Anthem
And Its Affiliate HealthKeepers, Inc.

Coverage and clinical guideline update

Coverage guidelines effective January 1, 2022

SPECIAL NOTE:

The services addressed in ALL the coverage guidelines presented in this document will require authorization for all our products offered by HealthKeepers, Inc. with the exception of Anthem HealthKeepers Plus (Medicaid) and the Commonwealth Coordinated Care Plus (Anthem CCC Plus) plan. 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.

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, 2022***. These guidelines impact all our products – with the exception of Anthem HealthKeepers Plus (Medicaid), Medicare Advantage, the Commonwealth Coordinated Care Plus (Anthem CCC Plus) plan, 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 August 12, 2021.

If applicable, 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.

The guidelines addressed in this edition of *Provider News* are:

- Neuromuscular Electrical Training for the Treatment of Obstructive Sleep Apnea or Snoring (DME.00043)

- TruGraf Blood Gene Expression Test for Transplant Monitoring (GENE.00058)

- Serum Biomarker Tests for Risk of Preeclampsia (LAB.00040)
- Molecular Signature Test for Predicting Response to Tumor Necrosis Factor Inhibitor Therapy (LAB.00042)
- Microprocessor Controlled Knee-Ankle-Foot Orthosis (OR-PR.00007)
- Ultraviolet Light Therapy Delivery Devices for Home Use (CG-DME-41)
- Electric Tumor Treatment Field (TTF) (CG-DME-44)
- Cardiac Resynchronization Therapy with or without an Implantable Cardioverter Defibrillator for the Treatment of Heart Failure (CG-SURG-63)

Neuromuscular Electrical Training for the Treatment of Obstructive Sleep Apnea or Snoring (DME.00043)

This new coverage guideline addresses the use of neuromuscular electrical training of the tongue muscles as a treatment of obstructive sleep apnea (OSA) or snoring. The eXciteOSA® (Signifier Medical Technologies, Needham, MA) is the first OSA treatment device to be used while awake and is intended to improve tongue function.

The use of a neuromuscular electrical training device is considered ***investigational and not medically necessary*** for the treatment of obstructive sleep apnea or snoring

The HCPCS code associated with this new coverage guideline is E1399.

TruGraf Blood Gene Expression Test for Transplant Monitoring (GENE.00058)

This new coverage guideline addresses the TruGraf® blood gene expression test which is a blood-based gene expression assay designed to identify transplant recipients who are inadequately immunosuppressed.

TruGraf blood gene expression test is considered ***investigational and not medically necessary*** for monitoring immunosuppression in transplant recipients and for all other indications.

The CPT code associated with this new coverage guideline is 81479.

Serum Biomarker Tests for Risk of Preeclampsia (LAB.00040)

This new coverage guideline addresses serum biomarker testing to identify individuals at increased risk of preeclampsia during pregnancy. Serum biomarkers that can be used to predict preeclampsia include placental growth factor (PlGF) and pregnancy-associated plasma protein-A

(PAPP-A), levels of which tend to drop during pregnancy in asymptomatic individuals who later develop preeclampsia.

Serum biomarker tests to diagnosis, screen for, or assess risk of preeclampsia are considered ***investigational and not medically necessary***

The CPT codes associated with this new coverage guideline are 0243U and 81599.

Molecular Signature Test for Predicting Response to Tumor Necrosis Factor Inhibitor Therapy (LAB.00042)

This new coverage guideline addresses molecular signature testing (PrismRA, Schipher Medicine, Durham, NC) to predict response to Tumor Necrosis Factor inhibitor (TNFi) therapy.

Molecular signature testing to predict response to Tumor Necrosis Factor inhibitor (TNFi) therapy is considered ***investigational and not medically necessary*** for all uses, including but not limited to guiding treatment for rheumatoid arthritis.
The CPT codes associated with this new coverage guideline are 81479 and 81599.

Microprocessor Controlled Knee-Ankle-Foot Orthosis (OR-PR.00007)

This new coverage guideline addresses the use of a microprocessor-controlled knee-ankle-foot orthosis (for example, the C-Brace®, Ottobock HealthCare LP, Austin, TX) that provides support for individuals with lower extremity weakness. This microprocessor-controlled device is a stance and swing phase control orthosis (SSCO) intended to augment the function of individuals with peripheral or central neurologic conditions that result in weakness or paresis of the quadriceps and/or other knee extensor muscles.

The use of a microprocessor-controlled knee-ankle-foot orthosis is considered ***medically necessary*** when **all** of the following criteria set forth in (A) and (B) below have been met:

A. Selection criteria:
    1. Individual is ambulatory and use of a knee-ankle-foot orthosis (KAFO) is appropriate; **and**
    2. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology; **and**
    3. The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a KAFO; **and**
    4. There is documented need for ambulation in situations where the device will provide benefit (for example, regular need to ascend/descend stairs, traverse uneven surfaces or ambulate for long distances [generally 400 yards or greater cumulatively]).

B. Documentation and performance criteria:
    1. Complete multidisciplinary assessment of individual including an evaluation by a certified orthotist. The assessment must objectively document that all of the above selection criteria have been evaluated and met.

The use of a microprocessor-controlled knee-ankle-foot orthosis is considered ***not medically necessary*** when the criteria above have not been met.

The HCPCS code associated with this new coverage guideline is L2006.

Ultraviolet Light Therapy Delivery Devices for Home Use (CG-DME-41)

This clinical UM guideline addresses the use of home ultraviolet light (UV) therapy to treat various skin conditions.

An in-home Ultraviolet B (UVB) light therapy delivery device is considered ***medically necessary*** when conditions A and B are met:

A. The treatment is for **one** of the following conditions:
    1. Atopic dermatitis, when topical treatment alone has failed; **or**
    2. Pityriasis lichenoides; **or**
    3. Pruritus of hepatic disease; **or**
    4. Pruritus of renal failure; **or**
    5. Psoriasis, when topical treatment alone has failed; **or**
    6. Cutaneous T-cell lymphoma including mycosis fungoides and Sézary syndrome.

    and
B. The treatment meets the **all** of the following criteria:
    1. Treatment is conducted under a physician's supervision with regularly scheduled exams; **and**
    2. Treatment is expected to be long term (3 months or longer); **and**
    3. The individual meets **any** of the following:
        a. The individual is unable to attend office-based therapy due to a serious medical or physical condition (for example, confined to the home, leaving home requires special services or involves unreasonable risk); **or**
        b. Office-based therapy has failed to control the disease, and it is likely that home-based therapy will be successful; **or**
        c. The individual suffers from severe psoriasis with a history of frequent flares which require immediate treatment to control the disease.

An in-home UVB delivery device is considered ***not medically necessary*** for all other conditions not mentioned above, including but not limited to vitiligo, and when the criteria above are not met.

Home ultraviolet light therapy using ultraviolet A (UVA) light devices are considered ***not medically necessary*** for all indications.

The HCPCS codes associated with this clinical UM guideline are E0691, E0692, E0693, and E0694.

Electric Tumor Treatment Field (TTF) (CG-DME-44)

This clinical UM guideline addresses electrical fields known as "tumor treatment fields (TTF)" that are created by low-intensity, intermediate frequency (100–200 kilohertz [kHz]) electric currents delivered to the malignant tumor site by insulated electrodes placed on the skin surface. TTF are felt to cause tumor cell death (apoptosis) by disrupting the assembly of microtubules during later stages of cell division.

It has been revised to include continuation of TTF therapy beyond the initial 90 days as ***medically necessary*** when both of the following criteria are met:

* Documentation of compliant use must be reported every 90 days as evidenced by the device monitor report showing the individual is using the device at least 18 hours every day; and

* There is no documented tumor progression.*

The CPT and HCPCS codes associated with this revised clinical UM guideline are 77299 and A4555

Cardiac Resynchronization Therapy with or without an Implantable Cardioverter Defibrillator for the Treatment of Heart Failure (CG-SURG-63)

This clinical UM guideline addresses biventricular cardiac pacing to deliver cardiac resynchronization therapy (CRT) to alleviate the symptoms of moderate to severe congestive heart failure associated with left ventricular dyssynchrony. It also addresses a hybrid device that combines CRT with an implantable cardioverter defibrillator (ICD).

Effective with dates of service on or after January 1, 2022, CPT codes 33228, 33229, 33263, and 33264 will be subject to review of this clinical UM guideline.

The coverage guidelines are available for review on our website at www.anthem.com.

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