

Coverage and clinical guideline update

Coverage guidelines effective November 1, 2018

Anthem Blue Cross and Blue Shield in Virginia and our affiliate, HealthKeepers, Inc., will implement the following new and revised coverage guidelines effective **November 1, 2018**. These guidelines impact all our products – with the exception of Anthem HealthKeepers Plus (Medicaid), the Commonwealth Coordinated Care Plus (Anthem CCC Plus), Medicare Advantage, and the Blue Cross and Blue Shield Service Benefit Plan (also called the Federal Employee Program or FEP). Furthermore, the guidelines were among those recently approved at the Medical Policy and Technology Assessment Committee meeting held on May 3, 2018.

Services related to specialty pharmacy drugs (non-cancer related) require a medical necessity review, which includes site of care criteria, as outlined in the applicable coverage or clinical UM guideline listed below.

The following guidelines are addressed in this edition of the *Network Update*:

- Eculizumab (Soliris®) (DRUG.00111)
- Lutetium Lu 177 dotatate (Lutathera®) (DRUG.00098)
- Epidermal Growth Factor Receptor (EGFR) Testing (GENE.00006)
- Recombinant Erythropoietin Products (CG-DRUG-05)
- White Blood Cell Growth Factors (CG-DRUG-16)
- Romidepsin (Istodax®) (CG-DRUG-51)
- Antihemophilic Factors and Clotting Factors (CG-DRUG-78)
- Adenoidectomy (CG-SURG-36)

SPECIAL NOTE

The services addressed in ALL the coverage guidelines presented in this document will require authorization for all of our products offered by HealthKeepers, Inc. with the exception of Anthem HealthKeepers Plus (Medicaid) and the Commonwealth Coordinated Care Plus (Anthem CCC Plus). Other exceptions are Medicare Advantage and the Blue Cross and Blue Shield Service Benefit Plan (also called the Federal Employee Program or FEP).

A pre-determination can be requested for our Anthem PPO products.

Eculizumab (Soliris®) (DRUG.00111)

This document addresses the use of eculizumab in the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis, and other conditions.

The criteria for continuation of eculizumab to treat atypical hemolytic uremic syndrome has been revised to include "until an individual becomes a candidate for physician-directed cessation as evidenced by the following (1 and 2):

1. Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent; and
2. Duration of clinical remission has been stable for 2 months.

NOTE: Close monitoring after cessation is essential (for example: regular laboratory monitoring including complete blood count, peripheral smear, lactate dehydrogenase, renal function, and urine protein beginning the week of the held dose and weekly for four weeks, every two weeks for one month, and then monthly for three months at the discretion of the treating clinician).

Criteria for resuming treatment has also been added.

Resumption of eculizumab is considered **medically necessary** when relapse occurs in an individual who has discontinued therapy. Relapse is defined as the occurrence of **any** of the following:

1. Reduction in platelet count to less than 150,000/mm³; **or**
2. Mechanical hemolysis (having 2 or more features of hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 2 times upper limit of normal, undetectable haptoglobin, or presence of schistocytes on smear); **or**
3. Acute kidney injury with serum creatinine increase greater than 15% from baseline levels.

The HCPCS code associated with this revised coverage guideline is J1300.

Lutetium Lu 177 dotatate (Lutathera®) (DRUG.00098)

This new coverage guideline addresses the use of lutetium Lu 177 dotatate (Lutathera)

Lutetium Lu 177 dotatate is considered **medically necessary** for the treatment of locally advanced, inoperable, or metastatic well-differentiated gastroenteropancreatic neuroendocrine tumors including foregut, midgut and hindgut neuroendocrine tumors, when the following criteria are met:

- A. Individual is 18 years of age or older; and
- B. Tumor has progressed while receiving greater than or equal to 4 months of somatostatin analog therapy (such as octreotide LAR) with evidence of tumor progression on imaging; and

- C. Individual has target lesions overexpressing somatostatin receptors confirmed by an appropriate somatostatin receptor scintigraphy imaging study (such as, indium-IN 111-pentetreotide, 68Ga-DOTA0-Tyr3-octreotate, or 68Ga-edotreotide imaging); and
- D. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2; **and**
- E. Individual has not received prior treatment with a radiolabeled somatostatin analog.

Lutetium Lu 177 dotatate is considered **investigational and not medically necessary** when the above criteria are not met and for all other indications.

The CPT and HCPCS codes associated with this new coverage guideline are 79101, A9699, C9031, and J9999.

Epidermal Growth Factor Receptor (EGFR) Testing (GENE.00006)

This coverage guideline addresses the use of epidermal growth factor receptor (EGFR) mutation and gene testing amplification from tissue samples for predicting the response to drug therapy in individuals with non-small cell lung cancer (NSCLC), and for all other indications

Effective with date of service on or after November 1, 2018, CPT codes 88271 and 88275 will be subject to review of this coverage guideline.

Recombinant Erythropoietin Products (CG-DRUG-05)

This coverage guideline addresses recombinant, or man-made, erythropoietin products. It has been revised to include clinically equivalent cost effective agents.

NOTE: When recombinant erythropoietin is determined to be medically necessary, the benefit plan may have in addition a medically necessary criterion that the treatment be cost effective.

A benefit plan may select any one or more of the following as clinically equivalent cost effective recombinant erythropoietin agents: Aranesp (Darbepoetin Alfa), Epogen (Epoetin Alfa), Mircera (Methoxy polyethylene glycol-epoetin beta) and Procrit (Epoetin Alfa).

In benefit plans where there is a requirement to use a cost effective recombinant erythropoietin agent, requests for a recombinant erythropoietin agent that is not cost effective may be approved when the following criteria are met:

- A. The individual has had a trial and inadequate response or intolerance to one cost effective agent; or
- B. For the prescribed indication, the cost effective agent(s) is/are not FDA-approved or does not meet the off-label drug use criteria of CG-DRUG-01 Off-Label Drug and Approved Orphan Drug Use (see below); or
- C. The cost effective agent is not acceptable due to the following concomitant clinical situation(s):
 - 1. If Epogen (epoetin alfa) and Procrit (epoetin alfa) are not designated as cost effective agents, either may be approved if individual is requesting for anemia associated with one of the following:

- a. Chronic kidney disease and between 1 month and less than 12 months of age; or
- b. Myelosuppressive chemotherapy and between 5 years and less than 18 years of age.

The HCPCS codes associated with this revised coverage guideline are J0881, J0882, J0885, J0887, J0888, J3590, Q4081, and S9537.

White Blood Cell Growth Factors (CG-DRUG-16)

This coverage guideline addresses white blood cell growth factors, also known as colony stimulating factors (CSF). It has been revised to include clinically equivalent cost effective agents.

NOTE: When a white blood cell growth factor, also known as a colony stimulating factor (CSF) is determined to be medically necessary. The benefit plan may have in addition a medically necessary criterion that the treatment be cost effective.

A benefit plan may select any one or more of the following as a clinically equivalent cost effective white blood cell growth factors: Filgrastim (Neupogen), pegfilgrastim (Neulasta), and Tbo-filgrastim (Granix).

NOTE: Pegfilgrastim (Neulasta) must be selected as one of the clinically equivalent cost effective white blood cell growth factor agents

In benefit plans where there is a requirement to use a cost effective white blood cell growth factor, requests for a white blood cell growth factor that is not cost effective may be approved when the following criteria are met:

1. The individual has had a trial and inadequate response or is intolerant to one cost effective agent; or
2. For the prescribed indication, the cost effective agent is not FDA-approved or does not meet the off-label drug use criteria of *CG-DRUG-01 Off-Label Drug and Approved Orphan Drug Use*.

The CPT and HCPCS codes associated with this revised coverage guideline are 96377, J1442, J1447, J2505, J2820, Q5101, and S9537.

Romidepsin (Istodax®) (CG-DRUG-51)

This document addresses the clinical uses of romidepsin (Istodax®).

Romidepsin is considered **medically necessary** for the following indications:

1. Individuals with relapsed or refractory T-cell lymphoma or leukemia following at least one prior systemic therapy; **or**
2. Individuals with mycosis fungoides or Sézary Syndrome.

Effective with date of service on or after November 1, 2018, HCPCS code J9315 will be subject to review of this clinical UM guideline.

Antihemophilic Factors and Clotting Factors (CG-DRUG-78)

This document addresses select hemophilia and clotting factor replacement treatments created from blood products (human plasma-derived) and others that are manufactured (recombinant). It has been revised to include clinically equivalent cost effective agents.

NOTE: When a hemophilia and clotting factor replacement treatment is determined to be medically necessary based on the clinical criteria, the benefit plan may have in addition a medically necessary criterion that the treatment be cost effective.

A benefit plan may select any one or more of the following agents within a designated product class (classes A through H listed below) as clinically equivalent cost effective hemophilia and clotting factor replacement treatment agents:

- A. Antihemophilic factor (factor VIII) Human plasma-derived (Hemofil M, Koate-DVI, Monoclate-P)
- B. Antihemophilic factor (factor VIII) Recombinant (Advate, Afstyla, Helixate FS, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha)
- C. Antihemophilic factor (factor VIII) - Long-Acting Recombinant, pegylated (Adynovate); Recombinant Antihemophilic Factor Fc Fusion Protein (Eloctate)
- D. Antihemophilic Factor VIII/von Willebrand Factor Complex (Alphanate, Humate-P, Wilate)
- E. Coagulation Factor IX, Human plasma-derived (Alphanine SD, Mononine)
- F. Factor IX Complex, Human plasma-derived (Bebulin, Profilnine SD)
- G. Factor IX Recombinant (Benefix, Ixinity, Rixubis)
- H. Coagulation Factor IX - Long-Acting Recombinant, Albumin Fusion Protein (Idelvion); Recombinant Coagulation Factor IX, Fc Fusion Protein (Aprolix); Recombinant Coagulation Factor IX, GlycoPEGylated (Rebinyn)

In benefit plans where there is a requirement to use a cost effective hemophilia and clotting factor replacement treatment agent, requests for a hemophilia and clotting factor replacement treatment agent that is not cost effective may be approved when the following criteria are met (A, B, C, or D):

- A. The cost effective agent is not acceptable due to the following concomitant clinical situation(s):
 - 1. The individual is currently medically stable on another hemophilia and clotting factor replacement treatment agent; **or**
 - 2. The individual has inhibitors specific to the cost effective agent and the presence of these inhibitors is expected to contribute to a difficulty in controlling bleeding events; **or**
- B. The cost effective agent is not readily available in the individual's geographic treatment area; **or**

- C. The individual has had a trial with a cost effective agent in the designated product class and has demonstrated one of the following:
 - 1. Shorter than expected half-life degradation of the agent based on trough level dosing that is considered to be clinically significant (that is: expected to contribute to a difficulty in controlling bleeding events); **or**
 - 2. Intolerance to the agent; **or**
- D. For the prescribed indication, the cost effective agent(s) is/are not FDA-approved or does not meet the off-label drug use criteria of CG-DRUG-01 Off-Label Drug and Approved Orphan Drug Use.

The HCPCS codes associated with this revised clinical UM guideline are J7198, J7189, J7190, J7182, J7185, J7192, J7209, J7210, J7211, J7205, J7207, J7199, J3590, Q9995, J7188, J7191, J7183, J7186, J7187, J7179, J7193, J7194, J7195, J7200, J7201, J7202, C9468, J7175, J7180, J7181, and J7178.

Adenoidectomy (CG-SURG-36)

This clinical UM guideline addresses the use of adenoidectomy used to treat an array of conditions.

Adenoidectomy is considered **medically necessary** for individuals under the age of 18 years old when any of the following conditions are met:

- 1. Chronic (greater than or equal to 12 weeks in duration) adenoiditis with rhinorrhea, despite a minimum of 3 weeks of appropriate antibiotic treatment; **or**
- 2. Chronic (greater than or equal to 12 weeks in duration) rhinosinusitis, despite a minimum of 3 weeks of appropriate antibiotic treatment and one or more of the following:
 - a. CT findings suggestive of obstruction or infection (for example, but not limited to, air fluid levels, air bubbles, significant mucosal thickening, pansinusitis, or diffuse opacification); **or**
 - b. Nasal endoscopy findings suggestive of significant disease; **or**
 - c. Physical exam findings suggestive of chronic/recurrent disease (for example mucopurulence, erythema, edema, inflammation); **or**
- 3. Four or greater episodes of recurrent adenoiditis with purulent rhinorrhea in the prior 12 months in a child less than 12 years of age. At least one episode should be documented by intranasal examination or diagnostic imaging; **or**
- 4. Chronic otitis media with effusion (OME) in children 4 years of age or older with a history of prior failed tube tympanostomy and no evidence of nasal obstruction, recurrent sinusitis, or chronic sinusitis, when done in conjunction with either a) myringotomy or b) tube tympanostomy; **or**
- 5. Adenoid hypertrophy documented by imaging (for example, lateral neck X-ray), nasopharyngoscopy or endoscopy with symptomatic airway obstruction as demonstrated by any of the following:

- a. In children less than 3 years of age, sleep-disordered breathing (SDB) with documentation of symptoms for more than 3 months in duration and the child's parent or caregiver reports regular episodes of nocturnal choking, gasping, apnea, or breath holding; or
- b. In children 3 to 17 years of age, SDB with documentation of abnormalities of respiratory pattern or the adequacy of ventilation during sleep, including but not limited to snoring, mouth breathing, and pauses in breathing*; or
- c. A condition related to SDB (including but not limited to growth retardation, poor school performance, enuresis, and behavioral problems) that is likely to improve after adenoidectomy; or
- d. Obstructive sleep apnea as diagnosed by polysomnogram with an Apnea-Hypopnea Index (AHI) greater than 1.0.

***NOTE:** Documentation of SDB can be made based on physical and history only, and does not require polysomnography. A history of snoring alone is not sufficient to make a diagnosis of SDB.

Adenoidectomy is also considered **medically necessary** for individuals of any age for suspected adenoid tumor based on imaging (for example, CT), nasopharyngoscopy or endoscopy.

Adenoidectomy is considered **not medically necessary** for all other indications and when criteria above are not met, including, but not limited to, use in children less than 4 years of age with acute or recurrent otitis media.

Effective with date of service on or after November 1, 2018, CPT codes 42830, 42831, 42835, and 42836 will be subject to review of this clinical UM guideline.

These coverage guidelines became available on June 28, 2018, for review on our website at www.anthem.com.

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