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Medical Policy Manual Surgery, Policy No. 44

Percutaneous Neuromodulation Therapy (PNT)

Effective: September 1, 2018

Next Review: July 2019
Last Review: July 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous neuromodulation therapy (PNT) is an electrical stimulation therapy in which 10 fine filament electrodes are temporarily placed in the deep tissues near the area causing pain (with or without radiating lower extremity pain).

MEDICAL POLICY CRITERIA

Percutaneous neuromodulation therapy (PNT) is considered **investigational** for all indications, including but not limited to treatment of pain.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07
2. Electrical Stimulation and Electromagnetic Therapy for the Treatment of Arthritis, Durable Medical Equipment, Policy No. 83.10
3. Transcutaneous Electrical Modulation Pain Reprocessing, Medicine, Policy No. 143
4. Peripheral Subcutaneous Field Stimulation, Surgery, Policy No. 188
5. Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin, Surgery, Policy No. 205

BACKGROUND

Treatment regimens consist of 30-minute sessions, once or twice a week for 8 to 10 sessions. PNT differs from percutaneous electrical nerve stimulation (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.

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 labeled indications for this system are as follows: "Percutaneous neuromodulation therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunct treatment in the management of post-surgical pain and post-trauma pain" (p. 2).[1]

- The Deepwave® Percutaneous Neuromodulation Pain Therapy System (Biowave Corp.) received 510(k) approval in 2006, listing the Vertis Neuromodulation system and a Biowave TENS unit as predicate devices. The Deepwave system was also cleared for marketing for "[s]ymptomatic relief of chronic, intractable pain, postsurgical and post-traumatic acute pain" along with relief of pain following operation or trauma. The system includes a sterile single-use percutaneous electrode array that contains 1014 microneedles in a 1.5 inch diameter area. The needles are 736 microns (0.736 millimeters) in length; the patch is reported to feel like sandpaper or Velcro.[2]

EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from percutaneous neuromodulation therapy (PNT) provides a significant advantage over placebo.

Treatment with PNT must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with PNT should be compared to other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

RANDOMIZED CONTROLLED TRIAL

To date, a sole randomized placebo-controlled trial has been identified in the published literature.

Wanich published results in 2011 from their randomized controlled trial comparing the Deepwave device with sham treatment among 23 patients following total knee replacement surgery.[3] Primary outcomes included reduction in the Visual Analog Scale (VAS) scale of pain, along with reduction in use of opioids. Among the 21 patients who completed the study (two patients in the treatment group dropped out of the study, citing fatigue from daily

treatment), no differences were found in opioid use, although a significant difference was found in average pain reduction favoring the treatment group (19 vs. 25 mm on the 100mmVAS scale, p<0.05), although there was no discussion as to the clinical significance of these results. In addition, application of a per-protocol analysis is likely to have overestimated the treatment benefit where it truly existed, limiting interpretation of results from this study. Larger comparative randomized clinical trials are needed before conclusions can be made about the use of PNT for treatment in pain in total knee replacement surgery or any other indication.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of percutaneous neuromodulation therapy for the treatment of pain, or any other indication.

SUMMARY

There is not enough research to show that percutaneous neuromodulation therapy (PNT) improves health outcomes for people with pain or any other indication. In addition, there are no evidence-based clinical practice guidelines that recommend the use of PNT for the treatment of pain, or any other indication. Therefore, the use of PNT is considered investigational for all indications including but not limited to treatment of pain.

REFERENCES

1. US Food and Drug Administration. 510(k) Summary of Safety and Effectiveness. Vertis Neuroscience, Inc. Percutaneous Neuromodulation Therapy (PNT)™ Control Unit and Accessories. July 7, 2002. [cited 7/19/2018]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf2/K022241.pdf
2. US Food and Drug Administration. 510(k) Summary for the Biowave Deepwave Percutaneous Neuromodulation Pain Therapy System. July 19, 2006. [cited 7/19/2018]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf6/K061166.pdf
3. Wanich, T, Gelber, J, Rodeo, S, Windsor, R. Percutaneous neuromodulation pain therapy following knee replacement. *The journal of knee surgery*. 2011 Sep;24(3):197-202. PMID: 21980881
4. BlueCross BlueShield Association Medical Policy Reference Manual "Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy." Policy No. 7.01.29

CODES

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

Codes	Number	Description
HCPCS	None	

Date of Origin: *April 1998*