMOTHERAPY AND DOCUMENTATION THAT PADCEV WILL BE PRESCRIBED IN COMBINATION WITH KEYTRUDA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PALYNZIQ

Affected Drugs:

Palynziq

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of phenylketonuria (PKU) AND documentation of phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: METABOLIC SPECIALIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION THAT THE MEMBER HAS (OR WILL RECEIVE) A PRESCRIPTION FOR EPINEPHRINE AUTO-INJECTOR. DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KUVAN. DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH KUVAN. REAUTHORIZATION WILL REQUIRE ONE OF THE FOLLOWING: DOCUMENTATION OF PRESCRIBER ASSESSED IMPROVEMENT IN NEUROPSYCHIATRIC SYMPTOMS OR AN INCREASE IN PHE TOLERANCE OR DOCUMENTATION OF A 20% REDUCTION IN PHE CONCENTRATION FROM BASELINE OR A BLOOD PHE CONCENTRATION LESS THAN 600 MICROMOL/L.

PANRETIN

Affected Drugs:

Panretin

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PEMAZYRE

Affected Drugs:

Pemazyre

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of unresectable locally advanced or metastatic cholangiocarcinoma AND documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by an FDA approved test AND documentation of trial of one prior line of therapy. DOCUMENTATION OF RELAPSED OR REFRACTORY MYELOID/LYMPHOID NEOPLASMS (MLNs) WITH FIBROBLAST GROWTH FACTOR 1 (FGR1) REARRANGEMENT.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PEPAXTO

Affected Drugs:

Pepaxto

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND DOCUMENTATION OF TREATMEANT WITH AT LEAST 4 PRIOR THERAPIES AND ARE REFRACTORY TO AT LEAST ONE ANTI-CD38 MONOCLONAL ANTIBODY, ONE PROTEASOME INHIBITOR, AND ONE IMMUNOMODULATORY AGENT

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PERFOROMIST

Affected Drugs:

Formoterol Fumarate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF COPD

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

GHP Medicare Formulary - Prior Authorization Criteria

PERSERIS

Affected Drugs:

Perseris

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Documentation of a diagnosis of schizophrenia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:Documentation of a therapeutic failure on or intolerance to the oral equivalent form of the medication.

GHP Medicare Formulary - Prior Authorization Criteria

PIQRAY

Affected Drugs:

Piqray (200 MG Daily Dose) Piqray (250 MG Daily Dose) Piqray (300 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) AND documentation of a PIK3CA mutation determined using a FDA approved test, AND documentation that member is either a male or a postmenopausal female.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Documentation of a therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy AND documentation of use in combination with fulvestrant. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

POLIVY

Affected Drugs:

Polivy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA, NOT OTHERWISE SPECIFIED AND DOCUMENTATION OF USE IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB AND DOCUMENTATION OF USE AS SUBSEQUENT THERAPY AFTER A TRIAL OF 2 OR MORE PRIOR THERAPIES. DIAGNOSIS OF PREVIOUSLY UNTREATED DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED OR HIGH-GRADE B-CELL LYMPHOMA (HGBL) AND DOCUMENTATION OF INTERNATIONAL PROGNOSTIC INDEX SCORE OF 2 OR GREATER AND DOCUMENATION THAT POLIVY WILL BE USED IN COMBINATION WITH RITUXIMAB, CYCLOPHOSPHAMIDE, DOXORUBICIN, AND PREDNISONE (R-CHP).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria: REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUMENTATION THAT THE FDA APPROVED TREATMENT DURATION (6, 21 DAY CYCLES) HAS NOT BEEN EXCEEDED. TREATMENT BEYOND FDA APPROVED LABELING 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.

POMALYST

Affected Drugs:

Pomalyst

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MULTIPLE MYELOMA and DOCUMENTATION THAT POMALYST IS BEING PRESCRIBED IN COMBINATION WITH DEXAMETHASONE OR DOCUMENTATION THAT THE PATIENT IS STEROID INTOLERANT. Documentation of Kaposi sarcoma with one of the following: 1) AIDS-related Kaposi sarcoma with documentation of progression despite the use of antiretroviral therapy AND documentation that antiretroviral therapy will be continued OR 2) documentation of HIV-negative status.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:For Multiple Myeloma: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO PRIOR THERAPIES: BORTEZOMIB (VELCADE) AND LENALIDOMIDE (REVLIMID). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

PORTRAZZA

Affected Drugs:

Portrazza

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF METASTATIC SQUAMOUS NON-SMALL CELL LUNG CANCER AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH GEMCITABINE AND CISPLATIN

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION OF DISEASE PROGRESSION OR AN INTOLERANCE TO ONE ALTERNATIVE CATEGORY 1 OR CATEGORY 2 RECOMMENDED REGIMEN PER NCCN GUIDELINES. SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

PRALUENT

Affected Drugs:

Praluent

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), INCUDING ACUTE CORONARY SYNDROMES (A HX OF MI OR UNSTABLE ANGINA), CORONARY OR OTHER ARTERIAL REVASCULARIZATION, STROKE TIA OR PAD PRESUMED TO BE OF ATHEROSCLEROTIC ORIGIN. PRIMARY HYPERLIPIDEMIA. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) WITH ONE OF THE FOLLOWING: GENETIC TESTING TO CONFIRM MUTATION IN THE LDL RECEPTOR, PCSK9, OR APOB GENE OR DX OF DEFINITE HEFH (SCORE GREATER THAN 8) ON THE DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH), WITH ONE OF THE FOLLOWING: (1) GENETIC TESTING TO CONFIRM DX SHOWING A MUTATION IN THE LDL RECEPTOR, PCSK9 GENE, APOB GENE OR LDL PROTEIN RECEPTOR ADAPTOR 1 (LDLRAP1) GENE OR (2) DX MADE BASED ON A HISTORY OF UNTREATED LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) GREATER THAN 500 MG/DL AND EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS. DOCUMENTATION OF A BASELINE LDL DRAWN WITHIN 3 MONTHS. OF THE START OF PCSK9 THERAPY SHOWING AN LDL GREATER THAN 100 IF USING FOR PRIMARY PREVENTION OR AN LDL GREATER THAN 70 IF USING FOR SECONDARY PREVENTION. DOCUMENTATION THAT PRALUENT IS NOT BEING USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR. 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 PRALUENT IS STARTED. FOR STATIN INTOLERANT PATIENTS, DOCUMENTATION OF REASON FOR STATIN INTOLERANCE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria: 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 DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. FOR HOFH ONE OF THE FOLLOWING: GENETIC TESTING TO CONFIRM DIAGNOSIS SHOWING AT LEAST ONE LOW-DENSITY LIPOPROTEIN (LDL) RECEPTOR-DEFECTIVE MUTATION OR DX MADE BASED ON HISTORY OF AN UNTREATED LDL-C GREATER THAN 500 MG/DL AND EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) IN BOTH PARETNS. 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 PRALUENT 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. RENEWAL CRITERIA: DOCUMENTATION OF AN UP TO DATE LDL CHOLESTEROL LEVEL SINCE THE PREVIOUS REVIEW SHOWING A CLINICALLY SIGNIFICANT RESPONSE TO TREATMENT AND DOCUMENTATION OF NO SIGNIFICANT ADVERSE EVENTS RELATED TO THERAPY AND DOCUMENTATION OF STILL TAKING STATIN (IF STATIN TOLERANT) AND DOCUMENTATION THAT PRALUENT CONTINUES TO NOT BE USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR.

PRETOMANID

Affected Drugs:

Pretomanid

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of pulmonary infection due to Mycobacterium tuberculosis AND either documentation of extensively drug resistant tuberculosis OR treatment-intolerant or nonresponsive multidrug-resistant tuberculosis.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:By or in consultation with a physician specializing in infection disease

Coverage Duration:26 WEEKS

Other Criteria:Documentation that medication will be used in combination with bedaquiline and linezolid.

PREVYMIS

Affected Drugs:

Prevymis

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH A HEMATOLOGIST, ONCOLOGIST, INFECTIOUS DISEASE OR TRANSPLANT SPECIALIST

Coverage Duration: 100 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). Requests for injectable form will require documentation of intolerance to or reason why Preymis tablets cannot be used

PROCYSBI

Affected Drugs:

Procysbi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF NEPHROPATHIC CYSTINOSIS

Age Restrictions: MUST BE 1 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

PROLIA

Affected Drugs:

Prolia

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Dx of postmenopausal osteoporosis with documentation of previous osteoporotic fracture or high risk of fracture defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate. Dx of osteopenia in those at high risk of fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Dx of osteoporosis with documentation of previous osteoporotic fracture or high risk of fracture defined as a spine or hip DXA T-score of less than or equal to -2.0, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate. Dx of osteopenia in those at high risk of fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. Dx of glucocorticoid induced osteoporosis AND documentation of high risk of fracture defined as a DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate AND documentation of either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone AND documentation of expectation of remaining on glucocorticoid therapy for at least 6 months.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:For high risk of fracture receiving aromatase inhibitor or androgen deprivation therapy: failure on, intolerance to, or contraindication to one oral bisphosphonate

PROMACTA

Affected Drugs:

Promacta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIC PURPURA (ITP) WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS AND A PLATELET COUNT LESS THAN 30,000/MICROL WITH SYMPTOMATIC ITP WITH BLEEDING SYMPTOMS OR AN INCREASED RISK OF BLEEDING. 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).

Age Restrictions:N/A

Prescription Order Restrictions: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: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.

PROMETHAZINE HRM

Affected Drugs:

Promethazine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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. DIAGNOSIS OF ALLERGIC CONDITIONS (PRURITUS, URTICARIA, SEASONAL OR PERENNIAL ALLERGIES) WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DESLORATADINE AND LEVOCETIRIZINE. DIAGNOSIS OF NAUSEA AND VOMITING WILL REQUIRE DIAGNOSIS OF CANCER OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONDANSETRON AND PROCHLORPERAZINE. DIAGNOSIS OF MOTION SICKNESS WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MECLIZINE. FOR USE IN SEDATION INCLUDING PRODUCTION OF LIGHT SLEEP, REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ramelteon AND doxepin (generic Silenor).

PROVIGIL

Affected Drugs:

Modafinil

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

PULMOZYME

Affected Drugs:

Pulmozyme

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 375 of 591

Effective 12/2023

PYRUKYND

Affected Drugs:

Pyrukynd Pyrukynd Taper Pack

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF PYRUVATE KINASE DEFICIENCY (PKD).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 AND DOCUMENTATION THAT MEMBER REQUIRED RED BLOOD CELL (RBC) TRANSFUSIONS FOR HEMOLYTIC ANEMIA DUE TO PKD WITHIN THE LAST 12 MONTHS. REAUTHORIZATION WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF PROVIDER ASSESSED IMPROVEMENT IN HEMOGLOBIN FROM BASELINE OR REDUCTION IN TRANSFUSION BURDEN.

QALSODY

Affected Drugs:

Qalsody

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) WITH A CONFIRMED MUTATION IN THE SUPEROXIDE DISMUTASE (SOD1) GENE.

Age Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST, NEUROMUSCULAR SPECIALIST, OR PHYSICIAN SPECIALIZING IN ALS TREATMENT

Coverage Duration:12 MONTHS

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 THAT MEMBER IS TOLERATING AND COMPLIANT WITH PRESCRIBED QALSODY REGIMEN AND DOCUMENTATION OF REGULAR PHYSICIAN FOLLOW-UP.

QINLOCK

Affected Drugs:

Qinlock

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of advanced gastrointestinal stromal tumor (GIST) AND documentation of prior treatment with three or more kinase inhibitors, including imatinib.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

QUDEXY

Affected Drugs:

Topiramate ER

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 Restrictions:12 YEARS OR OLDER FOR MIGRAINE PROPHYLAXIS, 2 YEARS OF AGE OR OLDER FOR OTHER INDICATIONS

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES, ONE OF WHICH MUST BE IMMEDIATE-RELEASE TOPIRAMATE.

QUININE

Affected Drugs:

quiNINE Sulfate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:FOR TREATMENT OF UNCOMPLICATED PLASMODIUM FALCIPARUM MALARIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:7 DAYS

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 380 of 591

Effective 12/2023

QULIPTA

Affected Drugs:

Qulipta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria: DOCUMENTATION OF THE NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AIMOVIG AND EMGALITY. DOCUMENTATION OR ATTESTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF BEING USED IN COMBINATION ATTESTATION OF THE FOLLOWING: THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF A THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTIVE 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 EITHER ATTESTATION THAT THE MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF THE REQUEST IS FOR COMBINATION USE WITH BOTOX ATTESTATION OF THE FOLLOWING: PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND ATTESTATION OF A PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST AND ATTESTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP RECEPTOR ANTAGONIST INDICATED FOR THE PREVENTIVE TREATMENT OF MIGRAINE.

RADICAVA

Affected Drugs:

Radicava Radicava ORS Radicava ORS Starter Kit

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 Restrictions:N/A

Prescription Order Restrictions: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.

RADICAVA IV

Affected Drugs:

Radicava

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 Restrictions:N/A

Prescription Order Restrictions: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.

RAVICTI

Affected Drugs:

Ravicti

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF UREA CYCLE DISORDER (UCD) AND DOCUMENTATION OF INCREASED BLOOD AMMONIA LEVELS

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC DISORDER SPECIALIST OR GENETICIST

Coverage Duration:6 MONTHS

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SODIUM PHENYLBUTYRATE POWDER AND TABLETS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN EITHER FASTING AMMONIA LEVELS, 24 HOUR AUC, OR NUMBER OF HYPERAMMONEMIC CRISES.

REBLOZYL

Affected Drugs:

Reblozyl

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

REBYOTA

Affected Drugs:

Rebyota

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 Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

RECARBRIO

Affected Drugs:

Recarbrio

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

Effective 12/2023

REGRANEX

Affected Drugs:

Regranex

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs:

Releuko

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. 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. FOR NEUPOGEN ONLY: HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

Age Restrictions:N/A

Prescription Order Restrictions: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

GHP Medicare Formulary - Prior Authorization Criteria

Page 389 of 591

Effective 12/2023

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).

RELISTOR

Affected Drugs:

Relistor

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:MEDICAL RECORD DOCUMENTATION OF OPIOID INDUCED CONSTIPATION IN THOSE WITH ADVANCED ILLNESS RECEIVING PALLIATIVE CARE AND CONCURRENT USE OF OPIOID THERAPY OR FOR OPIOID INDUCED CONSTIPATION WITH CHRONIC NONCANCER PAIN, INCLUDING PATIENTS WITH CHRONIC PAIN RELATED TO PRIOR CANCER AND ITS TREATMENT AND CONCURRENT USE OF OPIOID THERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR OPIOID INDUCED CONSTIPATION WITH ADAVANCED ILLNESS RECEIVING PALLIATIVE CARE: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LACTULOSE AND POLYETHYLENE GLYCOL 3350. FOR OPIOID INDUCED CONSTIPATION WITH CHRONIC NONCANCER PAIN: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LACTULOSE or POLYETHYLENE GLYCOL 3350 AND AMITIZA

RELYVRIO

Affected Drugs:

Relyvrio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF AMYOTROPHIC LATERAL SCLEROSIS (ALS).

Age Restrictions:N/A

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE THAT MEMBER IS TOLERATING PRESCRIBED RELYVRIO REGIMEN AND DOCUMENTATION OF REGULAR PHYSICIAN FOLLOW-UP.

REPATHA

Affected Drugs:

Repatha Repatha Pushtronex System Repatha SureClick

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD), INCUDING ACUTE CORONARY SYNDROMES (A HX OF MI OR UNSTABLE ANGINA), CORONARY OR OTHER ARTERIAL REVASCULARIZATION, STROKE TIA OR PAD PRESUMED TO BE OF ATHEROSCLEROTIC ORIGIN. PRIMARY HYPERLIPIDEMIA. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) WITH ONE OF THE FOLLOWING: GENETIC TESTING TO CONFIRM MUTATION IN THE LDL RECEPTOR, PCSK9, OR APOB GENE OR DX OF DEFINITE HEFH (SCORE GREATER THAN 8) ON THE DUTCH LIPID CLINIC NETWORK DIAGNOSTIC CRITERIA. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH), WITH ONE OF THE FOLLOWING: (1) GENETIC TESTING TO CONFIRM DX SHOWING A MUTATION IN THE LDL RECEPTOR, PCSK9 GENE, APOB GENE OR LDL PROTEIN RECEPTOR ADAPTOR 1 (LDLRAP1) GENE OR (2) DX MADE BASED ON A HISTORY OF UNTREATED LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) GREATER THAN 500 MG/DL AND EITHER XANTHOMA BEFORE 10 YEARS OF AGE OR EVIDENCE OF HEFH IN BOTH PARENTS. DOCUMENTATION OF A LDL DRAWN WITHIN 3 MONTHS OF THE START OF PCSK9 THERAPY SHOWING AN LDL GREATER THAN 130 IN PEDIATRIC PATIENTS 10 YEARS OF AGE OR OLDER IF USING FOR PRIMARY PREVENTION, AN LDL GREATER THAN 100 IN ADULT PATIENTS USING FOR PRIMARY PREVENTION OR AN LDL GREATER THAN 70 IF USING FOR SECONDARY PREVENTION. FOR STATIN TOLERANT PATIENTS, DX OF AN INABILITY TO ACHIEVE AND MAINTAIN LDL GOAL WITH ONE OF THE FOLLOWING (1) MAX TOLERATED DOSE OF A HIGH INTENSITY STATIN (ATORVASTATIN 40 MG OR HIGHER OR ROSUVASTATIN 20 MG OR HIGHER) OR (2) A MAX TOLERATED DOSE OF ANY STATIN GIVEN THAT THE PATIENT HAS HAD A PREVIOUS TRIAL OF EITHER ATORVASTATIN OR ROSUVASTATIN, WITH PRESCRIBER'S DOCUMENTATION REGARDING LENGTH OF PREVIOUS TRIALS OF STATINS. PATIENT MUST INTEND TO CONTINUE ON MAXIMAL STATIN THERAPY ONCE REPATHA STARTED. FOR STATIN INTOLERANT PATIENTS DOCUMENTATION OF REASON FOR STATIN INTOLERANCE AND IN THOSE WITH HOFH, DX OF AN INABILITY TO ACHIEVE AND MAINTAIN LDL GOAL ON AT LEAST 12 WEEKS ON MAXIMAL LIPID LOWERING THERAPY

Age Restrictions:FOR ASCVD: MUST BE 18 YEARS OF AGE OR OLDER. FOR HOFH or HEFH: MUST BE 10 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria: DX THAT REPATHA IS NOT BEING USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR. IF REQUESTING SYRINGE OR SURECLICK DOSING OF 420 MG: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO USE OF REPATHA PUSHTRONEX. IF REQUESTING 420 MG EVERY 2 WEEKS: DOCUMENTATION OF A DIAGNOSIS OF HOFH AND ONE OF THE FOLLOWING: DOCUMENTATION THAT THE MEMBER HAS BEEN ON 420 MG ONCE MONTHLY FOR 12 WEEKS AND A CLINICALLY MEANINGFUL RESPONSE HAS NOT BEEN ACHIEVED OR DOCUMENTATION THAT THE MEMBER IS ON LIPID APHERESIS EVERY 2 WEEKS. THERAPEUTIC FAILURE IS DEFINED AS AN INABILITY TO REACH TARGET LDL GOALS (LESS THAN 130 FOR PEDIATRIC PATIENTS, LESS THAN 100 MG/DL FOR ADULT PATIENTS WITH HEFH OR HOFH IN PRIMARY PREVENTION OR LESS THAN 70 MG/DL FOR ASCVD OR FOR HEFH OR HOFH 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. RENEWAL CRITERIA: DOCUMENTATION OF AN UP TO DATE LDL CHOLESTEROL LEVEL SINCE THE PREVIOUS REVIEW SHOWING A CLINICALLY SIGNIFICANT RESPONSE TO TREATMENT AND DOCUMENTATION OF NO SIGNIFICANT ADVERSE EVENTS RELATED TO THERAPY AND DOCUMENTATION OF STILL TAKING STATIN (IF STATIN TOLERANT) AND DOCUMENTATION THAT REPATHA CONTINUES TO NOT BE USED IN COMBINATION WITH ANOTHER PCSK9 INHIBITOR, AND IF REQUESTING SYRINGE OR SURECLICK DOSING OF 420 MG: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO USE OF REPATHA PUSHTRONEX. IF REQUESTING 420 MG EVERY 2 WEEKS: DOCUMENTATION OF A DIAGNOSIS OF HOFH AND ONE OF THE FOLLOWING: DOCUMENTATION OF THERAPEUTIC FAILURE ON 420 MG ONCE MONTHLY FOR 12 WEEKS OR DOCUMENTATION THAT THE MEMBER IS ON LIPID APHERESIS EVERY 2 WEEKS.

RETEVMO

Affected Drugs:

Retevmo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of diagnosis of RET-fusion positive non-small cell lung cancer (NSCLC). Documentation of advanced metastatic RET-mutant medullary thyroid cancer (MTC) AND documentation that systemic therapy is required. Documentation of advanced or metastatic RET-fusion positive thyroid cancer AND documentation that systemic therapy is required AND documentation that patient radioactive-iodine refractory when radioactive iodine is appropriate. Documentation of a locally advanced or metastatic solid tumor with a RET gene fusion AND either documentation of progression on or following prior systemic therapy OR that member has no satisfactory alternative treatment options.

Age Restrictions:NSCLC AND SOLID TUMORS: 18 YEARS OR OLDER. THYROID CA: 12 YEARS OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

REVATIO

Affected Drugs:

Sildenafil Citrate

Off-Label Uses:N/A

Exclusion Criteria:CONCOMITANT USE OF ORGANIC NITRATES

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

REVCOVI

Affected Drugs:

Revcovi

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 Restrictions:N/A

Prescription Order Restrictions: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 CANDIDATE FOR HEMATOPOIETIC CELL TRANSPLANTATION AND GENE THERAPY AT THE TIME OF THE REQUEST.

REVLIMID

Affected Drugs:

Lenalidomide Revlimid

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF MULTIPLE MYELOMA. DX OF MYELODYSPLASTIC SYNDROMES (MDS) EITHER WITH A DELETION 5Q CYTOGENETIC ABNORMALITY WITH OR WITHOUT ADDITIONAL CYTOGENETIC ABNORMALITIES OR WITH NO DELETION 5Q CYTOGENETIC ABNORMALITY. DX OF RELAPSED, REFRACTORY, OR PROGRESSIVE MANTLE CELL LYMPHOMA WITH THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE PRIOR THERAPY INCLUDING BUT NOT LIMITED TO HYPERCVAD, NORDIC REGIMEN, CALGB REGIMEN, RCHOP/RICE, RCHOP/RDHAP, BENDAMUSTINE PLUS RITUXIMAB, CHOP PLUS RITUXIMAB, CLADRIBINE PLUS RITUXIMAB, CVP PLUS RITUXIMAB, EPOCH PLUS RITUXIMAB. DX OF FOLLICULAR LYMPHOMA OR MARGINAL ZONE LYMPHOMA, USED IN COMBINATION WITH RITUXIMAB, FOLLOWING THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST 1 PRIOR THERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: FOR MDS WITH NO DELETION 5Q CYTOGENETIC ABNORMALITY: DOCUMENTATION OF INITIAL USE IN LOWER RISK PATIENT WITH SYMPTOMATIC ANEMIA AND SERUM ERYTHROPOIETIN LEVELS GREATER THAN 500 MU/ML AND A LOW PROBABILITY (DEFINED AS MEMBERS WHO LACK ANY OF THE FOLLOWING FEATURES: AGE LESS THAN OR EQUAL TO 60, OR THOSE WITH HYPOCELLULAR MARROW, HLA-DR 15 OR PHN CLONE POSITIVITY) OF RESPONSE TO IMMUNOSUPPRESSIVE THERAPY OR DOCUMENTATION OF LOWER RISK PATIENT WITH SYMPTOMATIC ANEMIA AND NO RESPONSE TO INITIAL TREATMENT WITH EPOETIN ALFA OR DARBOPOETIN ALFA, HYPOMETHYLATING AGENTS, OR IMMUNOSUPPRESSIVE THERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

REXULTI

Affected Drugs:

Rexulti

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF SCHIZOPHRENIA OR ADJUNCTIVE TREATMENT FOR MAJOR DEPRESSIVE DISORDER (MDD).

Age Restrictions: Schizophrenia: 13 years of age or older. MDD: 18 years of age or older

Prescription Order Restrictions: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 COMBINATION THERAPY WITH ARIPIPRAZOLE AND AN ANTIDEPRESSANT AND EITHER DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF COMBINATION ANTIDEPRESSANT THERAPY (SUCH AS AN SSRI AND BUPROPION OR AN SNRI AND BUPROPION) OR DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF AN ANTIDEPRESSANT WITH AUGMENTATION THERAPY (INCLUDING, BUT NOT LIMITED TO LITHIUM, VALPROATE, CARBAMAZEPINE AND LAMOTRIGINE). 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).

REZLIDHIA

Affected Drugs:

Rezlidhia

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA AND DOCUMENTATION OF A SUSCEPTIBLE ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA-APPROVED TEST.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

REZUROCK

Affected Drugs:

Rezurock

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF STEROID REFRACTORY GRAFT-VERSUS-HOST DISEASE (GVHD) AND DOCUMENTATION OF THERAPEUTIC FAILURE OF TWO OR MORE PRIOR LINES OF SYSTEMIC THERAPY.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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) IF CONCURRENTLY TAKING WITH A PROTON PUMP INHIBITOR (PPI), MEDICAL RECORD DOCUMENTATION THAT TREATMENT WITH A PPI IS MEDICALLY NECESSARY AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A H2-BLOCKER. 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) IF CONCURRENTLY TAKING WITH A PROTON PUMP INHIBITOR (PPI), MEDICAL RECORD DOCUMENTATION THAT TREATMENT WITH A PPI IS MEDICALLY NECESSARY AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A H2-BLOCKER.

RINVOQ

Affected Drugs:

Rinvoq

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).

Age Restrictions: FOR AD: MUST BE 12 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:RHEUMATOLOGIST, DERMATOLOGIST, ALLERGIST, IMMUNOLOGIST, 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 HUMIRA OR ENBREL. FOR PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA OR ENBREL. 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 DUPIXENT. FOR UC: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ENBREL OR HUMIRA. FOR NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR

GHP Medicare Formulary - Prior Authorization Criteria

Page 402 of 591

CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF CIMZIA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION

GHP Medicare Formulary - Prior Authorization Criteria

Page 403 of 591

RITUXAN

Affected Drugs:

Riabni Ruxience Truxima

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 CHRONIC LYMPHOID LEUKEMIA. DX OF MICROSCOPIC POLYARTERITIS NODOSA USED IN COMBO WITH GLUCOCORTICOIDS. DX OF DIFFUSE NON-HODGKINS 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).

Age Restrictions: FOR RA AND PV: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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: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

GHP Medicare Formulary - Prior Authorization Criteria

Page 404 of 591

AND A 12-WEEK TRIAL OF AT LEAST ONE NONSTEROIDAL IMMUNOMODULATORY MEDICATION (I.E. AZATHIOPRINE, CYCLOPHOSPHAMIDE OR MYCOPHENOLATE)

GHP Medicare Formulary - Prior Authorization Criteria

Page 405 of 591

RITUXAN HYCELA

Affected Drugs:

Rituxan Hycela

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) GIVEN IN COMBINATION WITH FLUDARABINE AND CYCLOPHOSPHAMIDE AND DOCUMENTATION OF TOLERATING A MINIMUM OF ONE CYCLE OF INTRAVENOUS RITUXIMAB. DIAGNOSIS OF DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) AND DOCUMENTATION OF NO PRIOR TREATMENT FOR DLBCL AND DOCUMENTATION OF BEING GIVEN IN COMBINATION WITH CYCLOPHOSPHAMIDE, DOXORUBICIN, VINCRISTINE AND PREDNISONE (CHOP) OR OTHER ANTHRACYCLINE-BASED CHEMOTHERAPY REGIMEN AND DOCUMENTATION OF TOLERATING A MINIMUM OF ONE CYCLE OF INTRAVENOUS RITUXIMAB. DIAGNOSIS OF FOLLICULAR LYMPHOMA (FL) AND DOCUMENTATION OF TOLERATING A MINIMUM OF ONE CYCLE OF INTRAVENOUS RITUXIMAB.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ROLVEDON

Affected Drugs:

Rolvedon

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

ROZLYTREK

Affected Drugs:

Rozlytrek

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND one of the following 1)documentation of progression following treatment or 2) documentation of no satisfactory alternative treatments. Diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.

Age Restrictions: For NTRK positive tumors: 12 yrs or older. For NSCLC: 18 yrs or older

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

RUBRACA

Affected Drugs:

Rubraca

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:For maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer after a complete or partial response to platinum based chemotherapy. Diagnosis of a deleterious BRCA mutation (germline and/or somatic)-associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND medication is being used for maintenance treatment after a complete or partial response to platinum based chemotherapy. Diagnosis of deleterious BRCA mutation (germline or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) with documentation of prior treatment with androgen receptor-directed therapy and a taxane based chemotherapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:For mCRPC: documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently OR documentation of bilateral orchiectomy. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

RUXOLITINIB

Affected Drugs:

Jakafi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, INCLUDING PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS OR POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS AND PLATELET COUNT GREATER THAN OR EQUAL TO 50 X 10(9)/L AND SPLENOMEGALY AND BASELINE TOTAL SYMPTOM SCORE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF). DIAGNOSIS OF POLYCYTHEMIA VERA REQUIRING THE PRESENCE OF SPLENOMEGALY, AND MEMBER REQUIRES PHLEBOTOMY. DIAGNOSIS OF (1) STEROID REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE (GVHD) OR (2) DIAGNOSIS OF CHRNOIC GRAFT-VERSUS-HOST DISEASE WITH DOCUMENTATION OF THERAPEUTIC FAILURE OF ONE OR TWO PRIOR LINES OF SYSTEMIC THERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST, HEMATOLOGIST OR TRANSPLANT SPECIALIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH ANOTHER JANUS KINASE INHIBITOR (I.E. FEDRATINIB). FOR MYELOFIBROSIS: CONTINUED COVERAGE EVERY 6 MONTHS WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF PLATELET COUNT GREATER THAN OR EQUAL TO 50 X 10(9)/L IF BASELINE COUNT WAS GREATER THAN 100 X 10(9)/L OR GREATER THAN 25 X 10(9)/L IF BASELINE COUNT WAS BETWEEN 50 AND 100 X 10(9)/L, AND DOCUMENTATION OF RESPONSE TO THERAPY SUCH AS A REDUCTION FROM PRETREATMENT BASELINE SPLEEN VOLUME OR A REDUCTION IN THE TOTAL SYMPTOM SCORE FROM BASELINE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF). FOR POLYCYTHEMIA VERA DOCUMENTATION OF OF AN INADEQUATE RESPONSE OR INTOLERANCE TO EITHER HYDROXYUREA OR INTERFERON THERAPY OR DOCUMENTATION OF POST POLYCYTHEMIA VERA MYELOFIBROSIS WITH HYDROXYUREA REFRACTORY SYMPTOMATIC SPLENOMEGALY. REAUTHORIZATION FOR GRAFT VERSUS

GHP Medicare Formulary - Prior Authorization Criteria

Page 410 of 591

HOST DISEASE AND POLYCYTHEMIA VERA WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 411 of 591

RYBREVANT

Affected Drugs:

Rybrevant

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND DOCUMENTATION OF EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 20 INSERTION MUTATATIONS AS DETERMINED BY AN FDA APPROVED TEST AND DOCUMENTATION OF DISEASE PROGRESSION ON OR FOLLOWING PRIOR TREATEMENT WITH A PLATINUM BASED THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

RYDAPT

Affected Drugs:

Rydapt

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by a Food and Drug Administration (FDA)-approved test used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation OR documentation of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS RENEWAL

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

RYLAZE

Affected Drugs:

Rylaze

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE AS A COMPONENT OF A MULTI-AGENT CHEMOTHERAPEUTIC REGIMEN IN PATIENTS WITH A DIAGNOSIS OF ACTUE LYMPHOBLASTIC LEUKEMIA (ALL) OR LYMPHOBLASTIC LYMPHOMA (LBL)

Age Restrictions:1 MONTH OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF A HYPERSESITIVITY TO E.COLI-DERIVED ASPARAGINASE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

SABRIL

Affected Drugs:

Vigabatrin Vigadrone

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF REFRACTORY COMPLEX PARTIAL SEIZURES. DX OF INFANTILE SPASMS.

Age Restrictions: INFANTILE SPASMS - 1 MONTH TO 2 YEARS OF AGE

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR REFRACTORY COMPLEX PARTIAL SEIZURES MUST BE ON CONCOMMITANT THERAPY WITH ANOTHER SEIZURE CONTROL MEDICATION

SANTYL

Affected Drugs:

Santyl

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of use for debriding chronic dermal ulders or severely burned areas.

Age Restrictions:N/A

Prescription Order Restrictions: 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.

SAPHNELO

Affected Drugs:

Saphnelo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF MODERATE TO SEVERE SYSTEMIC LUPUS ERYTHEMATOSUS.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION THAT MEMBER DOES NOT HAVE 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.

SAPHRIS

Affected Drugs:

Asenapine Maleate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF BIPOLAR DISORDER OR SCHIZOPHRENIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:MEDICAL RECORD DOCUMENTATION OF TRIAL ON TWO FORMULARY ALTERNATIVES (aripiprazole, ziprasidone, risperidone, quetiapine, olanzapine).

SARCLISA

Affected Drugs:

Sarclisa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ONE OF THE FOLLOWING (1) DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF USE IN COMBINATION WITH POMALIDOMIDE AND DEXAMETHASONE AND DOCUMENTATION OF PRIOR TREATMENT WITH AT LEAST TWO THERAPIES WHICH INCLUDED LENALIDOMIDE AND A PROTEASOME INHIBITOR (INCLUDING BUT NOT LIMITED TO VELCADE, KYPROLIS OR NINLARO) OR (2) DIAGNOSIS OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND DOCUMENTATION OF USE IN COMBINATION WITH CARFILZOMIB AND DEXAMETHASONE AND DOCUMENTATION OF PRIOR TREATMENT WITH ONE TO THREE LINES OF THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

GHP Medicare Formulary - Prior Authorization Criteria

Page 419 of 591

SCEMBLIX

Affected Drugs:

Scemblix

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA (PH+ CML) IN CHRONIC PHASE (CP) AND ONE OF THE FOLLOWING: 1) DOCUMENTATION OF PREVIOUS TREATMENT WITH TWO OR MORE TYROSINE KINASE INHIBITORS (TKIS) OR 2) DOCUMENTATION OF A T315I CELL MUTATION.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:IF THE REQUESTED DOSE IS 200 MG TWICE DAILY: DOCUMENTATION OF A T315I CELL MUTATION. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

SECUADO

Affected Drugs:

Secuado

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of schizophrenia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:Medical record documentation of a therapeutic failure on, intolerance to or contraindication to asenapine (Saphris) sublingual tablets and one other formulary alternative (aripiprazole, ziprasidone, risperidone, quetiapine, olanzapine)

GHP Medicare Formulary - Prior Authorization Criteria

SEROSTIM

Affected Drugs:

Serostim

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:FOR THE TREATMENT OF HIV PATIENTS WITH WASTING OR CACHEXIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

SIGNIFOR

Affected Drugs:

Signifor

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 Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KETOCONAZOLE AND METYRAPONE. REAUTHORIZATION REQUIRES DOCUMENTATION OF IMPROVEMENT IN URINARY FREE CORTISOL LEVELS COMPARED TO BASELINE

SIGNIFOR LAR

Affected Drugs:

Signifor LAR

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 Restrictions:N/A

Prescription Order Restrictions: 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 AND METYRAPONE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT URINARY FREE CORTISOL LEVELS ARE WITHIN NORMAL LIMITS.

SIKLOS

Affected Drugs:

Siklos

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Documentation of a diagnosis of sickle cell anemia.

Age Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:Documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of generic hydroxyurea

SIMPONI

Affected Drugs:

Simponi

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).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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, HUMIRA, RINVOQ, XELJANZ). FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR AS (COSENTYX, ENBREL, HUMIRA, XELJANZ, RINVOQ). FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, TREMFYA). FOR ULCERATIVE COLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

SIRTURO

Affected Drugs:

Sirturo

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 AT LEAST THREE OTHER DRUGS TO WHICH THE PATIENT'S MULTI DRUG RESISTANT TB ISOLATE HAS BEEN SHOWN TO BE SUSCEPTIBLE IN VITRO

Age Restrictions:N/A

Prescription Order Restrictions: 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 AT LEAST 4 OTHER DRUGS TO WHICH THE PATIENTS MDR-TB ISOLATE IS LIKELY TO BE SUSCEPTIBLE

SIVEXTRO

Affected Drugs:

Sivextro

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 Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions:DIAGNOSED AND DOCUMENTED WITH INFECTIOUS DISEASE CONSULTATION

Coverage Duration: ONE-TIME COURSE OF THERAPY OF 6 DAYS

Other Criteria: 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.

SKYCLARYS

Affected Drugs:

Skyclarys

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 Restrictions:16 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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).

SKYRIZI

Affected Drugs:

Skyrizi Skyrizi (150 MG Dose) Skyrizi Pen

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR DISEASE AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. DIAGNOSIS OF ACTIVE PSORIATIC ARTHRITIS WITH A HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. DX OF PERIPHERAL PSA OR AXIAL PSA. DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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. FOR PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE 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 CD: DOCUMENTATION OF MODERATE OR HIGH-RISK PATIENT OR A DX OF CROHNS DISEASE WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING CONVENTIONAL THERAPIES: 6-MERCAPTOPURINE, AZATHIOPRINE, CORTICOSTEROIDS OR METHOTREXATE OR DIAGNOSIS OF CROHN'S WITH ACTIVE DRAINING FISTULAS. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

SLEEPERS HRM

Affected Drugs:

Eszopiclone Zaleplon Zolpidem Tartrate Zolpidem Tartrate ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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).

SORIATANE

Affected Drugs:

Acitretin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF SEVERE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS

Age Restrictions:N/A

Prescription Order Restrictions: 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.

SPEVIGO

Affected Drugs:

Spevigo

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.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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

GHP Medicare Formulary - Prior Authorization Criteria

Page 433 of 591

Effective 12/2023

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.

SPRAVATO

Affected Drugs:

Spravato (56 MG Dose) Spravato (84 MG Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF TREATMENT-RESISTANT MAJOR DEPRESSION DISORDER (MDD). 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.

Age Restrictions: MUST BE 18 YEARS OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: 1 MONTH INITIAL, 12 MONTHS CONTINUATION. MDD WITH SI: 1 MONTH

Other Criteria: DOCUMENTATION THAT SIGNIFICANT 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 BENEFICIARY ABOUT THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT). FOR TREATMENT RESISTANT MDD: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO OLANZAPINE/FLUOXETINE CAPSULES. DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH A NEWLY INITIATED ANTIDEPRESSANT. 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

GHP Medicare Formulary - Prior Authorization Criteria

Page 435 of 591

Effective 12/2023

LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 436 of 591

Effective 12/2023

SPRYCEL

Affected Drugs:

Sprycel

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF NEWLY DIAGNOSED CHRONIC PHASE CML or DX OF CHRONIC, ACCELERATED, OR MYELOID/LYMPHOID BLAST PHASE Ph+ CML or DX OF Ph+ ALL

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR CHRONIC, ACCELERATED OR BLASTIC PHASE Ph+ CML -DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR THERAPY, INCLUDING IMATINIB. FOR PH+ ALL - DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR THERAPY OR DOCUMENTATION OF USE TO TREAT NEWLY DIAGNOSED Ph+ ALL IN PEDIATRIC PATIENTS IN COMBINATION WITH CHEMOTHERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

STELARA

Affected Drugs:

Stelara

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE 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 Restrictions:FOR PP AND PSA: MUST BE 6 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PP (COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, TREMFYA). FOR PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR PSA (COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, TREMFYA). PEDIATRIC PP (6 TO 18 YEARS OF AGE): DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO TOPICAL CORTICOSTEROIDS. FOR CD: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED AGENTS FOR CD (HUMIRA, CIMZIA, INFLIXIMAB). FOR UC: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO PREFERRED BIOLOGIC AGENTS FOR UC (HUMIRA, SIMPONI, XELJANZ, RINVOQ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

STIMUFEND

Affected Drugs:

Stimufend

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

STIVARGA

Affected Drugs:

Stivarga

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC COLORECTAL CANCER OR DOCUMENTATION OF LOCALLY ADVANCED, UNRESTECTABLE OR METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST). DOCUMENTATION OF HEPATOCELLULAR CARCINOMA WITH FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO SORAFENIB.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR METASTATIC COLORECTAL CANCER: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THREE OF THE FOLLOWING PRIOR THERAPIES (BASED ON CLINICAL TRIAL DESIGN) - FLUOROPYRIMIDINE BASED CHEMO, OXALIPLATIN BASED CHEMO, IRINOTECAN BASED CHEMO, ANTI-VEGF THERAPY (BEVACIZUMAB) OR IF KRAS WILD TYPE AN ANTI-EGFR THERAPY (CETUXIMAB OR PANITUMUMAB). FOR GIST: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO IMATINIB MESYLATE (GLEEVEC) AND SUNITINIB MALATE (SUTENT). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

STRATTERA

Affected Drugs:

Atomoxetine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ADD/ADHD

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 441 of 591

Effective 12/2023

STRENSIQ

Affected Drugs:

Strensiq

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 OF LOW TOTAL SERUM ALKALINE PHOSPHATASE ACTIVITY AND DOCUMENTATION THAT MEMBER WILL RECEIVE A WEIGHT AND DIAGNOSIS APPROPRIATE DOSING REGIMEN

Age Restrictions:N/A

Prescription Order Restrictions:ENDOCRINOLOGIST, GENETICIST OR METABOLIC SPECIALIST

Coverage Duration: 3 MONTH INITIAL AND 12 MONTH CONTINUATION

Other Criteria:SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

SULFONYLUREAS HRM

Affected Drugs:

glyBURIDE glyBURIDE Micronized glyBURIDE-metFORMIN

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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 AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GLIPIZIDE

SUNOSI

Affected Drugs:

Sunosi

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

SUPPRELIN LA

Affected Drugs:

Supprelin LA

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF CENTRAL PRECOCIOUS PUBERTY

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LUPRON DEPOT-PED

SUTENT

Affected Drugs:

SUNItinib Malate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF GASTROINTESTINAL STROMAL TUMOR (GIST). DX OF PROGRESSIVE, WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE TUMORS (pNET) WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE. DX OF ADVANCED RENAL CELL CARCINOMA. DX OF ADJUVANT TREATMENT OF RENAL CELL CARCINOMA WITH HIGH RISK OF RECURRENT DISEASE FOLLOWING NEPHRECTOMY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR GASTROINTESTINAL STROMAL TUMOR THERE MUST BE A FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO IMATINIB. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

SYLVANT

Affected Drugs:

Sylvant

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MULTICENTRIC CASTLEMAN DISEASE

Age Restrictions:N/A

Prescription Order Restrictions: 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 100000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 75 X 100000000 (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 100000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 50 X 100000000 (10 TO THE 9TH POWER) / L AND HGB LESS THAN 17 G/DL.

SYMDEKO

Affected Drugs:

Symdeko

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 Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:Reauthorization will require documentation of improvement or stabilization in the signs of symptoms of cystic fibrosis.

SYMLIN

Affected Drugs:

SymlinPen 120 SymlinPen 60

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 Restrictions:N/A

Prescription Order Restrictions: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

SYMPAZAN

Affected Drugs:

Sympazan

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF LENNOX-GASTAUT SYNDROME

Age Restrictions:N/A

Prescription Order Restrictions: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

SYNAGIS

Affected Drugs:

Synagis

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:5 MONTHS

Other Criteria:DOCUMENTATION THAT MEMBER HAS NOT RECEIVED BEYFORTUS DURING THE CURRENT RSV SEASON.

SYNERCID

Affected Drugs:

Synercid

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS CAUSED BY STREPTOCOCCUS PYOGENES OR METHICILLIN-SENSITIVE STAPHYLOCOCCUS AUREUS.

Age Restrictions:N/A

Prescription Order Restrictions:INFECTIOUS DISEASE SPECIALIST OR UPON CONSULT FROM INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

Page 452 of 591

Effective 12/2023

SYNRIBO

Affected Drugs:

Synribo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OR MORE TYROSINE KINASE INHIBITORS (GLEEVEC, SPRYCEL, TASIGNA, BOSULIF). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

SYPRINE

Affected Drugs:

Trientine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF WILSON DISEASE

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:Documentation of a therapeutic failure on, intolerance to or contraindication to penicillamine

GHP Medicare Formulary - Prior Authorization Criteria

TABRECTA

Affected Drugs:

Tabrecta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TAFAMIDIS MEGLUMINE

Affected Drugs:

Vyndamax Vyndaqel

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of cardiomyopathy resulting from wild type transthyretinmediated 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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a cardiologist

Coverage Duration:12 MONTHS

Other Criteria:Documentation of NYHA Class I, II, or III heart failure. Reauthorizations will require prescriber attestation that the patient continues to benefit from tafamidis therapy AND no documenTation of NYHA class IV heart failure.

TAFINLAR

Affected Drugs:

Tafinlar

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of unresectable or metastatic melanoma with one of the following: documentation for use as single therapy OR documentation of use in combination with Mekinist (trametinib). Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test. Diagnosis of metastatic non-small cell lung cancer with concomitant use of Mekinist AND documentation of BRAF V600E mutation as detected by an FDA-approved test. Diagnosis of use for adjuvant treatment of melanoma with involvement of lymph nodes following complete resection AND documentation. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND documentation of concurrent use of Mekinist (trametinib) AND documentation of BRAF V600E mutation. Documentation of unresectable or metastatic solid tumors AND documentation of BRAF V600E mutation. Documentation of low-grade glioma (LGG) AND documentation of BRAF V600E mutation AND documentation of concurrent use of Mekinist (trametinib)

Age Restrictions: For LGG: age greater than or equal to one year and less than 18 years.

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR UNRESECTABLE OR SOLID TUMORS, DOCUMENTATION OF PREVIOUS TREATMENT RESULTING IN DISEASE PROGRESSION AND DOCUMENTATION OF USE IN COMBINATION WITH MEKINIST. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

TAGRISSO

Affected Drugs:

Tagrisso

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC EGFR T790M MUTATION POSITIVE NON SMALL CELL LUNG CANCER AS DETECTED BY AN FDA APPROVED TEST with DOCUMENTATION OF FAILURE ON OR INTOLERANCE TO PRIOR TYROSINE KINASE INHBITOR THERAPY (IRESSA, GILOTRIF, OR TARCEVA). DOCUMENTATION OF USE AS FIRST LINE THERAPY FOR METASTATIC NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETION OR EXON 21 L858R MUTATION AS DETECTED BY AN FDA APPROVED TEST. DOCUMENTATION OF ADJUVANT TREAMENT FOLLOWING COMPLETE TUMOR RESECTION OF NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETION OR EXON 21 L858R MUTATION AS DETECTED BY AN FDA APPROVED TEST.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. ADJUVANT TREATMENT OF NON-SMALL CELL LUNG CANCER BEYOND 3 YEARS WILL REQUIRE DOCUMENTATION THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

TAKHZYRO

Affected Drugs:

Takhzyro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1-INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

TALVEY

Affected Drugs:

Talvey

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND DOCUMENTATION OF TREATMENT WITH AT LEAST 4 PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT, AND AN ANTI-CD38 MONOCLONAL ANTIBODY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

TALZENNA

Affected Drugs:

Talzenna

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of deleterious or suspected deleterious germline BRCAmutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer as verified by an FDA approved test. DIAGNOSIS OF HOMOLOGOUS RECOMBINATION REPAIR (HRR) GENE-MUTATED METASTATIC CASTRATION-RESISTANT PROSTATE CANCER AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH ENZALUTAMIDE (XTANDI).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorization will require documentation of continued disease improvement or lack of disease progression.

TARCEVA

Affected Drugs:

Erlotinib HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH ONE OF THE FOLLOWING: USED AS FIRST LINE TREATMENT or MAINTENANCE TREATMENT or SECOND LINE OR GREATER TREATMENT AFTER PROGRESSION ON AT LEAST ONE PRIOR CHEMOTHERAPY REGIMEN. DOCUMENTATION OF ONE OF THE FOLLOWING EGFR MUTATIONS AS DETECTED BY AN FDA APPROVED TEST: EXON 19 DELETION OR EXON 21 (L858R) SUBSTITUTION. DOCUMENTATION OF LOCALLY ADVANCED, UNRESECTABLE OR METASTASIZED PANCREATIC CANCER IN COMBO THERAPY WITH GEMCITABINE.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TARPEYO

Affected Drugs:

Tarpeyo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN) VERIFIED BY BIOPSY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEPHROLOGIST

Coverage Duration:10 MONTHS

Other Criteria:DOCUMENTATION THAT PATIENT IS AT HIGH RISK OF DISEASE PROGRESSION. DOCUMENTATION OF EGFR GREATER THAN OR EQUAL TO 35 ML/MIN/1.73 M2. DOCUMENTATION THAT PATIENT HAS RECEIVED A STABLE DOSE OF A RAS INHIBITOR AT A MAXIMALLY TOLERATED DOSE FOR GREATER THAN OR EQUAL TO 90 DAYS. DOCUMENTATION THAT A RAS INHIBITOR WILL BE USED IN COMBINATION WITH TARPEYO. DOCUMENTATION THAT MEMBER HAS NOT PREVIOUSLY COMPLETED A 9 MONTH TREATMENT COURSE OF TARPEYO. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A GLUCOCORTICOID.

TASIGNA

Affected Drugs:

Tasigna

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF NEWLY DIAGNOSED (NOT PREVIOUSLY TREATED) CHRONIC PHASE PH+ CML. DIAGNOSIS OF ADULT CHRONIC OR ACCELERATED PHASE PH+ CML IN PATIENT'S RESISTENT TO, OR INTOLERANT TO PRIOR THERAPY INCLUDING GLEEVEC. DIAGNOSIS OF CHRONIC OR ACCELERATED PHASE PH+ CML IN PEDIATRIC PATIENT'S RESISTENT TO, OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TAVALISSE

Affected Drugs:

Tavalisse

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

TAVNEOS

Affected Drugs:

Tavneos

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

TAZORAC

Affected Drugs:

Tazarotene Tazorac

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ACNE, ACNE VULGARIS, ADULT ONSET ACNE, OR PLAQUE PSORIASIS

Age Restrictions:N/A

Prescription Order Restrictions: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.

TAZVERIK

Affected Drugs:

Tazverik

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of metastatic or locally advanced epithelioid sarcoma AND documentation that member is not eligible for complete resection. Diagnosis of relapsed or refractory follicular lymphoma with documentation of one of the following: 1)documentation of an EZH2 mutation as detected by an FDA approved test with documentation of trial of at least two prior systemic therapies OR 2)documentation of no satisfactory alternative treatment options.

Age Restrictions: SARCOMA: 16 YRS OR OLDER. LYMPHOMA: 18 YRS OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

TCA HRM

Affected Drugs: Amitriptyline HCI Amoxapine chlordiazePOXIDE-Amitriptyline Doxepin HCI Imipramine HCI Imipramine Pamoate Perphenazine-Amitriptyline Protriptyline HCI Trimipramine Maleate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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 AND WILL REQUIRE DOCUMENTATION OF AN FDA LABELED INDICATION AND DOCUMENTATION THAT THE PRESCRIBER HAS INDICATED THAT THE BENEFITS OF THE REQUESTED HIGH RISK MEDICATION OUTWEIGHS THE RISKS FOR THE PATIENT AND DOCUMENTATION THAT THE PROVIDER DISCUSSED THESE RISKS AND POTENTIAL SIDE EFFECTS OF THE REQUESTED HIGH RISK MEDICATION WITH THE PATIENT.

TECENTRIQ

Affected Drugs:

Tecentriq

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF NON SMALL CELL LUNG CANCER MEETING ONE OF THE FOLLOWING:1) DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM CONTAINING CHEMOTHERAPY OR 2) PROGRESSION ON AT LEAST ONE FDA APPROVED THERAPY TARGETING EGFR OR ALK IF THE PATIENT HAS EGFR OR ALK GENOMIC TUMOR ABERRATIONS OR 3)DOCUMENTATION OF NON-SQUAMOUS HISTOLOGIC SUBTYPE USED AS FIRST LINE IN COMBINATION WITH EITHER 1) BEVACIZUMAB, PACLITAXEL AND CARBOPLATIN OR 2) PACLITAXEL PROTEIN-BOUND AND CARBOPLATIN WITH NO EGFR OR ALK GENOMIC TUMOR ABERRATIONS OR 4)AS FIRST LINE TREATMENT FOR METASTATIC DISEASE WITH HIGH PD-L1 EXPRESSION (PD-L1 STAINED TUMOR CELLS OF AT LEAST 50% OR PD-L1 STAINED TUMOR INFILTRATING IMMUNE CELLS COVERING 10% OR MORE OF THE TUMOR AREA AS DETERMINED BY AN FDA APPROVED TEST) AND DOCUMENTATION OF NO EGFR OR ALK GENOMIC TUMOR ABERRATIONS OR 5) ADJUVANT TREATMENT AS A SINGLE AGENT FOR STAGE II TO IIIA DISEASE FOLLOWING RESECTION AND PLATINUM BASED THERAPY AND WHOSE TUMORS HAVE PD-L1 EXPRESSION ON AT LEAST 1% OF TUMOR CELLS AS DETERMINED BY AN FDA APPROVED TEST. DX OF USE AS FIRST LINE TREATMENT FOR EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC) AND DOCUMENTATION OF USE IN COMBINATION WITH CARBOPLATIN AND ETOPOSIDE. DX OF UNRESECTABLE OR METASTATIC HEPATOCELLULAR CARCINOMA (HCC) USED IN COMBINATION WITH BEVACIZUMAB AND DOCUMENTATION OF NO PRIOR SYSTEMIC TREATMENT FOR HCC. DX OF UNRESECTABLE OR METASTATIC MELANOMA WITH DOCUMENTATION OF BRAF V600 MUTATION AS DETERMINED BY AN FDA APPROVED TEST AND DOCUMENTATION OF USE IN COMBINATION WITH COBIMETINIB AND VEMURAFENIB. DX OF UNRESECTABLE OR METASTATIC ALVEOLAR SOFT PART SARCOMA (ASPS).

Age Restrictions: FOR ASPS: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. AUTHORIZATION BEYOND

GHP Medicare Formulary - Prior Authorization Criteria

Page 470 of 591

Effective 12/2023

12 MONTHS FOR ADJUVANT TREATMENT OF STAGE II TO IIIA NSCLC FOLLOWING RESECTION AND PLATINUM BASED CHEMOTHERAPY WILL REQUIRE PEER REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

TECVAYLI

Affected Drugs:

Tecvayli

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND TREAMENT WITH AT LEAST 4 PRIOR LINES OF THERAPY, INCLUDING A PROTEASOME INHIBITOR, AN IMMUNOMODULATORY AGENT, AND AN ANTI-CD38 MONOCLONAL ANTIBODY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

TEGSEDI

Affected Drugs:

Tegsedi

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:Neurologist, 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.

TEPEZZA

Affected Drugs:

Tepezza

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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. 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.

TEPMETKO

Affected Drugs:

Tepmetko

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TEZSPIRE

Affected Drugs:

Tezspire

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 Restrictions:12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 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.

THIORIDAZINE HRM

Affected Drugs:

Thioridazine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions: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 AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE)

GHP Medicare Formulary - Prior Authorization Criteria

TIBSOVO

Affected Drugs:

Tibsovo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: 1) DIAGNOSIS OF RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA WITH DOCUMENTATION OF AN ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA APPROVED TEST OR 2) DIAGNOSIS OF NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA IN MEMBERS GREATER THAN OR EQUAL TO 75 YEARS OF AGE OR IN THOSE WITH COMORBIDITIES THAT PRECLUDE THE USE OF INTENSIVE INDUCTION CHEMOTHERAPY AND DOCUMENTATION OF AN ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA APPROVED TEST AND DOCUMENTATION OF USE AS MONOTHERAPY OR IN COMBINATION WITH AZACITIDINE 3) DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA AND DOCUMENTATION OF AN ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA APPROVED TEST AND DOCUMENTATION OF TREATMENT WITH AT LEAST ONE PRIOR THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorizations will require documentation of continued disease improvement or lack of disease progression

TIGLUTIK

Affected Drugs:

Tiglutik

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Diagnosis of ALS (amyotrophic lateral sclerosis)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 riluzole tablets OR documentation that the patient has dysphagia or is unable to swallow tablets.

GHP Medicare Formulary - Prior Authorization Criteria

TIVDAK

Affected Drugs:

Tivdak

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RECURRENT OR METASTATIC CERVICAL CANCER AND DOCUMENTATION OF DISEASE PROGRESSION ON OR AFTER CHEMOTHERAPY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

TLANDO

Affected Drugs:

Tlando

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: PRIMARY HYPOGONADISM (CONGENITAL OR ACQUIRED) OR HYPOGONADOTROPIC HYPOGONADISM (CONGENITAL OR ACQUIRED).

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ANDROGEN ALTERNATIVES.

TOBI

Affected Drugs:
Tobi Podhaler
Off-Label Uses:N/A
Exclusion Criteria:N/A
Required Medical Information: DIAGNOSIS OF CYSTIC FIBROSIS
Age Restrictions:N/A
Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST
Coverage Duration: REMAINDER OF CONTRACT YEAR
Other Criteria:N/A

TOBRAMYCIN NEB

Affected Drugs:

Tobramycin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

TORISEL

Affected Drugs:

Temsirolimus

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ADVANCED RENAL CELL CARCINOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

GHP Medicare Formulary - Prior Authorization Criteria

TRACLEER

Affected Drugs:

Bosentan Tracleer

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 Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

TREMFYA

Affected Drugs:

Tremfya

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 5% OR GREATER INVOLVEMENT OF BODY SURFACE AREA OR DISEASE INVOVLING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, OR GENITALS. DOCUMENTATION OF ACTIVE PSORIATIC ARTHRITIS. DX OF PERIPHERAL PSA OR AXIAL PSA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 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 PERIPHERAL PSA: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ONE 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 CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

TRETINOIN

Affected Drugs:

Tretinoin Tretinoin Microsphere Tretinoin Microsphere Pump

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF ACNE, ACNE VULGARIS, OR ADULT ONSET ACNE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

TRIKAFTA

Affected Drugs:

Trikafta

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 Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions:By or in consultation with a pulmonologist or physician who specializes in the treatment of CF

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

TRIPTODUR

Affected Drugs:

Triptodur

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF CENTRAL PRECOCIOUS PUBERTY

Age Restrictions:N/A

Prescription Order Restrictions: 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

TRODELVY

Affected Drugs:

Trodelvy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTATION OF DIAGNOSIS OF UNRESECTABLE LOCALLY ADVANCED OR METASTATIC TRIPLE NEGATIVE BREAST CANCER WITH DOCUMENTATION OF TRIAL OF AT LEAST TWO PREVIOUS LINES OF SYSTEMIC THERAPY, OR WHICH AT LEAST ONE WAS FOR METASTATIC DISEASE. DOCUMENTATION OF DIAGNOSIS OF UNRESECTABLE LOCALLY ADVANCED OR METASTATIC HORMONE RECEPTOR (HR) POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE (IHC 0, IHC 1+ OR IHC 2+/ISH-) BREAST CANCER AND DOCUMENTATION OF PREVIOUSLY RECEIVING ENDOCRINE-BASED THERAPY AND DOCUMENTATION OF PREVIOUSLY RECEIVING AT LEAST TWO ADDITIONAL SYSTEMIC THERAPIES IN THE METASTATIC SETTING. DOCUMENTATION OF DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER AND DOCUMENTATION OF PROGRESSION ON PLATINUM-CONTAINING CHEMOTHERAPY AND DOCUMENTATION OF PROGRESSION ON A PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH-LIGAND 1 (PDL1) INHIBITOR.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TROKENDI XR

Affected Drugs:

Topiramate ER Trokendi XR

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 Restrictions:12 YEARS OR OLDER FOR MIGRAINE PROPHYLAXIS, 6 YEARS OF AGE OR OLDER FOR OTHER INDICATIONS

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TOPIRAMATE ER SPRINKLE (GENERIC QUDEXY XR).

TRUSELTIQ

Affected Drugs:

Truseltiq (100MG Daily Dose) Truseltiq (125MG Daily Dose) Truseltiq (50MG Daily Dose) Truseltiq (75MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF UNRESECTABLE LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA AND DOCUMENTATION OF A FIBROBLAST GROWTH FACTOR RECEPTOR 2 (FGFR2) FUSION OR OTHER REARRANGEMENT AS VERIFIED BY AN FDA APPROVED TEST AND DOCUMENTATION OF TRIAL OF ONE PRIOR LINE OF THERAPY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TUKYSA

Affected Drugs:

Tukysa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of advanced unresectable or metastatic HER2positive breast cancer, including those with brain metastases AND documentation of prior treatment with at least one anti-HER2 based regimen in the metastatic setting. DIAGNOSIS OF RAS WILD-TYPE HER2-POSITIVE UNRESECTABLE OR METASTATIC COLORECTAL CANCER AND DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBO W/ TRASTUZUMAB AND DOCUMENTATION OF PRIOR TREATMENT WITH FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-BASED CHEMOTHERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR BREAST CANCER: DOCUMENTATION THAT MEDICATION WILL BE GIVEN IN COMBINATION WITH TRASTUZUMAB AND CAPECITABINE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

TURALIO

Affected Drugs:

Turalio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of tenosynovial giant cell tumor that meets both of the following criteria 1) associated with functional limitations or severe morbidity and 2) that condition is not amenable to improvement with surgery.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TYKERB

Affected Drugs:

Lapatinib Ditosylate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE IN COMBINATION WITH LETROZOLE FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE, HER2+ METASTATIC BREAST CANCER OR DOCUMENTATION OF USE IN COMBINATION WITH CAPECITABINE FOR ADVANCED OR METASTATIC BREAST CANCER WHOSE TUMORS OVEREXPRESS HER2 AND HAVE RECEIVED PRIOR THERAPY INCLUDING AN ANTHRACYCLINE, A TAXANE, AND TRASTUZUMAB (HERCEPTIN)

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

TYMLOS

Affected Drugs:

Tymlos

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 Restrictions:N/A

Prescription Order Restrictions: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)

TYSABRI

Affected Drugs:

Tysabri

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), DOCUMENTATION OF TYSABRI BEING USED AS MONOTHERAPY AND 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. DIAGNOSIS OF MODERATE TO SEVERE CROHN'S BASED ON CLINICAL SIGNS AND SYMPTOMS.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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. FOR RELAPSING/REMITTING MS: DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR 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: HUMIRA, CIMZIA 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.

GHP Medicare Formulary - Prior Authorization Criteria

Page 497 of 591

Effective 12/2023

TYVASO

Affected Drugs:

Tyvaso Tyvaso Refill Tyvaso Starter

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 Restrictions:N/A

Prescription Order Restrictions: 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

TYVASO DPI

Affected Drugs:

Tyvaso DPI Maintenance Kit Tyvaso DPI Titration Kit

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 Restrictions:N/A

Prescription Order Restrictions: 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.

TZIELD

Affected Drugs:

Tzield

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).

Age Restrictions:8 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

UBRELVY

Affected Drugs:

Ubrelvy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of use for the acute treatment of migraine with or without aura.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary triptans (e.g., almotriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan). Documentation that medication will not be used concurrently with another CGRP antagonist indicated for the actue treatment of migraine.

UDENYCA

Affected Drugs:

Udenyca

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. Documentation of Hematopoietic syndrome of Acute Radiation Syndrome (HSARS) with documentation of an acute exposure to myelosuppressive doses of radiation.

Age Restrictions:N/A

Prescription Order Restrictions: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).

UNITUXIN

Affected Drugs:

Unituxin

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:5 MONTHS

Other Criteria:N/A

UPTRAVI

Affected Drugs:

Uptravi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF WHO GROUP I PULMONARY HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: 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).

UPTRAVI IV

Affected Drugs:

Uptravi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF WHO GROUP I PULMONARY HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: 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.

UZEDY

Affected Drugs:

Uzedy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF SCHIZOPHRENIA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY.

VALCHLOR

Affected Drugs:

Valchlor

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF STAGE IA OR IB MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING SKIN-DIRECTED THERAPIES: TOPICAL CORTICOSTEROID, TOPICAL RETINOID, TOPICAL NITROGEN MUSTARD, OR PHOTOTHERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

VANDETANIB

Affected Drugs:

Caprelsa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MEDULLARY THYROID CANCER IN PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC DISEASE.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

VANFLYTA

Affected Drugs:

Vanflyta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) AND DOCUMENTATION THAT MEMBER IS FLT3 INTERNAL TANDEM DUPLICATION (ITD)-POSITIVE AS DETECTED BY AN FDA-APPROVED TEST AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH STANDARD CYTARABINE AND ANTHRACYCLINE INDUCTION, IN COMBINATION WITH CYTARABINE CONSOLIDATION, AND AS MAINTENANCE MONOTHERAPY FOLLOWING CONSOLIDATION CHEMOTHERAPY (EXCLUDES MAINTENANCE MONOTHERAPY FOLLOWING ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION).

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. THE FDA-APPROVED TREATMENT DURATION IS UP TO 2 CYCLES OF INDUCTION, UP TO 4 CYCLES OF CONSOLIDATION, AND UP TO 36 CYCLES AS MAINTENANCE. REQUESTS BEYOND THE FDA-APPROVED TREATMENT DURATION WILL REQUIRE DOCUMENTATION OF PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

VARUBI

Affected Drugs:

Varubi (180 MG Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF USE FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY TO HIGHLY EMETOGENIC CHEMOTHERAPY REGIMENS and DOCUMENTATION THAT MEDICATION IS BEING USED IN COMBINATION WITH OTHER ANTIEMETIC AGENTS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:N/A

VECTIBIX

Affected Drugs:

Vectibix

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF METASTATIC COLORECTAL CANCER IN COMBINATION WITH FOLFOX AS FIRST LINE THERAPY OR AS MONOTHERAPY WITH DISEASE PROGRESSION ON (OR INTOLERANCE OR CONTRAINDICATION TO) FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN CONTAINING CHEMOTHERAPY REGIMENS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF WILD-TYPE RAS (DEFINED AS WILD-TYPE (NEGATIVE) IN BOTH KRAS AND NRAS) AS DETERMINED BY AN FDA-APPROVED TEST.

VELCADE

Affected Drugs:

Bortezomib

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MULTIPLE MYELOMA OR DIAGNOSIS OF MANTLE CELL LYMPHOMA.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

VELTASSA

Affected Drugs:

Veltassa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MILD TO MODERATE HYPERKALEMIA (SERUM POTASSIUM GREATER THAN OR EQUAL TO 5.1 MEQ/L AND LESS THAN 6.5 MEQ/L)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTATION THAT ATTEMPT HAS BEEN MADE TO IDENTIFY AND CORRECT THE UNDERLYING CAUSE OF THE HYPERKALEMIA OR RATIONALE AS TO WHY THE UNDERLYING CAUSE CANNOT BE CORRECTED.

VEMURAFENIB

Affected Drugs:

Zelboraf

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION AS DETECTED BY AN FDA APPROVED TEST. DIAGNOSIS OF ERDHEIM-CHESTER DISEASE (ECD) WITH BRAF V600 MUTATION AS DESTECTED BY AN FDA APPROVED TEST.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

VENCLEXTA

Affected Drugs:

Venclexta Venclexta Starting Pack

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) or SMALL LYMPHOCYTIC LEUKEMIA (SLL). DOCUMENTATION OF NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) USED IN COMBINATION WITH AZACITIDINE, DECITABINE, OR LOW-DOSE CYTARABINE and DOCUMENTATION OF AGE GREATER THAN 75 YEARS or DOCUMENTATION OF A COMORBIDITY THAT PRECLUDES PATIENT FROM RECEIVING INTENSIVE INDUCTION CHEMOTHERAPY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

VENTAVIS

Affected Drugs:

Ventavis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:FOR THE TREATMENT OF PRIMARY PULMONARY HYPERTENSION (WORLD HEALTH ORGANIZATION [WHO] GROUP I) IN PATIENTS WITH NEW YORK HEART ASSOCIATION (NYHA) CLASS III or CLASS IV SYMPTOMS AND 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).

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

VERQUVO

Affected Drugs:

Verquvo

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

VERZENIO

Affected Drugs:

Verzenio

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF HORMONE RECEPTOR POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 NEGATIVE (HR+/HER2-) ADVANCED OR METASTATIC BREAST CANCER WITH ONE OF THE FOLLOWING (1) ADMINISTERED WITH FULVESTRANT IN PATIENTS WHO EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR ENDOCRINE THERAPY AND DOCUMENTATION OF POSTMENOPAUSAL STATUS OR IF PRE/PERIMENOPAUSAL OR MALE, THAT THE MEMBER HAS RECEIVED A GONADOTROPIN-RELEASING HORMONE AGONIST FOR AT LEAST 4 WEEKS PRIOR TO AND WILL CONTINUE FOR THE DURATION OF VERZENIO THERAPY OR (2) USED AS MONOTHERAPY IF THE PATIENT EXPERIENCED DISEASE PROGRESSION FOLLOWING PRIOR ENDOCRINE THERAPY AND PRIOR CHEMOTHERAPY IN THE METASTATIC SETTING OR (3) FOR INITIAL ENDOCRINE-BASED THERAPY IN COMBINATION WITH AN AROMATASE INHIBITOR WITH DOCUMENTATION OF POSTMENOPAUSAL STATUS OR IF PRE/PERIMENOPAUSAL OR MALE, THAT THEY HAVE RECEIVED A GONADOTROPIN-RELEASING HORMONE AGONIST (I.E., LHRH AGONIST) FOR AT LEAST 4 WEEKS PRIOR TO THERAPY AND WILL CONTINUE FOR THE DURATION OF MEDICATION THERAPY and DOCUMENATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH AN AROMATASE INHIBITOR. 2) DIAGNOSIS OF HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE, NODE-POSITIVE EARLY BREAST CANCER AND DOCUMENTATION OF A HIGH RISK OF RECURRENCE AND DOCUMENTATION THAT MEDICATION WILL BE USED AS ADJUVANT TREATMENT IN COMBINATION WITH ENDOCRINE THERAPY (SUCH AS BUT NOT LIMITED TO: TAMOXIFEN OR AN AROMATASE INHIBITOR).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Oncologist

Coverage Duration:12 MONTHS

Other Criteria:FOR EARLY BREAST CANCER, IF BEING USED WITH AN AROMATASE INHIBITOR, DOCUMENTATION OF POSTMENOPAUSAL STATUS OR IF THE PATIENT IS PRE/PERIMENOPAUSAL OR MALE, THEY THEY HAVE RECEIVED A GONADOTROPIN-RELEASING HORMONE AGONIST FOR AT LEAST 4 WEEKS PRIOR TO AND WILL CONTINUE

GHP Medicare Formulary - Prior Authorization Criteria

Page 518 of 591

Effective 12/2023

FOR THE DURATION OF THERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION REQUESTS FOR AJDUVANT TREATMENT OF HR-POSITIVE, HER2-NEGATIVE, NODE POSITIVE, EARLY BREAST CANCER BEYOND 2 YEARS WILL REQUIRE PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

Effective 12/2023

VIIBRYD

Affected Drugs:

Viibryd Starter Pack Vilazodone HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions:N/A

Prescription Order Restrictions: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).

VIJOICE

Affected Drugs:

Vijoice

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 Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

VILTEPSO

Affected Drugs:

Viltepso

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 Restrictions:N/A

Prescription Order Restrictions: 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 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.

VIMPAT

Affected Drugs:

Lacosamide Vimpat

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 GENERALZED TONIC-CLONIC SEIZURES

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:1 WEEK

Other Criteria:DOCUMENTATION OF INABILITY TO USE ORAL FORMULATION OF MEDICATION.

VIRAZOLE

Affected Drugs:

Ribavirin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:TREATMENT OF HOSPITALIZED INFANTS AND YOUNG CHILDREN WITH SEVERE LOWER RESPIRATORY TRACT INFECTIONS DUE TO RESPIRATORY SYNCYTIAL VIRUS (RSV).

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

VITRAKVI

Affected Drugs:

Vitrakvi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND documentation that the member must have progressed following treatment or have no satisfactory alternative treatments

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

VIVJOA

Affected Drugs:

Vivjoa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF HISTORY OF RECURRENT VULVOVAGINAL CANDIDIASIS (RVVC).

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:3 MONTHS

Other Criteria: RVVC IS DEFINED AS 3 OR MORE ACUTE VVC EPISODES WITHIN 12 MONTHS. DOCUMENTATION OF ONE OF THE FOLLOWING: (1) MEMBER IS POSTMENOPAUSAL OR (2) MEMBER IS 12 YEARS OF AGE OR OLDER AND THAT MEMBER IS POST-MENARCHAL AND THAT MEMBER IS NOT OF REPRODUCTIVE POTENTIAL (I.E., HISTORY OF TUBAL LIGATION, SALPINGO-OOPHORECTOMY, OR HYSTERECTOMY).

VIZIMPRO

Affected Drugs:

Vizimpro

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Reauthorization will require documentation of continued disease improvement or lack of disease progression.

VONJO

Affected Drugs:

Vonjo

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, INCLUDING PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS OR POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS AND DOCUMENTATION OF SEVERE PLATELET THROMBOCYTOPENIA WITH A PLATELET COUNT LESS THAN OR EQUAL TO 50 X 10(9)/L AND SPLENOMEGALY AND BASELINE TOTAL SYMPTOM SCORE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF).

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH ANOTHER JANUS KINASE INHIBITOR. CONTINUED COVERAGE EVERY 6 MONTHS WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF PLATELET COUNT LESS THAN OR EQUAL TO 50 X 10(9)/L AND DOCUMENTATION OF RESPONSE TO THERAPY SUCH AS A REDUCTION FROM PRETREATMENT BASELINE SPLEEN VOLUME OR A REDUCTION IN THE TOTAL SYMPTOM SCORE FROM BASELINE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF).

VORICONAZOLE

Affected Drugs:

Voriconazole

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 refratory to, other therapy.

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:3 MONTHS

Other Criteria:N/A

VOTRIENT

Affected Drugs:

PAZOPanib HCI Votrient

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ADVANCED RENAL CELL CARCINOMA WITH CLEAR CELL OR PREDOMINANTLY CLEAR CELL HISTOLOGY OR DX OF ADVANCED RENAL CELL CARCINOMA WITH NON-CLEAR CELL HISTOLOGY OR DX OF ADVANCED SOFT TISSUE SARCOMA (STS)

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR DX OF ADVANCED RENAL CELL CARCINOMA WITH NON-CLEAR CELL HISTOLOGY SUBTYPE: MUST HAVE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TEMSIROLIMUS AND SUTENT. FOR DX OF ADVANCED SOFT TISSUE SARCOMA MUST HAVE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE PRIOR CHEMOTHERAPY TREATMENT INCLUDING BUT NOT LIMITED TO DOXORUBICIN, IFOSFAMIDE, EPIRUBICIN, GEMCITABINE, DACARBAZINE, LIPOSOMAL DOXORUBICIN, TEMOZOLOMIDE, VINORELBINE, AD REGIMEN, AIM REGIMEN, MAID REGIMEN. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

VOWST

Affected Drugs:

Vowst

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 Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

VPRIV

Affected Drugs:

Vpriv

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 Restrictions: MUST BE 4 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

VRAYLAR

Affected Drugs:

Vraylar

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF SCHIZOPHRENIA OR ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER or documentation of use for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression). DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER (MDD) AND DOCUMENTATION THAT MEDICATION IS BEING USED AS ADJUNCTIVE THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:For schizophrenia or manic/mixed episodes associated with bipolar I: MEDICAL RECORD DOCUMENTATION OF TRIAL ON TWO FORMULARY ALTERNATIVES (ARIPIPRAZOLE, OLANZAPINE, QUETIAPINE, ZIPRASIDONE OR RISPERIDONE). For depressive episodes associated with bipolar I disorder (bipolar depression): medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine. FOR MDD: (1) DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4-WEEK TRIAL OF COMBINATION THERAPY WITH ARIPIPRAZOLE AND AN ANTIDEPRESSANT AND (2) DOCUMENTATION OF ONE OF THE FOLLOWING: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4-WEEK TRIAL OF COMBINATION ANTIDEPRESSANT THERAPY (SUCH AS AN SSRI AND BUPROPION OR AN SNRI AND BUPROPION) OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4-WEEK TRIAL OF AN ANTIDEPRESSANT WITH AUGMENTATION THERAPY (INCLUDING BUT NOT LIMITED TO LITHIUM, VALPROATE, CARBAMAZEPINE, OR LAMOTRIGINE).

VUITY

Affected Drugs: Vuity Off-Label Uses:N/A Exclusion Criteria:N/A Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF PRESBYOPIA. Age Restrictions:N/A Prescription Order Restrictions:OPTOMETRIST OR OPHTHALMOLOGIST Coverage Duration:REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

VYEPTI

Affected Drugs:

Vyepti

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A DIAGNOSIS OF MIGRAINE WITH OR WITHOUT AURA, BASED ON THE ICHD-III DIAGNOSTIC CRITERIA AND DOCUMENTATION OF THE NUMBER OF BASELINE MIGRAINE OR HEADACHE DAYS PER MONTH.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:BY OR IN CONSULTATION WITH A NEUROLOGIST OR HEADACHE SPECIALIST

Coverage Duration: 3 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria: DOCUMENTATION OF THE PATIENT EXPERIENCING FOUR OR MORE MIGRAINES PER MONTH. DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AIMOVIG AND EMGALITY. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF BEING USED IN COMBINATION DOCUMENTATION OF THE FOLLOWING: THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. DOCUMENTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER CGRP ANTAGONIST INDICATED FOR THE PREVENTIVE TREATMENT OF MIGRAINE. IF REQUEST IS FOR 300 MG EVERY 3 MONTH DOSING: DOCUMENTATION OF THERAPEUTIC FAILURE ON 100 MG EVERY 3 MONTH DOSING. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED OR SUSTAINED REDUCTION IN MIGRAINE OR HEADACHE FREQUENCY OR A DECREASE IN SEVERITY OR DURATION OF MIGRAINE AND EITHER DOCUMENTATION THE MEDICATION IS NOT BEING USED CONCURRENTLY WITH BOTULINUM TOXIN OR IF THE REQUEST IS FOR COMBINATION USE WITH BOTOX DOCUMENTATION OF THE FOLLOWING: PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF AT LEAST ONE CGRP ANTAGONIST WITHOUT THE CONCOMITANT USE OF BOTOX AND DOCUMENTATION OF A PREVIOUS THERAPEUTIC FAILURE ON A MINIMUM 6 MONTH TRIAL OF BOTOX WITHOUT THE CONCOMITANT USE OF A CGRP ANTAGONIST. DOCUMENTATION THAT MEDICATION WILL NOT BE USED CONCOMITANTLY WITH ANOTHER

GHP Medicare Formulary - Prior Authorization Criteria

Page 535 of 591

Effective 12/2023

CGRP ANTAGONIST INDICATED FOR THE PREVENTIVE TREATMENT OF MIGRAINE. IF REQUEST IS FOR 300 MG EVERY 3 MONTH DOSING: DOCUMENTATION OF THERAPEUTIC FAILURE ON 100 MG EVERY 3 MONTH DOSING.

GHP Medicare Formulary - Prior Authorization Criteria

Page 536 of 591

Effective 12/2023

VYONDYS

Affected Drugs:

Vyondys 53

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 Restrictions:N/A

Prescription Order Restrictions: 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 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.

VYXEOS

Affected Drugs:

Vyxeos

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF NEWLY-DIAGNOSED THERAPY-RELATED ACUTE MYELOID LEUKEMIA (T-AML) OR AML WITH MYELODYSPLASIA-RELATED CHANGES (AML-MRC).

Age Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF RATIONALE WHY CYTARABINE PLUS DAUNORUBICIN (7 PLUS 3) IS NOT A MEDICALLY APPROPRIATE TREATMENT. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

WELIREG

Affected Drugs:

Welireg

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF VON HIPPEL-LINDAU (VHL) DISEASE AND DOCUMENTATION THAT MEMBER DOES NOT REQUIRE IMMEDIATE SURGERY.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DISEASE CONFIRMED WITH A GERMLINE VHL ALTERANTION AND AT LEAST ONE OF THE FOLLOWING: ASSOCIATED RENAL CELL CARCINOMA (RCC) OR ASSOCIATED CENTRAL NERVOUS SYSTEM (CNS) HEMANGIOBLASTOMAS OR ASSOCIATED PANCREATIC NEUROENDOCRINE TUMORS (pNET). REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

XATMEP

Affected Drugs:

Xatmep

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ACUTE LYMPHOBLASTIC LEUKEMIA USED AS PART OF A COMBINATION CHEMOTHERAPY MAINTENANCE REGIMEN or DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS FOLLOWING AN INSUFFICIENT RESPONSE OR INTOLERANCE TO A 3 MONTH TRIAL OF A FORMULARY NSAID OR OTHER FIRST LINE THERAPY

Age Restrictions:18 YEARS OF AGE OR YOUNGER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:N/A

XCOPRI

Affected Drugs:

Xcopri Xcopri (250 MG Daily Dose) Xcopri (350 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Documentation of a diagnosis of partial onset seizures

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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.

XELJANZ

Affected Drugs:

Xeljanz Xeljanz XR

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.

Age Restrictions: PcJIA: MUST BE 2 YEARS OR OLDER. ALL OTHER DX:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 HUMIRA 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 HUMIRA OR ENBREL AND MEDICAL RECORD DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH NON-BIOLOGIC DMARD THERAPY (INCLUDING BUT NOT LIMITED TO METHOTREXATE, SULFASALAZINE, AND/OR LEFLUNOMIDE). FOR UC: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. FOR PCJIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA OR ENBREL. FOR AS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF ENBREL OR HUMIRA. FOR CONTINUED THERAPY: MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

GHP Medicare Formulary - Prior Authorization Criteria

Page 543 of 591

Effective 12/2023

XENLETA

Affected Drugs:

Xenleta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of community acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenza, Legionella pneumophila, Mycoplasma pneumoniae, or Chlamydophila pneumoniae.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration:1 week

Other Criteria:Documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to two other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

XENPOZYME

Affected Drugs:

Xenpozyme

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 Restrictions:N/A

Prescription Order Restrictions: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.

XERMELO

Affected Drugs:

Xermelo

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 Restrictions: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

XGEVA

Affected Drugs:

Xgeva

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF BONE METASTASES RELATED TO DISEASE PROGRESSION FROM A SOLID TUMOR (E.G. BREAST, PROSTATE, THYROID) or DOCUMENTATION OF TREATMENT OF ADULTS OR SKELETALLY MATURE ADOLESCENTS WITH GIANT CELL TUMOR OF BONE THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY or DOCUMENTATION OF HYPERCALCEMIA OF MALIGNANCY THAT IS REFRACTORY TO INTRAVENOUS BISPHOSPHONATE THERAPY OR DOCUMENTATION OF USE FOR THE PREVENTION OF SKELETAL RELATED EVENTS IN ADULT PATIENTS WITH MULTIPLE MYELOMA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:N/A

XIFAXAN

Affected Drugs:

Xifaxan

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of traveler's diarrhea (TD) OR diagnosis of hepatic encephalopathy (HE) OR Irritable bowel syndrome with diarrhea (IBS-D).

Age Restrictions:N/A

Prescription Order Restrictions: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. For TD: documentation of a therapeutic failure on, intolerance to or contraindication to azithromycin and one oral fluoroquinolone. For HE: documentation of use concurrently with lactulose or documentation of a therapeutic failure on, intolerance to, or contraindication to lactulose. For IBS-D: documentation of a therapeutic failure on, intolerance to, or contraindication to dicyclomine and loperamide. 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.

XOLAIR

Affected Drugs:

Xolair

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.

Age Restrictions: ASTHMA: 6 YRS OR OLDER, URTICARIA: 12 YRS OR OLDER, POLYPS: 18 YRS OR OLDER

Prescription Order Restrictions:ASTHMA: ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST. URTICARIA: ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST. POLYPS: BY OR IN CONSULTATION WITH ALLERGIST, PULMONOLOGIST OR OTOLARYNGOLOGIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH BENRALIZUMAB, DUPILUMAB, MEPOLIZUMAB, TEZEPELUMAB OR RESLIZUMAB. 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 MAXIMAL DOSE OF ONE ANTIHISTAMINE USED IN COMBINATION WITH EITHER A H2 RECEPTOR ANTAGONIST OR LEUKOTRIENE RECEPTOR MODIFIER OR ANTAGONIST. 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. REAUTHORIZATION FOR ALL INDICATIONS WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF DISEASE

GHP Medicare Formulary - Prior Authorization Criteria

Page 549 of 591

Effective 12/2023

XOSPATA

Affected Drugs:

Xospata

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Documentation of a diagnosis of relapsed or refractory acute myeloid leukemia (AML) AND documentation of a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA approved test

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

XPOVIO

Affected Drugs:

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)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of use in combination with dexamethasone for relapsed or refractory multiple myeloma AND documentation of previously receiving four prior regimens which include at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. Documentation of use for multiple myeloma, used in combination with bortezomib and dexamethasone following at least one prior therapy. Documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma AND documentation of treatment with at least two prior lines of therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

XTANDI

Affected Drugs:

Xtandi

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF PROSTATE CANCER AND DOCUMENTATION OF EITHER 1) NO LONGER RESPONDING TO CASTRATION OR HORMONE RESISTANT, OR 2) THAT MEMBER AS METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION THAT A GONADOTROPIN-RELEASING HORMONE (GnRH) ANALOG WILL BE USED CONCURRENTLY OR DOCUMENTATION OF BILATERAL ORCHIECTOMY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

XYREM

Affected Drugs:

Xyrem

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 Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:For excessive daytime sleepiness with narcolepsy: therapeutic failure on, intolerance to, or contraindication to modafinil AND either methylphenidate IR or amphetamine/dextroamphetamine IR. Reauthorization will require documentation of reduction in frequency of cataplexy attacks OR documentation of reduction in symptoms of excessive daytime sleepiness.

XYWAV

Affected Drugs:

Xywav

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 Restrictions: FOR IDIOPATHIC HYPERSOMNIA: 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 XYREM OR DOCUMENTATION OF REQUIRING A LOW SODIUM ALTERNATIVE 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 OF REDUCTION IN FREQUENCY OF CATPLEXY ATTACKS OR REDUCTION IN SYMPTOMS OF EXCESSIVE DAYTIME SLEEPINESS OR IDIOPATHIC HYPERSOMNIA.

YERVOY

Affected Drugs:

Yervoy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF UNRESECTABLE OR METASTATIC MELANOMA WITH ONE OF THE FOLLOWING: IN COMBO W/ NIVOLUMAB FOR FIRST LINE THERAPY OR AS A SINGLE AGENT OR IN COMBO W/ NIVOLUMAB AS SECOND LINE OR SUBSEQUENT THERAPY FOR DISEASE PROGRESSION IF NOT PREVIOUSLY USED OR DOCUMENTATION OF USE AS SINGLE AGENT REINDUCTION THERAPY IN SELECT PATIENTS WHO EXPERIENCED NO SIGNIFICANT TOXICITY DURING PRIOR IPILIMUMAB THERAPY AND WHO RELAPSE AFTER INITIAL CLINICAL RESPONSE OR PROGRESS AFTER STABLE DISEASE FOR GREATER THAN 3 MONTHS OR DOCUMENTATION OF USE AS A SINGLE AGENT FOR ADJUVANT THERAPY FOR STAGE IIIA WITH METASTASES GREATER THAN 1 MM, OR STAGE IIIB OR STAGE IIIC CUTANEOUS MELANOMA WITH NODAL METASTASES FOLLOWING A COMPLETE LYMPH NODE DISSECTION OR RESECTION OR FOLLOWING COMPLETE LYMPH NODE DISSECTION OR COMPLETE RESECTION OF NODAL RECURRENCE. DX OF PREVIOUSLY UNTREATED ADVANCED RENAL CELL CARCINOMA USED IN COMBO W/ NIVOLUMAB WITH DOCUMENTATION OF INTERMEDIATE TO POOR RISK (DEFINED AS HAVING 1 OR MORE PROGNOSTIC RISK FACTORS AS PER THE IMDC CRITERIA). DX OF MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR) METASTATIC COLORECTAL CANCER WITH PROGRESSION FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN OR IRINOTECAN BASED THERAPY AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBO W/ NIVOLUMAB. DOUMENTATION OF HEPATOCELLULAR CARCINOMA USED IN COMBO W/ NIVOLUMAB. DX OF FIRST LINE METASTATIC OR RECURRENT NON SMALL CELL LUNG CANCER (NSCLC) WITH DOCUMENTION OF NO EFGR OR ALK GENOMIC TUMOR ABBERATIONS AND EITHER DOCUMENTATION OF PD-L1 GREATER THAN 1% USED IN COMBO W/ NIVOLUMAB OR DOCUMENTATION OF USE IN COMBO W/ NIVOLUMAB AND 2 CYCLES OF PLATINUM DOUBLET CHEMOTHERAPY. DX OF UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA AND DOCUMENTATION OF USE IN COMBO W/ NIVOLOUMAB. DX OF UNRESECTABLE ADVANCED OR METASTATIC ESOPHAGEAL SQUAMOUS CELL CARCINOMA AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBO W/ NIVOLUMAB.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

GHP Medicare Formulary - Prior Authorization Criteria

Page 555 of 591

Effective 12/2023

Coverage Duration:ADJ. MELANOMA:6 MO W/12 MO REAUTH. NSCLC &MESOTHELIOMA:6 MO W/18 MO REAUTH. ALL OTHERS: 6 MO.

Other Criteria: FOR HCC: DOCUMENTATION OF A THERAPEUTIC FAILURE ON OR INTOLERANCE TO SORAFENIB. REAUTHORIZATION FOR ADJUVANT TREATMENT OF MELANOMA WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION FOR OTHER INDICATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND 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.

YONDELIS

Affected Drugs:

Yondelis

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF UNRESECTABLE OR METASTATIC LIPOSARCOMA OR LEIOMYOSARCOMA AND DOCUMENTATION OF PRIOR THERAPY WITH AN ANTHRACYCLINE CONTAINING REGIMEN

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

YONSA

Affected Drugs:

Yonsa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of prostate cancer with evidence of metastatic disease AND member is no longer responding to castration or is hormone resistant.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria: Documentation that methylprednisolone will be administered concomitantly with Yonsa. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

ZALTRAP

Affected Drugs:

Zaltrap

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC COLORECTAL CANCER THAT IS RESISTANT TO OR HAS PROGRESSED FOLLOWING AN OXALIPLATIN CONTAINING REGIMEN AND USE IN COMBINATION WITH IRINOTECAN OR FOLFIRI (5-FLUOROURACIL, LEUCOVORIN, IRINOTECAN)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZARXIO

Affected Drugs:

Zarxio

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. 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. FOR NEUPOGEN ONLY: HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

Age Restrictions:N/A

Prescription Order Restrictions: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

GHP Medicare Formulary - Prior Authorization Criteria

Page 560 of 591

Effective 12/2023

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).

ZAVESCA

Affected Drugs:

migLUstat

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF MILD TO MODERATE TYPE 1 GAUCHER DISEASE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:FOR WHOM ENZYME REPLACEMENT THERAPY IS NOT A THERAPEUTIC OPTION (I.E. BECAUSE OF CONSTRAINTS SUCH AS ALLERGY, HYPERSENSITIVITY, OR POOR VENOUS ACCESS).

ZEJULA

Affected Drugs:

Zejula

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER AND DOCUMENTATION THE MEDICATION IS BEING USED AS MAINTENANCE TREATMENT AND DOCUMENTATION OF COMPLETE OR PARTIAL RESPONSE TO FIRST-LINE PLATINUM-BASED CHEMOTHERAPY AND DOCUMENTATION THAT MEDICATION IS BEING GIVEN AT A DOSAGE CONSISTENT WITH PRODUCT LABELING. DIAGNOSIS OF DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BRCA-MUTATED RECURRENT EPITHELIAL OVARIAN, PRIMARY PERITONEAL, OR FALLOPIAN TUBE CANCER AND DOCUMENTATION OF RECEIVING AT LEAST 2 PRIOR PLATINUM-CONTAINING REGIMENS AND DOCUMENTATION THE MEDICATION IS BEING USED AS MAINTENANCE TREATMENT AND DOCUMENTATION OF COMPLETE OR PARTIAL RESPONSE TO THE MOST RECENT PLATINUM-BASED CHEMOTHERAPY AND DOCUMENTATION THAT MEDICATION IS BEING GIVEN AT A DOSAGE CONSISTENT WITH PRODUCT LABELING.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZEPOSIA

Affected Drugs:

Zeposia Zeposia 7-Day Starter Pack Zeposia Starter Kit

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF MULTIPLE SCLEROSIS. DIAGNOSIS OF MODERATE TO SEVERE ULCERATIVE COLITIS.

Age Restrictions: FOR UC: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: 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 (HUMIRA, SIMPONI, XELJANZ, RINVOQ). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

ZEPZELCA

Affected Drugs:

Zepzelca

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF METASTATIC SMALL CELL LUNG CANCER (SCLC) AND DOCUMENTATION OF DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:6 MONTHS

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZERBAXA

Affected Drugs:

Zerbaxa

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:Diagnosis of complicated intra-abdominal infection (cIAI) caused by one of the following susceptible microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, or Streptococcus salivarius OR Diagnosis of complicated Urinary tract infection (including pyelonephritis) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Pseudomonas aeruginosa OR Diagnosis of Hospital acquired bacterial pneumonia or Ventilator associated bacterial pneumonia (HABP/VABP) caused by Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Serratia marcescens.

Age Restrictions: FOR HABP/VABP ONLY: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration:For UTI 1 week. For cIAI or HABP/VABP 2 weeks.

Other Criteria:Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatements OR a documented history of previous intolerance to or contraindication to two preferred alternative formulary antibiotics shown to be susceptible on the culture and sensitivity.

ZIEXTENZO

Affected Drugs:

Ziextenzo

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.

Age Restrictions:N/A

Prescription Order Restrictions: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).

ZINPLAVA

Affected Drugs:

Zinplava

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.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:PRESCRIBED BY GASTROENTEROLOGIST OR WITH CONSULTATION FROM INFECTIOUS DISEASE PROVIDER

Coverage Duration: ONE FILL FOR ONE DOSE

Other Criteria:N/A

ZOKINVY

Affected Drugs:

Zokinvy

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF A CONFIRMED DIAGNOSIS THROUGH GENETIC TESTING OF ONE OF THE FOLLOWING: HUTCHINSON-GILFORD PROGERIA SYNDROME OR PROCESSING DEFICIENT PROGEROID LAMINOPATHY WITH EITHER 1) HETEROZYGOUS LMNA MUTATION WITH PROGERIN-LIKE PROTEIN ACCUMULATION OR 2) HOMOZYGOUS OR COMPOUND HETEROZYGOUS ZMPSTE24 MUTATIONS.

Age Restrictions: MUST BE 12 MONTHS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION OF BODY SURFATE AREA OF AT LEAST 0.39M2. DOCUMENTATION THAT THE REQUESTED DOSE IS APPROPRIATE BASED ON THE PATIENT'S BODY SURFACE AREA 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 TO THE BENEFICIARY REGARDING THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION THAT THE REQUESTED DOSE CONTINUES TO BE APPROPRIATE BASED ON THE PATIENT'S BODY SURFACE AREA 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 TO THE BENEFICIARY REGARDING THE RISKS ASSOCIATED WITH THE USE OF BOTH MEDICATIONS WHEN THEY INTERACT).

ZONTIVITY

Affected Drugs:

Zontivity

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF MYOCARDIAL INFARCTION (MI) OCCURRING LESS THAN 12 MONTHS PRIOR TO STARTING THERAPY OR DOCUMENTATION OF PERIPHERAL ARTERIAL DISEASE (PAD) AS INDICATED BY A HISTORY OF INTERMITTENT CLAUDICATION AND RESTING ANKLE/BRACHIAL INDEX (ABI) OF LESS THAN 0.85 OR AMPUTATION, PERIPHERAL BYPASS, OR PERIPHERAL ANGIOPLASTY OF THE EXTREMITIES SECONDARY TO ISCHEMIA.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR MI AND PAD: DOCUMENTATION OF NO PRIOR HISTORY OF STROKE, TIA, OR ICH AND DOCUMENTATION OF CONCOMITANT THERAPY WITH ASPIRIN ALONE, A THIENOPYRIDINE (CLOPIDOGREL) ALONE, OR A COMBINATION OF ASPIRIN AND CLOPIDOGREL.

ZORBTIVE

Affected Drugs:

Zorbtive

Off-Label Uses:N/A

Exclusion Criteria:DOCUMENTATION OF ACUTE ILLNESS DUE TO COMPLICATIONS FROM OPEN HEART OR ABDOMINAL SURGERY, MULTIPLE ACCIDENT TRAUMA, OR ACUTE RESPIRATORY FAILURE.

Required Medical Information:DIAGNOSIS OF SHORT BOWEL SYNDROME and DOCUMENTATION OF CURRENT, DAILY THERAPIES WITH PARENTERAL NUTRITION (TPN OR PPN) AND/OR ENTERAL NUTRITION SUPPORT.

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:2 MONTHS

Other Criteria:N/A

ZORTRESS

Affected Drugs:

Everolimus

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 Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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.

ZORYVE

Affected Drugs:

Zoryve

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PLAQUE PSORIASIS AND BODY SURFACE AREA LESS THAN OR EQUAL TO 20 PERCENT.

Age Restrictions:12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: DERMATOLOGIST OR RHEUMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

Other Criteria:THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST ONE OF THE FOLLOWING: (1) A HIGH- TO ULTRA-HIGH-POTENCY TOPICAL CORTICOSTEROID USED CONCURRENTLY WITH A GENERI TOPICAL CALCIPOTRIENE PRODUCT OR (2) A GENERIC CALCIPOTRIENE-BETAMETHASONE PRODUCT OR (3) A HIGH-TO ULTRA-HIGH-POTENCY TOPICAL CORTICOSTEROID USED CONCURRENTLY WITH GENERIC TAZAROTENE 0.1%. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT BASED ON SIGNS AND SYMPTOMS OF PLAQUE PSORIASIS.

ZTALMY

Affected Drugs:

Ztalmy

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 Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: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 OF AT LEAST TWO PREVIOUS ANTIEPILEPTIC THERAPIES. 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.

ZULRESSO

Affected Drugs:

Zulresso

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.)

Age Restrictions:N/A

Prescription Order Restrictions: 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.

ZYDELIG

Affected Drugs:

Zydelig

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR CLL - DOCUMENTATION OF CONCURRENT USE WITH RITUXIMAB. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZYKADIA

Affected Drugs:

Zykadia

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK) POSITIVE AS DETECTED BY AN FDA APPROVED TEST

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER: DOCUMENTATION OF RATIONALE FOR NOT TREATING WITH ALECENSA IF CLINICALLY APPROPRIATE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZYNLONTA

Affected Drugs:

Zynlonta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DOCUMENTATION OF RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA INCLUDING DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND HIGH-GRADE B-CELL LYMPHOMA AND DOCUMENTATION OF PRIOR TREATMENT WITH TWO OR MORE LINES OF SYSTEMIC THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

ZYNYZ

Affected Drugs:

Zynyz

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF METASTATIC OR RECURRENT LOCALLY ADVANCED MERKEL CELL CARCINOMA.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTH INITIAL, 12 MONTH CONTINUATION

Other Criteria:REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

ZYTIGA

Affected Drugs:

Abiraterone Acetate

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DIAGNOSIS OF PROSTATE CANCER WITH EVIDENCE OF METASTATIC DISEASE. DOCUMENTATION OF EITHER MEMBER IS NO LONGER RESPONDING TO CASTRATION OR IS HORMONE RESISTANT or THAT THE MEMBER HAS HIGH-RISK, CASTRATION SENSITIVE DISEASE.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION THAT PREDNISONE WILL BE ADMINISTERED CONCOMITANTLY WITH ABIRATERONE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Drugs that may be covered under Medicare Part B or Part D

Abelcet IV	Acetylcysteine INH
Acyclovir Sodium IV	Albuterol Sulfate INH
AmBisome IV	Aminosyn II IV
Aminosyn-PF IV	Aminosyn-PF 7% IV
Amphotericin B IV	Amphotericin B Liposome IV
Atgam IV	Azasan Oral Tab
azaTHIOprine Oral Tab	azaTHIOprine Sodium INJ
Bleomycin Sulfate INJ	Budesonide INH
Cladribine IV	Clinisol SF IV
Clinolipid IV	Cromolyn Sodium INH
cycloPHOSphamide Oral Cap	cycloSPORINE IV
cycloSPORINE Modified Oral Cap	Cytarabine INJ
Cytarabine (PF) INJ	Dextrose IV
DOBUTamine HCI IV	DOBUTamine in D5W IV
DOXOrubicin HCI IV	Engerix-B INJ
Envarsus XR Oral Tab ER 24H	Floxuridine INJ
Fluorouracil IV	Foscarnet Sodium IV
Ganciclovir Sodium IV	Gengraf Oral Cap
Granisetron HCI Oral Tab	Heparin Sodium (Porcine)
Heparin Sodium (Porcine) PF INJ	Heplisav-B

Imovax Rabies IM	Intralipid IV
Ipratropium Bromide INH	Ipratropium-Albuterol INH
Levalbuterol HCI INH	Methotrexate Sodium INJ
methyIPREDNISolone Oral Tab	Milrinone Lactate IV
Milrinone Lactate in Dextrose IV	Mycophenolate Mofetil IV
Mycophenolate Mofetil HCI IV	Mycophenolate Sodium Oral Tab
Nutrilipid IV	Ondansetron
Ondansetron HCI Oral Soln	Pentamidine Isethionate INH
prednisoLONE Oral Soln	prednisoLONE Sodium Phosphate Oral Soln
predniSONE Oral Soln	PreHevbrio IM
Premasol IV	Prograf IV
Prosol IV	RabAvert IM
Recombivax HB INJ	SandIMMUNE Oral Soln
Simulect IV	Sirolimus Oral Soln
Tacrolimus Oral Cap	Thymoglobulin IV
Travasol IV	TrophAmine IV
vinBLAStine Sulfate IV	vinCRIStine Sulfate IV
Yupelri INH	

Α

Abelcet	576
Abilify Asimtufii	20
Abilify Maintena	224
Abilify MyCite	21
Abilify MyCite Maintenance Kit	21
Abilify MyCite Starter Kit	
Abiraterone Acetate	
Abraxane	
Acetylcysteine	576
Acitretin	428
Actemra	23, 24
Actemra ACTPen	24
Acyclovir Sodium	
Adakveo	26
Adasuve	27
Adbry	28
Adcetris	29
Adempas	31
Aimovig	34
Ajovy	35
Akynzeo	36
Albuterol Sulfate	576
Aldurazyme	37
Alecensa	38
Aliqopa	40
Alkindi Sprinkle	41
Alunbrig	43
Alyq	30
AmBisome	
Ambrisentan	266
Aminosyn II	576
Aminosyn-PF	
Aminosyn-PF 7%	576
Amitriptyline HCI	465
Amondys 45	44
Amoxapine	465
Amphotericin B	
Amphotericin B Liposome	576
Amvuttra	45
Aprepitant	145
Aptiom	47

Azasan

В

Balversa Bavencio Baxdela Beconase AQ Beleodaq Benlysta Besponsa Besremi	64 65 66 67 70 71
Bexarotene	
Beyfortus	75
Bivigam	235
Bleomycin Sulfate	576
Blincyto	76
Bonjesta	
Bortezomib	508
Bosentan	481

Bosulif79Braftovi80Briumvi82Briviact83Brukinsa85Budesonide576Budesonide ER86Bylvay87Bylvay87
Bylvay (Pellets)

С

Cablivi Cabometyx Calquence Camzyos Caplyta Caprelsa Carbaglu	89 90 91 92 504 93
Carglumic Acid	
Cerezyme	
chlordiazePOXIDE-Amitriptyline	
Cholbam	
Chorionic Gonadotropin	
Cibinqo	
Cimzia Cimzia Starter Kit	
Cinryze	
Cladribine	
Clinisol SF	
Clinolipid	
Clofarabine	. 103
clomiPRAMINE HCI	
Columvi	
Cometriq (100 MG Daily Dose)	. 106
Cometriq (140 MG Daily Dose)	
Cometriq (60 MG Daily Dose)	
Corlanor	
Cosela	
Cosentyx	
Cosentyx (300 MG Dose)	
Cosentyx Sensoready (300 MG)	
Cosentyx Sensoready Pen	. 110

Cotellic Crinone Cromolyn Sodium Crysvita Cutaquig Cuvitru Cuvrior cycloPHOSphamide Cycloset cycloSPORINE cycloSPORINE Modified Cyproheptadine HCI Cyramza	113 576 115 235 235 116 576 117 576 576 118
Cytarabine	
Cytarabine (PF)	576
D	

D

Daliresp Danyelza Darzalex Darzalex Faspro Daurismo Daybue Deferasirox Deferasirox Granules Deferiprone Deferiprone Destrose	
Diacomit	
Diclofenac Epolamine	
Dificid	
DOBUTamine HCI	
DOBUTamine in D5W	
Dojolvi	132
Doptelet	133
Doxepin HCI	
DOXOrubicin HCI	576
Doxylamine-Pyridoxine	130
Drizalma Sprinkle	
droNABinol	
Droxidopa	
Duavee	
Dupixent	

Elaprase	. 139
Elelyso	. 140
Elfabrio	. 141
Elitek	. 143
Elrexfio	. 144
Emflaza	. 146
Emgality	. 147
Emgality (300 MG Dose)	
Empaveli	
Empliciti	
Emverm	
Enbrel	
Enbrel Mini	
Enbrel SureClick	
Endari	
Engerix-B	
Enhertu	
Enspryng	
Envarsus XR	
Epidiolex	
Epkinly	
Epogen	
Epoprostenol Sodium	
Eprontia	
Epronia	
Erivedge	
Erleada	
Erlotinib HCl	
Erwinase	
Erwinaze	
Esbriet	
Esomeprazole Sodium	
Eszopiclone	
Eucrisa	
Evenity	. 168
Everolimus	
Evkeeza	
Evrysdi	
Exkivity	
Exondys 51	
Exservan	
Eysuvis	. 175

F

Fabior	176
Fabrazyme	177
Farydak	
Fasenra	
Fasenra Pen	179
Fensolvi (6 Month)	180
fentaNYL Citrate	25
Ferriprox	182
Ferriprox Twice-A-Day	182
Fetroja	183
Fetzima	
Fetzima Titration	184
Filspari	185
Fintepla	186
Firdapse	188
Flebogamma DIF	
Floxuridine	576
Fluorouracil	576
Formoterol Fumarate	358
Foscarnet Sodium	576
Fotivda	191
Fyarro	192
Fycompa	
Fylnetra	194
•	

G

Effective 12/2023

glyBURIDE-metFORMIN	. 439
Granisetron HCI	
guanFACINE HCI ER	. 229

Η

Haegarda20Halaven20Heparin Sodium (Porcine)57Heparin Sodium (Porcine) PF57Heplisav-B57Hetlioz20Hetlioz LQ20Hizentra23Humira20Humira Pediatric Crohns Start20Humira Pen20Humira Pen20Humira Pen20Humira Pen-CD/UC/HS Starter20Humira Pen-Pediatric UC Start20Humira Pen-Psor/Uveit Starter20Humira Pen-Psor/Uveit Starter20Humira Pen-Psor/Uveit Starter20Humira Pen-Psor/Uveit Starter20HumuLIN R U-500 (CONCENTRATED)22HumuLIN R U-500 KwikPen22Hyftor21Hyftor21Hyravia23	5666775888888888888
Hyftor	5 5
I	

Ibandronate Sodium	77
Ibrance	
Icatibant Acetate	187
Iclusig	
IDHIFA	
Igalmi	
llaris	
Imbruvica	
Imfinzi	
Imipramine HCI	465
Imipramine Pamoate	465
Imjudo	
Imlygic	220
Imovax Rabies	577
Inflectra	221
Ingrezza	
Inlyta	225
Inqovi	226

Inrebic	
Intralipid	.577
Invega Hafyera	.230
Invega Sustenna	224
Invega Trinza	224
Ipratropium Bromide	577
Ipratropium-Albuterol	.577
Iressa	.231
Itraconazole	.233
Ivermectin	234
Ixempra Kit	

J

Jakafi	
Jatenzo	239
Jaypirca	240
Jemperli	241
Jevtana	242
Joenja	243
Juxtapid	244
Jynarque	245

Κ

Kadcyla	246
Kalydeco	
Kerendia	
Kevzara	
Keytruda	
Kimmtrak	
Kineret	
Kisqali (200 MG Dose)	
Kisqali (400 MG Dose)	
Kisqali (600 MG Dose)	
Kisqali Femara (400 MG Dose)	
Kisqali Femara (600 MG Dose)	
Kisqali Femara(200 MG Dose)	
Korlym	
Koselugo	
Krazati	
Krystexxa	
Kyprolis	
L	

_acosamide51	9
--------------	---

Μ

Margenza	287
Marqibo	288
Mavenclad (10 Tabs)	289
Mavenclad (4 Tabs)	289
Mavenclad (5 Tabs)	289
Mavenclad (6 Tabs)	289
Mavenclad (7 Tabs)	289

Mavenclad (8 Tabs)	280
Mavenclad (9 Tabs)	
Mavyret	
Mekinist	
Mektovi	293
Meprobamate	294
Mepsevii	295
Methotrexate Sodium	577
methyIPREDNISolone	
metyroSINE	
migLUstat	
Milrinone Lactate	
Milrinone Lactate in Dextrose	
Modafinil	
Monjuvi	
Mounjaro	
Mulpleta	298
Mycophenolate Mofetil	
Mycophenolate Mofetil HCI	
Mycophenolate Sodium	
Myfembree	
,	
Mylotarg	
Myrbetriq	301

Ν

Nuedexta Nulibry	
Nulojix	
Nuplazid	
Nurtec	325
Nutrilipid	577
Nuzyra	
Nyvepria	329

0

Ocrevus. Odomzo Ofev Olumiant. Ondansetron Ondansetron HCI Onivyde Onpattro Onureg Opdivo Opdualag Opsumit. Opzelura Orencia Orencia ClickJect Orgovyx. Oriahnn Orilissa Orkambi Orladeyo Orserdu	331 332 333 577 577 334 335 336 337 339 340 341 342 342 343 344 345 345 346 347 348 349 350
	350 351

Ρ

PACLitaxel Protein-Bound Part	22
Padcev	353
Palonosetron HCI	42
Palynziq	354
Panretin	355
Panzyga	
PAZOPanib HCI	526

_	
Pemazyre	356
Pentamidine Isethionate	577
Pepaxto	
Perphenazine-Amitriptyline	
Perseris	
Pimecrolimus	
Piqray (200 MG Daily Dose)	
Piqray (250 MG Daily Dose)	
Piqray (300 MG Daily Dose)	360
Pirfenidone	166
Polivy	
Pomalyst	
Portrazza	
Posaconazole	
Praluent	
prednisoLONE	
prednisoLONE Sodium Phosphate	
predniSONE	
Pregabalin ER	
PreHevbrio	
Premasol	
Pretomanid	
Prevymis	
Privigen	
Procrit	
Procysbi	
Prograf	
Prolastin-C	
Prolia	
Promacta	
Promethazine HCI	
Prosol	
Protriptyline HCI	
Pulmozyme	
Pyrimethamine	
Pyrukynd	
Pyrukynd Taper Pack	

Q

Qalsody	.375
Qinlock	.376
quiNINE Sulfate	.378
Qulipta	.379

R

RabAvert	
Radicava	
Radicava ORS	
Radicava ORS Starter Kit	
Ravicti	
Reblozyl	
Rebyota	384
Recarbrio	385
Recombivax HB	577
Regranex	386
Releuko	387
Relistor	389
Relyvrio	390
Renflexis	221
Repatha	
Repatha Pushtronex System	
Repatha SureClick	
Retacrit	
Retevmo	
Revcovi	
Revlimid	
Rexulti	
Rezlidhia	
Rezurock	
Riabni	
Ribavirin	
Rinvog	
RisperDAL Consta	
Rituxan Hycela	
Roflumilast	
Rolvedon	
romiDEPsin	
Rozlytrek	
Rubraca	
Rufinamide	
Ruxience	
Rybrevant	
Rydapt	
Rylaze	410
S	
SandIMMUNE	

Saphnelo Sapropterin Dihydrochloride	
Sarclisa	
Scemblix	
Secuado	
Serostim	
Signifor	
Signifor LAR	
Siklos	421
Sildenafil Citrate	394
Simponi	422
Simulect	577
Sirolimus	577
Sirturo	423
Sivextro	
Skyclarys	
Skyrizi	
Skyrizi (150 MG Dose)	
Skyrizi Pen	426
Sofosbuvir-Velpatasvir	
SORAfenib Tosylate	
Spevigo	
Spravato (56 MG Dose)	
Spravato (84 MG Dose)	
Sprycel	
Stelara	
Stimufend	
Stivarga	
Strensiq	
SUNItinib Malate	
Sunosi	
Supprelin LA	
Sylvant	
Symdeko	
SymlinPen 120	
SymlinPen 60	
Sympazan	
Synagis	
Synercid	
	443

Т

Tabrecta	451
Tacrolimus	577

	~ -
Tadalafil	
Tadalafil (PAH)	30
Tafinlar	453
Tagrisso	454
Takhzyro	455
Talvey	456
Talzenna	
Tarpeyo	
Tasigna	
Tasimelteon	
Tavalisse	
Tavneos	
Tazarotene	
Tazverik	
Tecentriq	
Tecvayli	
Tegsedi	
Temsirolimus	480
Tepezza	470
Tepmetko	471
Teriparatide (Recombinant)	190
Tezspire	
Thioridazine HCI	473
Thymoglobulin	
Tibsovo	
Tiglutik	
Tivdak	
Tlando	
Tobi Podhaler	
Tobramycin	•
Topiramate ER	
Tracleer	
Travasol	
Tremfya	
Tretinoin	
Tretinoin Microsphere	
Tretinoin Microsphere Pump	483
Trientine HCI	450
Trihexyphenidyl HCI	46
Trikafta	
Trimipramine Maleate	
Trintellix	
Triptodur	

U

Ubrelvy	497
Udenyca	
Unituxin	
Uptravi	
Uzedy	

V

vinBLAStine Sulfate	
vinCRIStine Sulfate	577
Vitrakvi	521
Vivjoa	
Vizimpro	
Vonjo	524
Voriconazole	525
Votrient	526
Vowst	
Vpriv	
Vraylar	
Vuity	
•	
Vyepti	531
Vyndamax	452
Vyndaqel	
Vyondys 53	
Vyxeos	
v yxeus	
W	

W

Welireg	535

Χ

Xalkori Xatmep Xcopri Xcopri (250 MG Daily Dose)	536 537
Xcopri (350 MG Daily Dose)	
Xeljanz	538
Xeljanz XR	538
Xembify	235
Xenleta	
Xenpozyme	540
Xermelo	
Xgeva	542
Xifaxan	
Xolair	
Xospata	
Xpovio (100 MG Once Weekly)	
Xpovio (40 MG Once Weekly)	
Xpovio (40 MG Twice Weekly)	

Xpovio (60 MG Once Weekly)	546
Xpovio (60 MG Twice Weekly)	546
Xpovio (80 MG Once Weekly)	546
Xpovio (80 MG Twice Weekly)	546
Xtandi	547
Xyrem	548
Xywav	549

Y

Yervoy	550
Yondelis	552
Yonsa	553
Yupelri	577

Ζ

Zaleplon	427
Zaltrap	
Zarxio	
Zejula	
Zelboraf	
Zeposia	
Zeposia 7-Day Starter Pack	
Zeposia Starter Kit	
Zepzelca	
Zerbaxa	
Ziextenzo	
Zinplava	
Zokinvy	
Zolpidem Tartrate	
Zolpidem Tartrate ER	
Zontivity	
Zorbtive	
Zoryve	568
Ztalmy	569
Zulresso	570
Zydelig	571
Żykadia	572
Żynlonta	
Źynyz	
ZyPREXA Relprevv	