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Medicare Advantage Policy Manual **Policy ID:** M-SUR44

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

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) been evaluated for the treatment of a variety of chronic musculoskeletal or neuropathic pain conditions including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia. These chronic pain conditions have typically failed other treatments, and the goal of treatment with PENS and PNT is to relieve unremitting pain. PENS 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. PENS is generally reserved for patients who fail to get pain relief from TENS. In PENS, the location of stimulation is determined by proximity to the pain.

PNT is an electrical stimulation therapy in which fine filament electrodes are temporarily placed in the deep tissues near the area causing pain. While some use the terms PENS and PNT interchangeably, PNT differs from PENS in the varying length of the needles and its placement which creates an electrical field that hyperpolarizes C-fibers, thus preventing action potential propagation along the pain pathway.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	For ***PENS***: ✓ Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) *(Criterion B in this NCD)*
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for PNT. Therefore, the health plan's medical policy is applicable.* For ***PNT***: ✓ Percutaneous Neuromodulation Therapy (PNT) and Percutaneous Electrical Nerve Stimulation (PENS), Surgery, Policy No. 44 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

Two devices have received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process:

- The Percutaneous Neuromodulation Therapy™ (Vertis Neurosciences) system received approval to market in 2002

- The Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave Corp.) received approval in 2006, listing the Vertis Neuromodulation system and a Biowave TENS unit as predicate devices.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-83

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS), Surgery, Policy No. M-205

REFERENCES

None

CODING

NOTE: There are no specific codes for PENS or PNT. The correct CPT code to use for PENS and PNT is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64561, 64590) are not appropriate since PENS and PNT use percutaneously temporarily inserted needles and wires rather than percutaneously implanted electrodes that are left in place.

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*