

# Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Medicare Advantage Medical Policy # MA-139

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*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.*

## 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 percutaneous electrical neurostimulation (PENS) to be **investigational**.\* (Note: See Policy Guidelines for exceptions.)

Based on review of available data, the Health Plan considers percutaneous electrical nerve field stimulation (PENFS) to be **investigational**.\*

Based on review of available data, the Health Plan considers percutaneous neuromodulation therapy (PNT) to be **investigational**.\*

## Policy Guidelines

Percutaneous electrical nerve stimulation is a diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of transcutaneous electrical nerve stimulation (TENS), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

The correct CPT code to use for percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (ie, 64553, 64555, and 64561) are not appropriate, because percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted, so CPT code 64590 is also not appropriate.

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## **Background/Overview**

### **Chronic Pain**

A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, presents a substantial burden to patients, adversely affecting function and quality of life. Certain racial and ethnic groups are at a higher risk of developing diabetes, which may also put them at higher risk of developing complications from diabetes, such as diabetic neuropathy. According to a 2018 to 2019 National Health Interview Survey and data from the Indian Health Service National Data Warehouse, American Indians and Alaska Natives had the highest reported rate of diagnosed diabetes at 14.5%. This was followed by 12.1% of Black individuals, 11.8% of Hispanic individuals, 9.5% of Asian individuals, and 7.4% of White individuals having diagnosed diabetes in 2018 or 2019.

### **Treatment**

These chronic pain conditions have typically failed other treatments, and percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated as treatments to relieve unremitting pain.

### **Percutaneous electrical neurostimulation (PENS)**

Percutaneous electrical nerve stimulation is similar in concept to transcutaneous electrical nerve stimulation (TENS) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. Percutaneous electrical nerve stimulation is generally reserved for patients who fail to get pain relief from TENS. Percutaneous electrical nerve stimulation is also distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS, the location of stimulation is determined by proximity to the pain.

### **Percutaneous neuromodulation therapy (PNT)**

Percutaneous neuromodulation therapy is a variant of PENS in which fine filament electrode arrays are placed near the area causing pain. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C fibers, thus preventing action potential propagation along the pain pathway.

### **Irritable Bowel Syndrome**

Irritable bowel syndrome (IBS) is estimated to affect 5% to 10% of the population globally, and accounts for between 2.4 and 3.5 million physician visits in the United States each year. Up to two-thirds of patients with IBS are female, and it is most common in patients less than 50 years of age. The cause of IBS remains unknown, but is believed to be due to a dysfunction in gut-brain interaction. Symptoms of IBS can include diarrhea, constipation, or both. Abdominal pain and bloating are also common IBS symptoms. These symptoms decrease patient quality of life and create a significant healthcare burden. The American College of Gastroenterology (ACG) recommends that

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patients diagnosed with IBS are categorized by subtypes: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS with mixed symptoms (IBS-M), or IBS without abnormal stools (IBS-U).

### Treatment of Irritable Bowel Syndrome

First-line treatment of patients with IBS generally involves dietary changes. If dietary changes fail to achieve therapeutic goals, there are numerous pharmacotherapeutic options for patients with IBS. Pharmacologic treatment is based on the IBS subtype, and the predominance of either constipation or diarrhea (Table 1). Notably, many IBS treatments are not Food and Drug Administration (FDA)-approved for children or adolescents. The American College of Gastroenterology recommends that gut-directed psychotherapy such as cognitive-behavior therapy and gut-directed hypnotherapy may be beneficial for global IBS symptoms.

**Table 1. Pharmacologic Treatment of Irritable Bowel Syndrome**

| IBS-D                                                                 | IBS-C                                                   | Abdominal Pain                                                  |
|-----------------------------------------------------------------------|---------------------------------------------------------|-----------------------------------------------------------------|
| Antidiarrheal agents (e.g., loperamide)                               | Laxatives (e.g., polyethylene glycol)                   | Antispasmodics (e.g., dicyclomine, hyoscyamine, peppermint oil) |
| Mu-opioid receptor agonist (eluxadoline for refractory patients only) | Chloride channel activator (lubiprostone)               | TCA                                                             |
| 5-HT3 receptor antagonist (alosetron or ondansetron)                  | Guanylate cyclase agonists (linaclotide or plecanatide) | SSRI                                                            |
| Antibiotic (rifaximin)                                                | Sodium/hydrogen exchanger 3 (tenapanor)                 |                                                                 |

HT: hydroxytryptamine (serotonin); IBS-C: irritable bowel syndrome with constipation; IBS-D: irritable bowel syndrome with diarrhea; SSRI: selective serotonin reuptake inhibitor; TCA: tricyclic antidepressant.

### Percutaneous Electrical Nerve Field Stimulation (PENFS)

Because there are few pharmacologic treatments for children and adolescents with IBS, nonpharmacologic options are commonly explored. Percutaneous electrical nerve field stimulation (PENFS) is a potential treatment option for these patients. PENFS involves a non-implantable device which stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal or neuropathic pain conditions or for patients with opioid withdrawal. The IB-Stim device is a type of PENFS that is intended for use only in patients with IBS. The device is disposable and battery-operated. Key components of the device include a percutaneous electrical nerve field stimulator placed behind the ear which connects to a multi-wire electrode array consisting of 4 leads.

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The electrodes have thin needles and attach to the ear at points (preauricular, lobule, and superior crus) where cranial nerve peripheral branches are located just beneath the skin. A pen light included with the device is used to visualize the neurovasculature features and aid in proper electrode placement.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

In 2002, the Percutaneous Neuromodulation Therapy<sup>TM†</sup> (Vertis Neuroscience) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The labeled indication is: "... for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain."

In 2006, the Deepwave<sup>®†</sup> Percutaneous Neuromodulation Pain Therapy System (Biowave) was cleared for marketing by FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the Vertis neuromodulation system and a Biowave neuromodulation therapy unit. The Deepwave<sup>®†</sup> system includes a sterile single-use percutaneous electrode array that contains 1014 microneedles in a 1.5-inch diameter area. The needles are 736  $\mu$ m (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro.

FDA product codes: NHI, QLK.

#### ***PENFS Devices***

In 2019, the IB-Stim device (previously known as Neuro-Stim; Innovative Health Solutions, Inc.) was cleared for marketing by the FDA through the de novo 513(f)(2) process (DEN180057). Both the IB-Stim and the similar NSS-2 BRIDGE device (Innovative Health Solutions, Inc.) are derivatives of the Electro Auricular Device (Navigant Consulting, Inc.). The IB-Stim device is indicated for patients 11 to 18 years of age with functional abdominal pain associated with IBS when combined with other IBS therapies. It is intended to be used for 120 hours per week up to 3 consecutive weeks. The First Relief v1 (DyAnsys, Inc.) device was deemed substantially equivalent to the IB-Stim device in 2020. FDA product code: QHH.

The IB-Stim device (Innovative Health Solutions (IHS), Inc. Versailles, IN) received de novo FDA approval in 2018. According to the FDA, the device is "intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS)". It is intended for use for up to 120 hours per week for up to 3 consecutive weeks; no safety data are available for longer-term use. The disposable, battery-powered device involves a stimulator that is placed behind the ear and percutaneous electrodes that are placed near the nerve branches in the ear. A pen light is used to aid in the placement of the electrodes. Electrical stimulation is delivered to branches of the cranial nerves V, VII, IX and X and the occipital nerves.

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IHS also markets the NSS-2 Bridge Device, which received de novo approval by the FDA in 2017 “as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination”. Device use is limited to 120 hours, after which it is disposable.

S.T. Genesis, Sperenza Therapeutics (Boca Raton, FL) is also described as a device that applies stimulation to branches of cranial nerves V, VII, IX, and X and the occipital nerve, and that aids in the reduction of opioid withdrawal symptoms.

The FDA cleared the Drug Relief<sup>®†</sup> device, DyAnsys, Inc.(San Mateo, CA) through the 510(k) process in 2018. The FDA stated that the device can be “used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of cranial nerves V, VII, IX and X, and the occipital nerves identified by transillumination.” DyAnsys, Inc. also has FDA 510(k) clearance for the PENFS device under the name First Relief<sup>®†</sup> v.1 that is intended ‘to be used up to 120 hours per week up to 3 consecutive weeks, through application to cranial nerves V, VII, IX and X and the occipital nerves identified to trans-illumination, as an aid in the reduction of pain when combined with other treatments for IBS.”

Another PENFS device, the Sparrow Ascent<sup>®†</sup>, was cleared by the FDA under the 510(k) process in 2023. It was originally cleared under the name the Sparrow Therapy System and cited the NSS-2 Bridge as a predicate device. According to FDA documents, the Sparrow Ascent, “is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel”.

### ***Non-Implantable PNT Devices***

An electrical stimulation device identified as Percutaneous Neuromodulation Therapy<sup>™†</sup> Nerve Stimulation System (Vertis Neuroscience, Inc, Vancouver, WA) received FDA 510(k) clearance in 2002. The clearance order stated that the therapy is “indicated for symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment for the management of post-surgical pain and post-trauma pain.” Its primary indication is for low back pain and spinal pain. The procedure involves the insertion of pairs of electrodes into the skin of the lower back area with the intent of stimulating nerve fibers that lie in the deep tissues. Treatments may be given several times a week, typically for about 30 minutes at a time.

The Axon Therapy<sup>®†</sup> Peripheral Nerve Stimulation System for Chronic Pain Relief (NeuraLace Medical, San Diego, CA).) received FDA 510k clearance in 2021. The device is indicated for pain relief in adults with chronic, intractable, post-traumatic or post-surgical pain. The system targets sensory nerve fibers with focused magnetic pulses. It is intended to be used in a clinical setting (e.g. pain management clinic or physical therapy clinic) and involves a series of 15-20 minute sessions.

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## **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.

## **Description**

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. Percutaneous electrical nerve stimulation is performed with needle electrodes while PNT uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue.

Percutaneous electrical nerve field stimulation involves the transmission of electrical impulses to cranial nerve bundles in the ear targeting brain areas involved in processing pain. In the case of patients with irritable bowel syndrome, nerves processing pain for the abdominal region are targeted.

## **Summary of Evidence**

For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia) who receive PENS, the evidence includes primarily small, controlled trials and 2 systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review concluded that PENS could decrease pain intensity but not related disability, while the other found no significant differences between PENS and TENS in mitigation of pain. These conclusions are uncertain due to important methodological limitations in individual trials included in these reviews, such as high heterogeneity with regard to application methods. In the highest quality trial of PENS conducted to date in chronic low back pain, no difference in outcomes was found between the active (30 minutes of stimulation with 10 needles) and the sham (5 minutes of stimulation with 2 needles) treatments. Smaller trials, which have reported positive results, are limited by unclear blinding and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions (e.g., knee osteoarthritis) who receive PNT, the evidence consists of a randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The single trial is limited by lack of investigator blinding, unclear participant blinding, and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with irritable bowel syndrome (IBS) who receive percutaneous electrical nerve field stimulation (PENFS), the evidence includes a subgroup analysis of a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-

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related morbidity. The RCT (N=115) included a heterogeneous population of adolescent patients aged 11 to 18 years with pain-related functional gastrointestinal disorders. Treatment was administered for 3 weeks, and reductions in pain were observed with the active device compared with a sham PENFS device at end of treatment and end of follow-up (maximum of 12 weeks). The subgroup of patients with IBS also had improved pain at the end of treatment with the active device compared with the sham device. However, the trial is limited by its small sample size, heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and the short duration of follow-up.

ECRI (12/2024) clinical evidence assessment concluded that there is moderate evidence from two double-blind, sham-controlled RCTs showing reduction of 30% or more in worst abdominal pain severity, however, results were primarily based on four weeks of treatment, and long-term efficacy data are lacking. The case series were all prospective pre/post studies but have a high risk of bias because they lack a control group, and patients were not blinded to treatment. Long-term data (i.e., > 5-year follow-up) are needed to enable higher confidence conclusions and to determine whether PENFS benefits are long term. Reviewers also noted that PENFS have not diffused into general practice for treating abdominal pain in patients with IBS and there are no clinical practice guidelines mentioning PENFS for treating IBS.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

#### **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 Academy of Neurology**

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation reaffirmed 2011 evidence-based guidelines on the treatment of painful diabetic neuropathy in 2016. The guidelines concluded that, based on a class I study, electrical stimulation is probably effective in lessening the pain of diabetic neuropathy and improving quality of life and recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B). The guidelines were retired and replaced in 2022 with a guideline dedicated to oral and topical treatment of painful

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diabetic polyneuropathy. In these updated guidelines, there is no mention of any electrical stimulation strategies for pain.

### **American College of Physicians and American Pain Society**

Joint practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicated uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture. The guidelines concluded that PENS is not widely available. The guidelines also concluded that transcutaneous electrical nerve stimulation has not been proven effective for chronic low back pain. These guidelines were updated in 2017 and authors stated that evidence was insufficient to determine harms associated with PENS thus, no recommendation was made.

### **American Society of Anesthesiologists et al**

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine indicated that subcutaneous peripheral nerve stimulation might be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies (category B2 evidence, observational studies).

### **National Institute for Health and Care Excellence**

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS. It concluded that the "Current evidence on the safety of [PENS] for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term."

### **American College of Gastroenterology**

The American College of Gastroenterology (ACG) updated their recommendations for irritable bowel syndrome (IBS) management in 2021. The ACG recommendations do not include percutaneous electrical nerve field stimulation.

### **The American Gastroenterological Association**

The American Gastroenterological Association (AGA) updated guidelines for both IBS with constipation and IBS with diarrhea in 2022. Neither of these guidelines include recommendations for percutaneous electrical nerve field stimulation.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

The Centers for Medicare & Medicaid Services currently has the following national coverage policy on PENS:

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"Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator....

### B. Percutaneous Electrical Nerve Stimulation (PENS)

This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

[I]t is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the [transcutaneous electrical nerve stimulation] on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage".

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

| NCT No.        | Trial Name                                                                                                                                                             | Planned Enrollment | Completion Date |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------|
| <i>Ongoing</i> |                                                                                                                                                                        |                    |                 |
| NCT04442321    | Effectiveness of Ultrasound-Guided Percutaneous Electrical Stimulation on Radial Nerve With Exercises in Patients With Lateral Epicondylalgia                          | 60                 | Sep 2023        |
| NCT04683042    | Fibromyalgia TENS in Physical Therapy Study (TIPS): an Embedded Pragmatic Clinical Trial                                                                               | 450                | Aug 2024        |
| NCT04428619    | Neuromodulation With Percutaneous Electrical Nerve Field Stimulation for Adults With Irritable Bowel Syndrome: A Randomized, Double-Blind, Sham-Controlled Pilot Study | 54                 | Nov 2024        |

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NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## **Policy History**

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09/16/2025 Utilization Management Committee review/approval. New policy.

10/21/2025 Exceptions for PENS added to policy guidelines.

Next Scheduled Review Date: 10/2026

## **Coding**

*The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character*

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*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              | 0720T, 64999          |
| HCPCS            | L8678                 |
| 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

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### 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.

### 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

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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.