Implantable Hormone Pellets

Medicare Advantage Medical Policy # MA-230
Original Effective Date: 10/01/2026
Current Effective Date: 10/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider implantable testosterone pellets for use in males for the treatment of primary or secondary hypogonadism OR delayed puberty to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility will be considered for implantable testosterone pellets when the following criteria are met:

- An established diagnosis of hypogonadism with androgen deficiency (see Policy Guidelines section) when **ALL** of the following criteria are met:
    - Persistently low testosterone levels; **AND**
    - Multiple symptoms of hypogonadism including at least 1 "more specific" symptom (see Policy Guidelines section); **AND**
    - **NO** dual therapy with another testosterone product; **AND**
    - Dosing does not exceed upper limit of the dosing range, i.e. 450 mg every 3 months or 6 pellets every 3 months (see Policy Guidelines section),

    OR

- Hormone pellet implantation is being used for treatment of delayed male puberty, dosing does not exceed upper limit of the dosing range, i.e. 450 mg every 3 months or 6 pellets every 3 months (see Policy Guidelines section) and pellets are not used in addition to another testosterone product.

  Note: For treatment of delayed male puberty a six-month-or-shorter course of androgen may be indicated for induction of puberty in patients with familial delayed puberty, a condition characterized by spontaneous, nonpathologic, late-onset puberty.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of implantable hormone testosterone pellets when patient selection criteria are not met, including but not limited to older men with type 2 diabetes mellitus and androgen deficiency or low testosterone levels in the absence of clinical signs and symptoms of hypogonadism, to be **investigational.***

Based on review of available data, the Health Plan considers the use of implantable hormone testosterone pellets for non-U.S. Food and Drug Administration (FDA) approved indications to be **investigational.***

Based on review of available data, the Health Plan considers the use of implantable hormone estradiol pellets to be **investigational.***

Policy Guidelines

This policy only addresses testosterone replacement therapy; it does not apply to treatments for gender transition.

Diagnosis of Androgen Deficiency

An established diagnosis of hypogonadism with androgen deficiency includes appropriate evaluation and diagnostic workup of a man who presents with symptoms of hypogonadism. Clinical practice guidelines recommend measuring serum testosterone only in men with consistent clinical manifestations of hypogonadism. Screening in asymptomatic populations is not recommended. Measurement of serum total testosterone is initially used; serum-free testosterone levels can be measured when total testosterone is in the low to normal range, and alterations of serum hormone-binding globulin are suspected. Once a persistently low testosterone level has been established, diagnostic testing of the hypothalamic-pituitary axis should be performed to distinguish primary hypogonadism from secondary hypogonadism. When secondary hypogonadism is identified, the underlying etiology should be identified and any reversible causes treated appropriately before consideration of testosterone replacement.

Men on chronic steroid treatment would be receiving ongoing treatment for a chronic condition as opposed to episodic treatment for an acute condition or acute flare of a chronic condition. The length of acute episodic steroid treatment may vary from several days to several months, but, in most cases, will be less than 4 to 6 weeks.

Persistently low testosterone levels refer to serum levels below the lower limit of normal on at least 2 occasions when measured in the early morning before 11 AM (ideally between 8 to 10 AM). The threshold lower limit for serum testosterone levels is not standardized. The Endocrine Society has recommended a lower limit for normal levels of 300 ng/dL for total testosterone and 9.0 ng/dL for

free testosterone. Joint guidelines from several European and American specialty societies have recommended that replacement therapy be considered at serum total testosterone levels less than 350 ng/dL.

"More specific" symptoms of hypogonadism, as classified by the Endocrine Society, include the following:

- Incomplete or delayed sexual development
- Decreased libido
- Decreased spontaneous erections
- Breast discomfort, gynecomastia
- Loss of axillar and/or pubic body hair
- Very small (<5 mL) or shrinking testes
- Infertility due to low sperm count
- Height loss due to vertebral fractures, low trauma fractures, low bone density
- Hot flushes, sweats.

Testosterone Dosage Guidelines

Dosing of testosterone varies, depending on age, baseline testosterone levels, comorbid disease, response to initial replacement levels, and adverse reactions. General dosing guidelines are provided by Endocrine Society (see Practice Guidelines and Position Statements section). Specific dosing guidelines for a few of the more commonly used preparations, taken from the product prescribing information, follow:

- Testopel: The recommended dosing range is 150 to 450 mg every 3 to 6 months. For 75-mg pellets, this would correspond to the implantation of 2 to 6 pellets every 3 to 6 months. The dosing interval is individualized because some patients will require redosing as early as every 3 months while others may not require redosing for up to 6 months.

Monitoring Strategies for Individuals on Testosterone Therapy

Monitoring of testosterone replacement should be performed beginning 3 to 6 months after replacement is initiated to ascertain whether serum levels are restored to the normal range, to determine whether clinical symptoms have improved, and to monitor for adverse events. The goal of testosterone replacement is to raise levels into the mid-normal range (800 ng/dL or less). Higher replacement levels are unlikely to improve symptoms further and may increase the incidence and/or severity of adverse events.

Recommendations for monitoring for testosterone-related adverse events have been provided by Endocrine Society guidelines on testosterone therapy in men with androgen deficiency (see Practice Guidelines and Position Statements section). These recommendations include:

- Determine hematocrit levels at baseline, at 3 to 6 months, and then annually. If the hematocrit level is above 54%, stop therapy until the hematocrit level decreases to a safe level, evaluate the individual for hypoxia and sleep apnea, and reinitiate therapy at a reduced dose.

- Repeat bone mineral density of the lumbar spine, femoral neck, and hip after 1 to 2 years of testosterone therapy in hypogonadal men with osteoporosis.
- For men 55 to 69 years of age, and for men 40 to 69 years of age who are at increased risk for prostate cancer, conduct a digital examination of the prostate and prostate-specific antigen (PSA) measurement before initiating treatment, at 2 to 3 months after initiating treatment, and then in accordance with evidence-based guidelines for prostate cancer screening, depending on the age and race of the individual.
- Obtain urologic consultation if there is:
    - An increase in serum or plasma PSA concentration greater than 1.4 ng/mL within 12-months of initiating testosterone treatment.
    - A confirmed PSA of more than 4 ng/mL at any time.
    - Detection of a prostatic abnormality on digital rectal examination.
    - Substantial worsening of lower urinary tract symptoms.

Background/Overview

Testosterone and Testosterone Levels

Testosterone is produced in males, primarily by the testes, in response to stimuli from the hypothalamic and pituitary glands. Low testosterone is caused by deficient production of the hormone and is also known as androgen deficiency. Primary androgen deficiency results from failure of testosterone production at the testicular level in the presence of normal hypothalamic and pituitary function. Secondary androgen deficiency results from failure of the pituitary gland to produce androgen-stimulating hormones (luteinizing hormone, follicle-stimulating hormone). It can be caused by dysfunction at the hypothalamic or pituitary level.

Hypogonadism

Diagnosis

Hypogonadism is the clinical syndrome associated with androgen deficiency. The signs and symptoms of hypogonadism depend on the age of onset. In prepubertal males, the hallmark of androgen deficiency is the failure to develop secondary male sex characteristics. In adults, the signs and symptoms are nonspecific, with the most specific symptoms related to sexual functioning such as decreased libido and erectile dysfunction. Symptoms are dependent on age, the severity of androgen deficiency, duration of androgen deficiency, sensitivity to androgen, and comorbid illness. Symptoms and signs other than sexual dysfunction include loss of body hair, hot flashes or sweats, decreased energy, depression, sleep disturbance, reduced muscle mass and strength, and/or increased body fat. All can occur in the absence of androgen deficiency and, therefore, the diagnosis of hypogonadism can be challenging. A systematic review by Zarotsky et al (2014) reported on risk factors, comorbidities, and consequences of male hypogonadism and identified multiple comorbid conditions that are consistently risk factors for hypogonadism, including advanced age, obesity, metabolic syndrome, and poor general health status. Multiple other conditions, including diabetes, coronary heart disease, hypertension, stroke, and peripheral artery disease, correlated with the presence of hypogonadism, although these were not identified as risk factors.

Testosterone levels decrease with age, beginning in the fourth or fifth decade of a person's life, and this decrease is sometimes referred to as male "andropause." In the European Male Aging Study of 3220 men, there was a decline in serum testosterone levels of 0.4% per year between the ages of 40 and 70. Because this decline is gradual and modest, the clinical impact is uncertain. While there are also parallel decreases in androgen-dependent factors with age, such as sexual function, lean body mass, and bone mineral density, the degree to which these changes are due to decreasing testosterone has not been determined with certainty.

Because of the decline in testosterone levels with age, more elderly males will have lower levels than younger men. Using a cutoff of 325 ng/dL as the lower limit of normal testosterone levels, Travison et al (2007) estimated, based on a prospective cohort of 890 men, that the rate of low testosterone is 20% for men in their 60s; 30% for men in their 70s; and 50% for men in their 80s.[5,] In this study, other factors were associated with decreased testosterone, such as obesity and severe emotional stress. A much lower percentage of men have a combination of low testosterone levels and definite symptoms of hypogonadism. In the European Male Aging Study, this was estimated to be present in 2.3% of men when using a cutoff of at least 3 symptoms potentially related to androgen deficiency.

Another factor that makes the diagnosis of hypogonadism challenging is the measurement of testosterone levels. Testosterone levels fluctuate substantially due to various factors. There is a diurnal variation, which is more pronounced in younger men, with peak levels occurring in the early morning. This makes the timing of measurement important and requires repeated measurement before making a determination that testosterone is consistently low. Also, there is a wide range of levels seen in healthy men and assigning the proper age-appropriate cutoff is controversial. Some men exhibit clear symptoms of hypogonadism with testosterone levels that are in the low to normal range, while other men with low levels do not experience any symptoms.

Treatment
There are numerous U.S. Food and Drug Administration (FDA) approved testosterone formulations available for replacement therapy. For most delivery preparations, approval was based on the ability to increase levels to the normal range, not to demonstrate beneficial clinical outcomes.

Subcutaneous Pellets
One of the depot formulations is a testosterone pellet. The pellets are placed subcutaneously in the buttocks, abdominal wall, or thigh under local anesthesia. Limitations include the need for minor surgical procedures, and local reactions at the implantation site (eg, infections, fibrosis).

Hormone pellets contain either estrogen (estradiol) or testosterone. The pellets provide a slow, continuous release of hormone into the bloodstream and, unlike oral hormone replacement, are not metabolized by the liver. The pellets can last up to six months, but are more typically replaced every three to four months. Frequently, this is the last resort being used after traditional methods of

administration (oral, injection or dermal patch) have failed or been poorly tolerated due to side effects.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Numerous preparations of testosterone have been approved by the FDA for use in testosterone replacement therapy. They include intramuscular, oral, topical, subcutaneous, nasal, and buccal (no longer available in the US) preparations.

In March 2015, the FDA issued a drug safety communication for prescription testosterone products. The communication stated: "We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests." The communication also stated: "FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use. These studies included aging men treated with testosterone. Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not."

As of February 2025, following the FDA's evaluation of a large clinical trial (TRAVERSE) that found testosterone therapy does not raise the risk of heart attack or stroke compared to a placebo, the agency is removing this risk from the Boxed Warning on all prescription testosterone products. Additionally, a warning about the potential for increased blood pressure is being added to the prescribing information for testosterone products that currently lack this information, based on findings from separate blood pressure monitoring studies.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Testosterone
Androgen deficiency, also known as hypogonadism, results from the sub-normal production of testosterone by the testes. Testicular failure may have a genetic or a developmental basis, or may be acquired. Hypogonadotropic (secondary) hypogonadism may result from either acquired or congenital defects in pituitary or hypothalamic function. The efficacy of long acting subcutaneous testosterone pellets as a form of maintenance treatment in hypogonadal males has been proven through randomized clinical trials.

The aging male population in the United States is expected to significantly increase between 2000 and 2030. The normal aging process in men is associated with a slow and irregular decline in blood testosterone levels. This testosterone deficiency produces symptoms similar to those associated with aging, such as loss of energy, depression, decreased libido, erectile dysfunction, loss of bone and muscle mass with decreased muscle strength, increased fat mass and frailty. Several randomized placebo-controlled studies of androgen therapy indicated that testosterone replacement can improve some of these symptoms. However, the studies have not assessed potential risks associated with testosterone replacement, in particular, cardiovascular or prostatic disease. Testosterone replacement therapy (TRT) is not recommended in healthy older men due to the uncertainty of the benefit/risk ratio.

For individuals who have androgen deficiency and type 2 diabetes who receive testosterone replacement therapy, the evidence includes systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are overall survival (OS), symptoms, morbid events, functional outcomes, and quality of life. The available systematic reviews have reported that testosterone replacement leads to modest improvements in glucose control (eg, hemoglobin A_{1c} levels, insulin sensitivity) and lipid parameters. There is a lack of trials reporting on clinical outcomes, and the small benefits may be outweighed by the adverse events of treatment. Current professional guidelines reflect the controversy regarding the balance of risks and benefits. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals (older men) with low testosterone levels without definite hypogonadism who receive testosterone replacement therapy, the evidence includes RCTs and systematic reviews. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, and quality of life. The available RCTs are mostly small and have reported on a limited range of clinical outcomes. For most outcomes, there was no benefit for testosterone replacement. Some studies have reported improvements in lean body mass and decreased body fat, and a recent RCT found improved sexual function. However, these studies did not report improvements in functional status or muscle strength. Although the adverse event profile of testosterone therapy is not well-defined, there are concerns about increased adverse prostate-related outcomes and cardiovascular outcomes. This uncertainty in the adverse event profile creates challenges in determining the risk-benefit profile of treatment in otherwise healthy men. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Estradiol
There were several randomized controlled trials evaluating the efficacy of estrogen pellet implants, along with a number of uncontrolled prospective clinical trials, case series reports and retrospective studies. In some studies, estrogen implant therapy was compared with placebo, while in others it was compared with oral or transdermal estrogen replacement therapy. Most of the studies identified for review involved relatively small numbers of subjects, especially considering the numbers of women who are potential candidates for HRT. Additionally, most of the studies did not involve any kind of blinding, and none were completely blinded. Moreover, the effect of estrogen implants on climacteric symptoms was determined largely with subjective and patient-reported measures. Therefore, these studies may be subject to bias due to a significant placebo effect. Evaluation of the ability of estrogen implants to reduce or prevent the development of osteoporosis involved objective measures of bone density, and was likely subject to fewer biases. Only three of the studies reported on the effect of estrogen implants on lipoprotein profiles, and none provided sufficient long term data to evaluate the impact of estrogen implant therapy on risk of future cardiac events. Duration of follow-up was generally one to three years, although a few studies provided data on patients who had received estrogen implant therapy for more than 10 years.

Supplemental Information

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Diabetes Association
The American Diabetes Association (ADA) Comprehensive Medical Evaluation and Assessment of Comorbidities: *Standards of Medical Care in Diabetes-2022* recommends screening with a morning serum testosterone level for men with diabetes who have symptoms of low testosterone (hypogonadism), such as decreased sexual desire or activity, or erectile dysfunction. Treatment in asymptomatic men is controversial. Testosterone replacement in men with symptomatic hypogonadism may have benefits including improved sexual function, well-being, muscle mass and strength, and bone density. In men with diabetes who have symptoms or signs of low testosterone (hypogonadism), a morning total testosterone level should be measured using an accurate and reliable assay. In men who have total testosterone levels close to the lower limit, it is reasonable to check sex hormone–binding globulin, as it is often low in diabetes and associated with lower testosterone levels. Further testing (such as measuring luteinizing hormone and follicle-stimulating hormone levels) may be needed to determine if the patient has hypogonadism. Testosterone replacement in older men with hypogonadism has been associated with increased coronary artery plaque volume and, in some studies, an increase in cardiovascular events, which should be considered when assessing the risks and benefits of treatment. The 2023, 2024, and 2025 ADA

Standards of Care echo the 2022 recommendations of screening with a morning serum testosterone level in men with diabetes who have symptoms or signs of hypogonadism.

American Urological Association
The 2018 guidelines for the evaluation and management of testosterone deficiency from the American Urological Association are summarized in Table 1.

Table 1. Practice Guidelines for Evaluation and Management of Testosterone Deficiency

Recommendation	SOR	LOE
Clinicians should adjust testosterone therapy dosing to achieve a total testosterone level in the middle tertile of the normal reference range.	Conditional	Grade C
Exogenous testosterone therapy should not be prescribed to men who are currently trying to conceive.	Strong	Grade A
Clinicians should not prescribe alkylated oral testosterone.	Moderate	Grade B
Commercially manufactured testosterone products should be prescribed rather than compounded testosterone, when possible.	Conditional	Grade C

SOR: strength of recommendation; LOE: level of evidence.

Endocrine Society
In 2018, the Endocrine Society published clinical practice guidelines on testosterone therapy in men with androgen deficiency (see Table 2).

Table 2. Practice Guidelines on Testosterone Therapy in Men With Hypogonadism

Recommendations	SOR	QOE
"We recommend testosterone therapy in hypogonadal men to induce and maintain secondary sex characteristics and correct symptoms of testosterone deficiency."	Recommend	Moderate
"We recommend against testosterone therapy in men planning fertility in the near term or in men with breast or prostate cancer, a palpable prostate nodule or induration, a prostate-specific antigen level > 4 ng/mL, a prostate-specific antigen level > 3 ng/mL combined with a high risk of prostate cancer (without further urological evaluation), elevated hematocrit, untreated severe obstructive sleep apnea, severe lower urinary tract symptoms, uncontrolled heart failure, myocardial infarction or stroke within the last 6 months, or thrombophilia."	Recommend	Low
"In hypogonadal men 55 to 69 years old, who are being considered for testosterone therapy and have a life expectancy >10 years, we suggest discussing the potential benefits and risks of evaluating prostate cancer	Suggest	Very low

Recommendations	SOR	QOE
risk and prostate monitoring and engaging the patient in shared decision making regarding prostate cancer monitoring. For patients who choose monitoring, clinicians should assess prostate cancer risk before starting testosterone treatment and 3 to 12 months after starting testosterone."		
"In hypogonadal men being considered for testosterone therapy who are 40 to 69 years old and at increased risk of prostate cancer (e.g., African Americans and men with a first-degree relative with diagnosed prostate cancer), we suggest discussing prostate cancer risk with the patient and offering monitoring options."	Suggest	Very low
"In men with type 2 diabetes mellitus who have low testosterone concentrations, we recommend against testosterone therapy as a means of improving glycemic control."	Recommend	Low

Adapted from Bhasin et al (2018).
SOR: strength of recommendation; QOE: quality of evidence.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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Policy History

Original Effective Date: 10/01/2026
Current Effective Date: 10/01/2026
mm/dd/yyyy Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 07/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	11980
HCPCS	J1073
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.