

Coverage and clinical guideline update

Coverage guidelines effective January 1, 2019

Anthem Blue Cross and Blue Shield in Virginia and our affiliate, HealthKeepers, Inc., will implement the following new and revised coverage guidelines effective **January 1, 2019**. These guidelines impact all our products – with the exception of Anthem HealthKeepers Plus (Medicaid), the Commonwealth Coordinated Care Plus (Anthem CCC Plus) plan, 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 July 26, 2018.

The services addressed in these coverage guidelines will require authorization for all of our HealthKeepers, Inc. products with the exception of Anthem HealthKeepers Plus (Medicaid), Anthem CCC Plus, and Medicare Advantage. A pre-determination can be requested for our PPO products. Please note that FEP is excluded from this requirement as well.

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. Coverage guidelines addressed here are:

- Cosmetic and Reconstructive Services: Skin Related (ANC.00007)
- Chelation Therapy (DRUG.00003)
- Ibalizumab-uiyk (Trogarzo™) (DRUG.00096)
- Epidermal Growth Factor Receptor (EGFR) Testing (GENE.00006)
- Circulating Tumor DNA Testing for Cancer (Liquid Biopsy) (GENE.00049)
- Neuromuscular Stimulation in the Treatment of Muscle Atrophy (CG-DME-03)
- Diagnostic Infertility Surgery (CG-SURG-34)

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.

Cosmetic and Reconstructive Services: Skin Related (ANC.00007)

This coverage guideline addresses the cosmetic, reconstructive, and medically necessary uses of a selection of techniques used in the treatment of skin lesions and related conditions.

It has been revised to include microneedling. Microneedling, also known as percutaneous collagen induction therapy or skin needling, is considered **cosmetic and not medically necessary** for all indications, including but not limited to the treatment of facial wrinkles and skin irregularities (for example, acne scars or blemishes).

Currently, there is not a specific CPT or HCPCS code for microneedling. CPT code 17999 is utilized to represent this service.

Chelation Therapy (DRUG.00003)

This revised document addresses the uses of chelation therapy. Chelation therapy uses naturally occurring or chemically designed molecules to reduce potentially dangerous levels of heavy metals within the body.

The administration of U.S. Food and Drug Administration (FDA) approved chelating agents is considered **medically necessary** treatment for individuals with relevant clinical findings suggestive of heavy metal toxicity and a probable exposure history in **any** of the following conditions **when confirmed by laboratory testing**.*

1. Individuals with disorders of iron metabolism (for example, primary or secondary hemochromatosis); **or**
2. Lead overload in cases of acute or long-term lead exposure; **or**
3. Individuals with disorders of copper metabolism (for example, Wilson's disease); **or**
4. Arsenic, mercury, iron, copper or gold poisoning when long-term exposure and toxicity has been confirmed; **or**
5. Aluminum overload in individuals on chronic hemodialysis.

***NOTE:** Laboratory testing to confirm heavy metal toxicity should include blood or plasma specimens. In the case of suspected arsenic or mercury toxicity, it may be more appropriate to confirm diagnosis through a non-challenged urinalysis.

The HCPCS codes associated with this revised coverage guideline are J0470, J0600, J0895, J3520, M0300, and S9355.

Ibalizumab-uiyk (Trogarzo™) (DRUG.00096)

This new coverage guideline addresses the uses for ibalizumab-uiyk (Trogarzo™; TaiMed Biologics, Irvine, CA). Ibalizumab-uiyk is a humanized monoclonal antibody (mAb) that belongs to the class of human immune deficiency virus (HIV) drugs known as entry and fusion inhibitors which prevent HIV from attaching to and entering human cells. This action hampers replication of HIV and can reduce the viral load in the body.

Ibalizumab-uiyk is considered **medically necessary** for the treatment of multidrug-resistant HIV in combination with other antiretroviral(s), when **all** of the following criteria are met:

- A. Individual is 18 years of age or older; **and**
- B. Has a viral load of ≥ 1000 copies/mL; **and**
- C. Has a history of at least 6 months on antiretroviral treatment; **and**
- D. Is receiving a failing antiretroviral regimen or has failed and is off therapy; **and**
- E. Documented resistance to at least one antiretroviral medication from each of the following three named classes as measured by resistance testing
 - 1. non-nucleoside reverse transcriptase inhibitors (NNRTIs); **and**
 - 2. nucleoside reverse transcriptase inhibitors (NRTIs); **and**
 - 3. protease inhibitors (PIs); **and**
- F. Documentation of full viral sensitivity/susceptibility to at least one antiretroviral agent, other than ibalizumab-uiyk, as determined by resistance tests.

Ibalizumab-uiyk is considered ***investigational and not medically necessary*** when the criteria above are not met and for all other indications, including but not limited to:

- A. Individuals who have received immunomodulating therapy within the 12 weeks preceding initiation of treatment with ibalizumab-uiyk (for example, interferon, systemic steroids or systemic chemotherapy);
- B. Individuals being treated for an acute infection secondary to HIV infection.

Currently there is not a specific HCPCS code for Ibalizumab-uiyk (Trogarzo™). HCPCS codes J3490 and J3590 are utilized to represent Ibalizumab-uiyk (Trogarzo™).

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

It has been revised to include circulating tumor DNA tests.

- A. Analysis of mutations in the gene for the EGFR is considered ***medically necessary*** as a technique to predict treatment response for individuals with non-small cell, non-squamous cell lung cancer when treatment with EGFR tyrosine kinase inhibitor (TKI) therapy (for example, afatinib [Gilotrif®], erlotinib [Tarceva®], gefitinib [Iressa®], or osimertinib [Tagrisso®]), is indicated for the management of individuals with an activating mutation in EGFR such as exon 19 deletions or exon 21 (L858R) substitution.
- B. Analysis for the T790M mutation in the gene for the EGFR receptor is considered ***medically necessary*** as a technique to predict treatment response for individuals with non-small cell, non-squamous cell lung cancer who have progressed on or after EGFR TKI therapy and treatment with osimertinib (Tagrisso) is indicated.
- C. Use of a circulating tumor DNA test to detect mutations of the EGFR gene is considered ***medically necessary*** when the volume of formalin-fixed paraffin-embedded tumor tissue (FFPET) available for testing is insufficient and the individual meets *either* criterion A. or B. above.

Use of a circulating tumor DNA test to detect mutations of the EGFR gene is considered *investigational and not medically necessary* for all other indications, including but not limited to when the criteria above have not been met.

The CPT codes associated with this revised coverage guideline are 81235, 88271, 88275, and 88365.

Circulating Tumor DNA Testing for Cancer (Liquid Biopsy) (GENE.00049)

This new coverage guideline addresses cell-free circulating tumor DNA (ctDNA) testing, from a blood sample, as an alternative to tissue biopsy in the diagnosis of cancer and for clinical response to targeted agents of cancer treatment. These tests are also known as liquid biopsies.

The use of a circulating tumor DNA (ctDNA) test for the diagnosis or treatment of cancer is considered *investigational and not medically necessary* for all indications.

Currently there is not a specific CPT code for circulating tumor DNA testing. CPT code 81479 is utilized to represent this service.

Neuromuscular Stimulation in the Treatment of Muscle Atrophy (CG-DME-03)

This clinical UM guideline addresses the use of neuromuscular stimulation (also known as neuromuscular electrical stimulation or NMES), which is the application of electrical stimulation for the treatment of muscular atrophy when the nerve supply to the muscle is intact.

FDA approved neuromuscular stimulator devices are considered *medically necessary* when prescribed for **any** of the following indications when muscular atrophy is present in the setting of an intact nerve supply to the muscle, including brain, spinal cord and peripheral nerves:

- A. As a component of post-operative rehabilitation in either of the following settings:
 - 1. When muscular atrophy is present before an orthopedic intervention (for example, repair of anterior cruciate ligament). In this setting, neuromuscular stimulation may be initiated immediately in the post-operative phase as an adjunct to physical therapy; **or**
 - 2. When muscular atrophy develops in the post-operative period. Individuals meeting this criterion typically are participating in a physical therapy program, but have experienced complications related to the surgery, which preclude successful physical therapy. In this setting, neuromuscular stimulation may be initiated only after the development of muscle atrophy; **or**
- B. As a treatment of muscular atrophy related to other medical conditions, such as disuse atrophy; **or**
- C. A neuromuscular stimulator garment is considered *medically necessary* when **any** of the following criteria are met:
 - 1. There is a large area or many sites to be stimulated and use of conventional electrodes, adhesive tapes and lead wires is not feasible; **or**
 - 2. The areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires; **or**

3. There is a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes and lead wires.

Neuromuscular stimulation is considered ***not medically necessary*** when the above criteria are not met and for all other indications, including but not limited to:

1. Prevention of muscle atrophy (for example, following an orthopedic procedure);
2. Treatment of pain for various musculoskeletal conditions, including, but not limited to patellofemoral syndrome, spinal stenosis, lumbago, muscle strains/sprains;
3. As a technique to increase circulation.

Effective with dates of service on or after January 1, 2019, HCPCS codes E0731 and E0745 are subject to review of this clinical UM guideline.

Diagnostic Infertility Surgery (CG-SURG-34)

This clinical UM guideline addresses the use of hysteroscopy and laparoscopy for diagnostic work-up of infertility.

Hysteroscopy is considered ***medically necessary*** in the evaluation of infertility for any of the following indications:

- Suspected uterine abnormality as evidenced by abnormal hysterosalpingogram or hysterosonogram (for example, but not limited to endometrial polyp, submucosal myoma, intrauterine synechia (scarring) or uterine anomaly (unicornuate, bicornuate, septate uteri); **or**
- Proximal tubal occlusion on hysterosalpingogram; **or**
- Cervical stenosis; **or**
- Inadequate or non-diagnostic hysterosalpingogram or sonohysterogram.

Hysteroscopy is considered ***not medically necessary*** when the criteria above are not met including, but not limited to all of the following:

- For the evaluation of infertility when the criteria above are not met; **or**
- For asymptomatic women who are infertile with normal physical examination, normal pelvic ultrasound, and normal hysterosalpingogram or hysterosonogram; **or**
- For evaluation of recurrent pregnancy loss in the absence of any of the above indications for hysteroscopy; **or**
- For evaluation of recurrent in vitro fertilization failure or implantation failure in the absence of any of the above indications for hysteroscopy.

Laparoscopy is considered ***medically necessary*** in the evaluation of infertility for any of the following indications:

- Suspected tubal pathology as evidenced by abnormal hysterosalpingogram (for example, but not limited to, proximal or distal tubal occlusion, hydrosalpinx, or suggestion of peritubal adhesions, or uterine anomaly); **or**

- Abnormal physical examination, hysterosalpingogram or hysterosonogram suggesting pelvic pathology (for example, but not limited to significant pelvic tenderness, suspected pelvic mass or suspected adnexal mass); **or**
- Significant pelvic pain suggesting pelvic or adnexal adhesions or other pathology such as endometriosis as suggested by any of the following:
 - Significant symptoms including severe dysmenorrhea or pelvic pain; **or**
 - Significant findings on physical examination including pelvic tenderness, pelvic or adnexal mass, or nodularity in the cul-de-sac; **or**
 - Significant findings on pelvic ultrasound including pelvic or adnexal mass.

Laparoscopy is considered *not medically necessary* when the criteria above are not met including, but not limited to all of the following:

- For the evaluation of infertility when the criteria above are not met; **or**
- For asymptomatic women who are infertile with normal physical examination, normal pelvic ultrasound, and normal hysterosalpingogram; **or**
- For evaluation of recurrent pregnancy loss in the absence of any of the above indications for laparoscopy; **or**
- For the evaluation of recurrent in vitro fertilization failure or implantation failure in the absence of any of the above indications for laparoscopy.

Effective with dates of service on or after January 1, 2019, CPT codes 49320 and 58555 will be subject to review of this clinical UM guideline.

These coverage guidelines are available for review on our website at www.anthem.com after August 29, 2018.

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