P&T Committee Meeting Minutes
Commercial/Marketplace/CHIP
August 27, 2021 e-vote

DRUG REVIEWS

AMONDYS 45 (casimersen)

Review: Amondys 45 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. Amondys 45 is the fourth antisense oligonucleotide approved for DMD and the first to target the DMD gene that is amenable to exon 45 skipping, which occurs in about 8% of patients with DMD. All four exon-skipping therapies (i.e., Viltepso, Exondys 51, Vyondys 53, and Amondys 45) work by increasing the levels of dystrophin in skeletal muscle, but it is unclear at this time whether increased dystrophin will lead to clinical improvement in survival or functional outcomes.

The effect of Amondys 45 on dystrophin production was evaluated in the ESSENCE trial, an ongoing, double-blind, placebo-controlled study in male patients with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. Patients are randomized 2:1 to received Amondys 45 or placebo for a 96-week double-blind period, followed by a 48-week open-label treatment period for all patients. Interim analysis was assessed as change from baseline in dystrophin protein level (% of dystrophin level in healthy subjects) at Week 48. This was evaluable in 43 patients who received Amondys 45 (n=27) or placebo (n=16) who had a muscle biopsy at Week 48 of the double-blind treatment period. Patients treated with Amondys 45 showed a statistically greater increase in dystrophin protein levels in skeletal muscle compared to patients treated with placebo (p=0.004).

There are no black box warnings for Amondys 45. There are warnings for kidney toxicity which was observed in animals treated with casimersen. Kidney toxicity has not been observed in clinical studies with Amondys 45, but it has been observed after administration of some antisense oligonucleotides and can include potentially fatal glomerulonephritis. During clinical trials, the most common adverse reactions (≥ 20% of patients and at least 5% more frequently than placebo) were upper respiratory tract infections, cough, pyrexia, headache, arthralgia, and oropharyngeal pain.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Amondys 45 is a medical benefit. When Amondys is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Amondys will require prior authorization with the following criteria:

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g., geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**

- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 45 skipping confirmed by a genetic counselor **AND**
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Amondys 45 is being given concurrently with oral corticosteroids unless contraindicated or intolerant **AND**
- Medical record documentation that patient will receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 30 mg/kg infused once weekly) **AND**
- Medical record 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 Amondys 45

Note: Exon Deletions* on the Duchenne Muscular Dystrophy Gene Theoretically Amenable to Exon 45 Skipping

7-44									
12-44	18-44								
44									
46	46-47	46-48	46-49	46-51	16-53	46-55	46-57	46-59	46-60
46-67	46-69	46-75	46-78						

*The first number represents the first exon deleted. The last number is the last exon deleted. The dash (-) represents all exons in between the first and last exon deleted.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation that the member continues to benefit from treatment with casimersen **AND**
- Medical record documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Amondys 45 continues to be given concurrently with oral corticosteroids unless contraindicated or intolerant **AND**
- Medical record documentation that the patient will continue to receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 30 mg/kg infused once weekly) **AND**
- Medical record documentation that the 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

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

BREZTRI (budesonide/glycopyrrolate/formoterol fumarate)

Review: Breztri Aerosphere is a metered-dose inhaler containing a fixed combination of an inhaled corticosteroids, a long-acting beta-2 agonist, and a long-acting muscarinic antagonist which all have different effects on clinical physiology and inflammation associated with COPD. Breztri Aerosphere is the second triple therapy approve for COPD after Trelegy Ellipta. Breztri and Trelegy have a similar side effect profile, and both have demonstrated improvements in lung function and reduction of COPD exacerbations. Trelegy may offer a

slight advantage with once daily dosing compared to twice daily for Breztri and it also has indications for maintenance treatment in adult patients with asthma while Breztri does not.

The efficacy of Breztri was evaluated in two randomized, double-blind, parallel group trials in patients with moderate to severe COPD who remained symptomatic while receiving 2 or more inhaled maintenance treatments for COPD for at least 6 weeks prior to screening.

The ETHOS trial included 8,588 patients randomized 1:1:1:1 to receive Breztri Aerosphere (320 mcg/18 mcg/9.6 mcg), budesonide/glycopyrrolate/formoterol fumarate MDI 160 mcg/18 mcg/9.6 mcg (not an approved dosage), glycopyrrolate/formoterol (GFF) MDI 18 mcg/9.6 mcg, or budesonide/formoterol (BFF) MDI 320 mcg/9.6 mcg, all administered twice daily. Treatment with Breztri demonstrated a reduction in the rate of on-treatment moderate or severe COPD exacerbations over 52 weeks, an increase in FEV1 area under the curve from 0-4 hours (FEV1 AUC0-4), and an increase change from baseline in morning pre-dose trough FEV1 at Week 24 compared with GFF MDI and BFF MDI.

The KRONOS trial included 1,896 patients randomized 2:2:1:1 to receive Breztri Aerosphere (320 mcg/18 mcg/9.6 mcg), glycopyrrolate/formoterol (GFF) MDI 18 mcg/9.6 mcg, or budesonide/formoterol (BFF) MDI 320 mcg/9.6 mcg, or an open-label active comparator, all administered twice daily. Breztri also demonstrated an increase in mean change from baseline in morning pre-dose FEV1 at Week 24 with GFF MDI, but this was not statistically significant. Treatment with Breztri reduced the annual rate of on-treatment moderate or severe COPD exacerbations compared to both GFF MDI (not statistically significant due to hierarchical analysis) and BFF MDI.

There are no black box warnings for Breztri Aerosphere. Warnings and precautions for Breztri Aerosphere are consistent with other dual- and triple-combination inhalers. During clinical trials of Breztri Aerosphere, the most common adverse reactions were upper respiratory infections, dysphonia, and muscle spasms.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Breztri Aerosphere is a pharmacy benefit and will be added to the Brand Preferred Tier of pharmacy formulary. Breztri Aerosphere will not require a prior authorization. The following quantity limits will apply:

QUANTITY LIMIT: 10.7 grams per 28 days

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

EVKEEZA (evinacumab-dgnb)

Review: Evkeeza is a recombinant human monoclonal antibody that binds to and inhibits angiopoietin-like 3 (ANGPTL3) indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH). It offers a new mechanism of action for the treatment of patients with HoFH who

often require multiple intensive LDL-lowering therapies to reach their LDL goals. The treatment guidelines for the management of dyslipidemias and HoFH have not been updated since the approval of Evkeeza but it is expected that placement in therapy will be similar to Juxtapid which is also is reserved for patients who have failed other LDL-C lowering therapies and lipoprotein apheresis.

The efficacy of Evkeeza was evaluated in the ELIPSE-HoFH trial, a double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of Evkeeza compared to placebo in 65 patients 12 years of age and older with homozygous familial hypercholesterolemia (HoFH). During the 24-week, double-blind treatment period, patients were randomized to treatment with Evkeeza 15 mg/kg IV every 4 weeks (n=43) or placebo (n=22). After the double-blind treatment period, 64 of 65 patients entered a 24-week open-label extension period during which all patients received treatment with Evkeeza.

The primary efficacy endpoint was percent change in LDL-C from baseline to week 24. At week 24, the least mean squares difference between Evkeeza and placebo in mean percent change in LDL-C from baseline was -49%. After 24 weeks of open-label treatment (Week 24 to 48), the observed LDL-C reduction from baseline was similar in patients who crossed over from placebo to Evkeeza and was maintained in patients who remained on Evkeeza for 48 weeks. At Week 24, the observed reduction in LDL-C was consistent across all predefined subgroups, including age, limited LDLR activity, concomitant treatment with lipoprotein apheresis, and concomitant background lipid-lowering medications.

There are no black box warnings for Evkeeza. There are warnings for serious hypersensitivity reactions (including 1 case of anaphylaxis during clinical trials) and embryo fetal toxicity based on animal reproduction studies. During clinical trials, the most common adverse reactions which occurred in over 3% of patients treated with Evkeeza and were greater than placebo included nasopharyngitis, influenza like illness, dizziness, rhinorrhea, nausea, pain in extremities and asthenia.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Evkeeza is a medical benefit. When Evkeeza is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Evkeeza will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene **AND**
- Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and low-density lipoprotein (LDL) apheresis treatment defined as:
    - Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 12 years of age and less than 18 years of age **OR**
    - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease **OR**
    - Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease

AND

- Medical record documentation of Evkeeza to be used in adjunct with maximum tolerated statin dose **AND** low density lipoprotein (LDL) apheresis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **AND**
- If the request is for use in combination with Juxtapid:
    - Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 6-month trial of maximum tolerated Juxtapid dose without the concomitant use of Evkeeza

QUANTITY LIMITS: 21 tablets/28 days

AUTHORIZATION DURATION: Initial authorization will be for a period of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year, requiring medical record documentation that current medical necessity criteria are met and that therapy has been effective.

Other Recommendations: The following updates are recommended for Juxtapid due to the discontinuation of Kynamro and the expanded approval of Praluent for HoFH. The following changes to the Juxtapid quantity limit are recommended due to the discontinuation of Juxtapid 40 mg and 60 mg capsules. Based on feedback, patients should not start Juxtapid and Evkeeza at the same time and should have an adequate trial of one medication before use in combination and it is recommended that criteria be added to both Juxtapid policies to require failure of Evkeeza prior to concomitant use. A 3-month trial of Evkeeza allows adequate time to initiate treatment and obtain LDL-C levels to assess efficacy of Evkeeza treatment.

Commercial Policy 293.0 Juxtapid

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene AND
- Medical record documentation that Juxtapid is prescribed by a hepatologist, lipidologist, or cardiologist registered with the Juxtapid risk evaluation and mitigation strategies (REMS) program AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and low-density lipoprotein (LDL) apheresis treatment defined as:
    - Greater than or equal to ~~200~~ 100 mg/dL in patients without cardiovascular disease
    - Greater than or equal to ~~160~~ 70 mg/dL in patients with established cardiovascular disease

AND

- Medical record documentation of Juxtapid to be used in adjunct with maximum tolerated statin dose AND low density lipoprotein (LDL) apheresis AND
- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kynamro* AND~~
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor.
- If the request is for use in combination with Evkeeza:
    - Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 3-month trial of Evkeeza without the concomitant use of Juxtapid

QUANTITY LIMIT: ~~1 capsule per day, 28 day supply per fill~~
5 mg and 10 mg capsules: 1 capsule per day, 28 day supply per fill
20 mg and 30 mg capsules: 2 capsules per day, 28 day supply per fill

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

LUMAKRAS (sotorasib)

Review: Lumakras is the first targeted treatment for any Kirsten rat sarcoma viral oncogene homologue (KRAS) mutation and is specifically indicated for patients with a KRAS G12C mutation. It forms an irreversible bond with the unique cysteine of KRAS which locks the protein into an inactive state and prevents downstream signaling, which leads to inhibition of cell growth and promoted apoptosis only in KRAS G12C tumor cell lines. Lumakras inhibition of KRAS in vitro and in vivo showed minimal detectable off-target activity. In mouse tumor xenograft models, it led to tumor regressions and prolonged survival and was associated with antitumor immunity in KRAS G12C modes.

Prior to the approval of Lumakras, there were no targeted therapies available for patients with KRAS G12C mutations, although immune checkpoint inhibitors have demonstrated efficacy with this mutation. First line treatments typically include platinum based chemotherapy and/or an immune checkpoint inhibitor.

The efficacy of Lumakras was evaluated in CodeBreaK 100, a single-arm, open-label trial in a subset of 124 adult patients with locally advanced or metastatic KRAS G12C mutated NSCLC with disease progression after receiving an immune checkpoint inhibitor and/or platinum-based chemotherapy. Patients were treated with Lumakras 960 mg once daily until disease progression or unacceptable toxicity. The major efficacy outcomes demonstrated a 36% objective response rate, with most patients achieving a partial response, and a median duration of response of 10 months.

There are no black box warnings for Lumakras. There are warnings for hepatotoxicity, which may lead to drug-induced liver injury and hepatitis, and interstitial lung disease (ILD) and pneumonitis. The most common adverse reactions (≥ 20%) included diarrhea, musculoskeletal pain, nausea, vomiting, constipation, abdominal pain, dyspnea, fatigue, hepatotoxicity, and cough. The most common laboratory abnormalities (≥ 25%) were decreased lymphocytes, hemoglobin, calcium, and sodium, and increased aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and urine protein.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Lumakras is a pharmacy benefit that will be added to the formulary at the OralOncBrandNP tier ($0 copay). Lumakras will require prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation that Lumakras is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a KRAS G12C mutation, as determined by an FDA-approved test* **AND**
- Medical record documentation of treatment with at least one prior systemic therapy.

***NOTE:** The FDA approved tests for the detection of KRAS G12C mutation in NSCLC are the therascreen KRAS RGQ PCR Kit and Guardant 360® CDx.

QUANTITY LIMIT: 8 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

REGEN-COV (casirivimab/imdevimab)

Review: REGEN-COV is a monoclonal antibody (mAb) indicated in adult and pediatric patients (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis to COVID-19 and for treatment of mild or moderate coronavirus disease 2019 (COVID-19) with positive results of direct SARS-CoV-2 viral testing in patients who are at a high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV is one of two available severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-specific mAbs designed to directly target epitopes on the spike protein of the virus and block the receptor-binding domain of the spike protein from interacting with human angiotensin-converting enzyme 2 (ACE2), preventing the virus from entering cells and inhibiting viral replication.

The efficacy of REGEN-COV was evaluated in two clinical trials, COV-2067 and COV-2069.
COV-2067 is a Phase 1/2/3, randomized, double-blind, placebo-controlled trial evaluated REGEN-COV for the treatment of subjects with a positive SARS-CoV-2 RT-qPCR result from nasopharyngeal (NP) swab with mild to moderate COVID-19 symptoms who were not hospitalized. Patients were randomized to receive a single intravenous infusion of 600 mg of casirivimab and 600 mg of imdevimab (n=838), 1,200 mg of casirivimab and 1,200 mg of imdevimab (n=1,529), 4,000 mg of casirivimab and 4,000 mg of imdevimab (n=700), or placebo (n=1,500). The primary endpoint was proportion of patients with at least 1 COVID-19-related hospitalization or all-cause death through Day 29 in the modified full analysis set (mFAS) (positive for SARS-CoV-2 and at least one risk factor for severe COVID-19). In the mFAS, 7 subjects (1%) treated with 600 mg of casirivimab and 600 mg of imdevimab had events (COVID-19 hospitalization or death) compared to 24 subjects (3%) treated with placebo. This demonstrated a 70% reduction in COVID-19-related hospitalizations or all-cause death compared to placebo. Similar results were observed for higher dosages, indicating the absence of a dose effect, leading to the authorization of the 600 mg of casirivimab and 600 mg of imdevimab dosage. Results also demonstrated a reduction in viral load and median time to resolution of symptoms in patients treated with REGEN-COV.

COV-2069 is a Phase 3, randomized, double-blind, placebo-controlled trial evaluating REGEN-COV for post-exposure prophylaxis of COVID-19 in asymptomatic household contacts of individuals infected with SARS-CoV-

2 (index case). The primary analysis population included 1,505 patients who were SARS-CoV-2 RT-qPCR negative and seronegative at baseline. Patients were randomized 1:1 to a single-dose of the 600 mg of casirivimab and 600 mg of imdevimab (n=753) or placebo (n=752) administered subcutaneously within 96 hours of collection of the index cases' positive SARS-CoV-2 diagnostic test. Following randomization and dosing, patients had SARS-CoV-2 RT-qPCR testing via nasopharyngeal swab every 7 days plus weekly investigator assessment of COVID-19 symptoms during the 28-day efficacy assessment period. The primary efficacy endpoint was proportion of patients who developed RT-qPCR-confirmed COVID-19 through Day 29. In the primary analysis population, there was an 81% risk reduction in the development of COVID-19 with REGEN-COV treatment compared to placebo [11/753 (1%) and 59/752 (8%)]. In post-hoc analysis in the subgroup of patients who met the criteria for high risk for progression to severe COVID-19, there was a 76% risk reduction in COVID-19 with REGEN-COV treatment compared to placebo [10/570 (2%) vs 42/567 (7%)].

There is limited clinical data available for REGEN-COV, but it does have warnings for hypersensitivity, including anaphylaxis, infusion related reactions, clinical worsening of COVID-19 after REGEN-COV administration, and limited benefit and potential for risk in patients with severe COVID-19. In clinical trials, adverse reactions included infusion related reactions, such as urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting, and rash, Injection site reactions, most commonly erythema and pruritis, and hypersensitivity reactions, including anaphylaxis, were also reported in clinical trials.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: REGEN-COV will be covered as medical benefit and will not be added to the pharmacy formulary. REGEN-COV will not require a prior authorization.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

TRUSELTIQ (infigratinib)

Review: Truseltiq is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. Pemazyre, another FGFR inhibitor, is a direct competitor to Truseltiq.

Patients should be selected for the treatment of Truseltiq based on the presence of an FGFR2 fusion or rearrangement, as detected by an FDA approved test.

Truseltiq is available as 25 mg capsules and 100 mg capsules. The capsules are supplied in 21-day blister packs. The 125 mg daily dose contains 21, 100 mg capsules and 21, 25 mg capsules. The 100 mg daily dose contains 21, 100 mg capsules. The 75 mg daily dose contains 63, 25 mg capsules. The 50 mg daily dose contains 42, 25 mg capsules. The recommended dosage of Truseltiq is 125 mg (one 100 mg capsule and one 25 mg capsule) orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Treatment should be continued until disease progression or unacceptable toxicity. For adverse reactions, it is recommended to reduce

the dose. The first dose reduction would be 100 mg (one 100 mg capsule), the second dose reduction would be 75 mg (three 25 mg capsules), and the third dose reduction would be 50 mg (two 25 mg capsules).

The efficacy of Truseltiq was studied in 108 patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement. All patients had received at least 1 prior line of systemic therapy, 32% had 2 prior lines of therapy, and 29% had 3 or more prior lines of therapy. Patients received Truseltiq at a dose of 125 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles until disease progression or unacceptable toxicity. The overall response rate was reached in 23% of patients (22% being partial responses). The median duration of response was 5.0 months. The median time to response was 3.6 months.

There are no contraindications. Truseltiq has warnings for retinal pigment epithelial detachment (RPED) and hyperphosphatemia. Serious adverse reactions occurred in 32% of patients receiving Truseltiq. Fatality occurred in 1 patient due to sepsis. Permanent discontinuation occurred in 15% of patients. Dose interruptions occurred in 64% of patients and dose reductions occurred in 60% of patients. The most common (≥20%) adverse reactions were nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar plantar erythrodysesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred and vomiting. Based on animal studies and its mechanism of action, Truseltiq can cause fetal harm or loss of pregnancy when administered to a pregnant woman. The safety and effectiveness in pediatric patients have not been established. The dose should be reduced in those with mild or moderate renal impairment. The recommended dose has not been established in patients with severe renal impairment/ESRD receiving hemodialysis. The dose should be reduced in those with mild or moderate hepatic impairment. The recommended dose has not been established in patients with severe hepatic impairment.

Per NCCN, Truseltiq is indicated for patients with intrahepatic and extrahepatic cholangiocarcinoma, as subsequent treatment as a single agent (useful in certain circumstances) for progression on or after systemic treatment for unresectable or metastatic disease with FGFR2 fusions or rearrangements (2A recommendation).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Truseltiq is a pharmacy benefit that will be added to the formulary at the OralOncBrandNP tier ($0 copay). Truseltiq will require prior authorization with the following criteria:

- Medical record documentation that Truseltiq is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by a Food and Drug Administration (FDA) approved test* **AND**
- Medical record documentation of one prior line of therapy

***NOTE:** The FDA approved test can be found at http://www.fda.gov/CompanionDiagnostics

QUANTITY LIMIT:

- Truseltiq 50 mg daily dose (GPI 2153223540B220): 42 capsules per 28 days

- Truseltiq 75 mg daily dose (GPI 2153223540B225): 63 capsules per 28 days
- Truseltiq 100 mg daily dose (GPI 2153223540B230): 21 capsules per 28 days
- Truseltiq 125 mg daily dose (GPI 2153223540B235): 42 capsules per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FAST FACTS

ACTEMRA (tocilizumab)

Updated Indication: Actemra subcutaneous injection is indicated for slowing the rate of decline in pulmonary function for adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Current formulary status: Pharmacy benefit, Brand Non-preferred tier, with a prior authorization required. Quantity limits apply.

Recommendation: There are no changes to formulary status at this time. However, it is recommended that the following prior authorization criteria be added to the Actemra subcutaneous policy.

Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation that member is 18 years of age or greater **AND**
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) **AND**
- Medical record documentation that medication is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
    - a. ≥ 10% fibrosis on a chest high resolution computer tomography **AND**
    - b. FVC ≥ 40% of predicted normal **AND**
    - c. DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

*Note: ACR/EULAR Diagnostic Criteria for Systemic Sclerosis:

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints *(sufficient criterion)*	–	9
Skin thickening of the fingers *(only count the higher score)*	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions *(only count the higher score)*	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	–	2
Abnormal nailfold capillaries	–	2
Pulmonary arterial hypertension and/or interstitial lung disease *(maximum score is 2)*	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	–	3
SSc-related autoantibodies (anticentromere, anti–topoisomerase I [anti–Scl-70], anti–RNA polymerase III) *(maximum score is 3)*	Anticentromere	3
	Anti–topoisomerase I	
	Anti–RNA polymerase III	

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).
† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥9 are classified as having definite SSc.

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: 3.6 mL per 28 days (for the Letter ONLY)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of SSc-ILD on six (6) months of Actemra is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of SSc-ILD while on Actemra therapy.

Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ARCALYST (rilonacept)

Updated indication: Arcalyst is approved for treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.

Arcalyst is also approved for maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more.

Previously, Arcalyst was approved for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

Current formulary status: Pharmacy benefit on the specialty tier or the Brand Non-preferred tier for members with a three-tier benefit, prior authorization required

Recommendation: There are no changes recommended to the formulary placement or quantity limit for Arcalyst. It is recommended to make the following changes to to incorporate the new indications:

- Medical record 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 **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret* AND Ilaris*

OR

- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Medical record documentation that remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) was induced by Kineret (anakinra)** **AND**

- Medical record documentation Arcalyst (rilonacept) is being used for maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret (anakinra) **AND**
- Medical record documentation of weight greater than or equal to 10 kg **AND**
- Prescription written by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders

OR

- Medical record documentation of a diagnosis of Recurrent Pericarditis (RP) as evidenced by a recurrence of pericarditis after a symptom free interval of 4 to 6 weeks or longer following a documented episode of acute pericarditis*** **AND**
- Prescription written by or in consultation with a cardiologist or rhuematologist **AND**
- Medical record documentation of age greater than or equal to 12 years old **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to colchicine AND a nonsteroidal anti-inflammatory drug (NSAID) or aspirin.

*prior authorization required
**Note: Inflammatory remission in clinical trial defined as having the following: normal acute-phase reactants (C-reactive protein (CRP) < 0.5 mg/dl), resolution of fever, skin rash and bone pain, and radiological evidence of no active bone lesions on x-ray.
***Note: The European Society of Cardiology (ESC) defines acute pericarditis to be an inflammatory pericardial syndrome diagnosed with at least 2 of the following 4 criteria: 1) pericarditic chest pain, 2) pericardial rubs, 3) new widespread ST elevations or PR depression on ECG or 4) pericardial effusion (new or worsening).

AUTHORIZATION DURATION: ~~The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Arcalyst will then require approval on a yearly basis~~

Initial approval will be for **3 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

AYVAKIT (avapritinib)

Updated Indication: Ayvakit is now indicated for the treatment of adult patients with Advanced Systemic Mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

Limitation of Use: Ayvakit is not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 x 10^9/L.

Previously, Ayvakit was only indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

Current formulary status: Ayvakit is available at the OralOncBrandNP tier. Ayvakit requires a prior authorization.

Recommendation: There are no changes to formulary status, authorization duration, or quantity limits. The quantity limit of 1 tablet per day should also apply to the 25 mg and 50 mg tablets. The prior authorization criteria should be updated to include a section for AdvSM.

AdvSM

- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a platelet count ≥ 50 x 10^9/L AND
- Medical record documentation of a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

KINERET (anakinra)

Updated Indication: Kineret is approved for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

Previously, Kineret was approved for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs) and for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

Current formulary status: Pharmacy benefit on the specialty tier or the Brand Non-preferred tier for members with a three-tier benefit, prior authorization required.

Recommendation: There are no changes recommended to the formulary placement or quantity limit for Kineret. It is recommended to make the following changes to incorporate the new indication:

For Rheumatoid Arthritis:

- Medical record documentation of a 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 **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kineret is prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz* **AND**
- Medical record documentation that Kineret is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on six (6) months of anakinra therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on anakinra therapy.

For Neonatal-Onset Multisystem Inflammatory Disease:
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

AUTHORIZATION DURATION: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of NOMID. Kineret will then require approval on a yearly basis.

For ~~Neonatal-Onset Multisystem Inflammatory Disease:~~ Cryopyrin–Associated Periodic Syndrome (CAPS):
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record 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 **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

AUTHORIZATION DURATION: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Kineret will then require approval on a yearly basis.

For Deficiency of Interleukin-1 Receptor Antagonist (DIRA):

- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Prescription written by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.

AUTHORIZATION DURATION: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of DIRA. Kineret will then require approval on a yearly basis.

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SHINGRIX (zoster vaccine recombinant, adjuvanted)

Updated Indication: Shingrix is a vaccine for prevention of herpes zoster (HZ) (shingles) now indicated in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.

Previously, Shingrix was indicated for prevention of HZ in adults aged 50 years and older.

Current formulary status: Vaccine tier, medical/pharmacy benefit; Age Limit: 50 to 99 years

Recommendation: There are no changes to the formulary placement of Shingrix. It is recommended that the Age limit be updated to 18 to 99 years to incorporate the new indication. A quantity limit of 2 per 999 days should also be added to Shingrix.

Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

CABENUVA QUANTITY LIMIT UPDATE

Background: Cabenuva is supplied in 2 dosing kits. Each kit contains one vial of cabotegravir extended-release injectable suspension and one vial of rilpivirine extended-release injectable suspension, co-packaged as:

Cabenuva 400 mg/600 mg Kit:

- One single-dose vial of cabotegravir extended-release injectable suspension containing 400 mg/2 mL cabotegravir
- One single-dose vial of rilpivirine extended-release injectable suspension containing 600 mg/2 mL rilpivirine

Cabenuva 600 mg/900 mg Kit:

- One single-dose vial of cabotegravir extended-release injectable suspension containing 600 mg/3 mL cabotegravir
- One single-dose vial of rilpivirine extended-release injectable suspension containing 900 mg/3 mL rilpivirine

Current quantity limits are based on the number of kits used according the FDA approved recommended dosing:

Current Quantity Limits:

- Cabenuva 600 mg/900 mg Kit: 1 kit per 180 days
- Cabenuva 400 mg/600 mg Kit: 1 kit per 28 days

Recommendations: Darwin claims process as the total number of mL for each kit. It is recommended that the current quantity limits be recommended to mL as follows:

- Cabenuva 600 mg/900 mg Kit: 6 mL per 180 days
- Cabenuva 400 mg/600 mg Kit: 4 mL per 28 days

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SITE OF CARE POLICY UPDATE

Background: On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program for infliximab products and intravenous/subcutaneous immune globulin products, which direct members to the most cost-effective, yet clinically appropriate location to receive drug infusions under the medical benefit. The site of care program is administered as part of the existing prior authorization program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria. Since that time, additional drugs have been added to the site of care program in phases.

On October 15, 2021 GHP will implement Phase 8 drugs (Aralast, Glassia, Prolastin-C, Zemaira) to the site of care program, The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs' respective existing clinical prior authorization program.

Recommendations: It is recommended that the following changes (highlighted in green) be made to MBP 181.0 so that this policy may apply to the Phase 8 drugs (Aralast, Glassia, Prolastin-C, Zemaira). In addition to the drugs outlined above, it is recommended that the criteria are updated to account for additional self-injected drugs:

MBP 181.0 Site of Care

I. Policy:
Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

II. Purpose/Objective:
To provide a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. Agalsidase Beta (Fabrazyme)
3. Alglucosidase Alfa (Lumizyme)
4. Alpha$_1$-Proteinase Inhibitor [Human] products
5. Belimumab (Benlysta IV)
6. Benralizumab (Fasenra)
7. C1 esterase Inhibitor [Human] (Cinryze)
8. Canakinumab (Ilaris)
9. Certolizumab (Cimzia)
10. Denosumab (Prolia, Xgeva)
11. Eptinezumab (Vyepti)
12. Galsulfase (Naglazyme)
13. Golimumab (Simponi Aria)
14. Immune Globulin (IVIG)
15. Imiglucerase (Cerezyme)
16. Infliximab & infliximab biosimilar products
17. Laronidase (Aldurazyme)
18. Mepolizumab (Nucala)
19. Omalizumab (Xolair)
20. Tildrakizumab (Ilumya)
21. Tocilizumab (Actemra IV)
22. Ustekinumab (Stelara)
23. Vedolizumab (Entyvio)

III. Responsibility:

A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
7. Site of Care – choice of physical location for administration of intravenous infusions or injections. Site of care locations include hospital inpatient, hospital based outpatient facilities, physician's office, ambulatory infusion centers, or home infusion services.
8. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion centers such as ambulatory infusion centers or physician's offices and home infusion

9. Hospital based outpatient facilities include ER services, intravenous drug infusions or injections, observation services, outpatient surgery, lab tests, or x-rays, or any other hospital services where the patient is not admitted as an inpatient.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital based outpatient setting. If medical necessity criteria for administration in the hospital based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Administration in the hospital based outpatient setting will be considered medically necessary and <u>LIMITED to a duration of 60 days</u> when one of the following criteria are met:

- This is the initial medication infusion **OR**
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days. Administration in the hospital based outpatient setting for longer than 60 days will be required to meet the authorization criteria in the section below.

Administration in the hospital based outpatient setting will be considered medically necessary for a <u>duration of greater than 60 days</u> when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label **OR**
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion **OR**
- All of the following:
    - All alternate non-hospital outpatient settings are not within a reasonable distance from the member's home (within 50 miles) **AND**
    - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access **AND**
    - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, certolizumab, golimumab, mepolizumab, omalizumab, tocilizumab, and ustekinumab: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.

  OR
- For IVIG any of the above criteria **OR**

    - Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) **OR**
    - Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

OR

- For Xgeva (denosumab) any of the above criteria **OR**
    - Patient is receiving Xgeva concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.

LIMITATIONS: If none of the above criteria are met and the proposed hospital based outpatient facility is considered a least costly site of care, the hospital outpatient infusion would be approved.

LINE OF BUSINESS:
This policy does not apply to the Medicaid or Medicare line of business. Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Voting responses were received from 22 of 39 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, September 21, 2021.

Meeting will be via phone/Microsoft Teams.