MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Peripheral Nerve Stimulators for Treatment of Pain-OH MCD-MM-1333	06/01/2023-04/30/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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Table of Contents

A. Subject....2
B. Background....2
C. Definitions....2
D. Policy....2
E. Conditions of Coverage....3
F. Related Policies/Rules....3
G. Review/Revision History....3
H. References....3

A. Subject

Peripheral Nerve Stimulators for Treatment of Pain

B. Background

The role of peripheral nerves as sources of pain and avenues of treatment when conservative therapy has failed is being more extensively explored than in previous years. Neuromodulation of peripheral nerves to treat refractory pain is one such area of interest. The neuromodulation of peripheral nerves to reduce pain, known as peripheral nerve stimulation (PNS), has been developed as a minimally invasive pain management modality intended to manage acute and chronic pain.

The proposed mechanism of action, referred to as the gate control theory, involves a method by which stimulation of large-diameter sensory neurons reduces transmission of painful stimuli from small nociceptive fibers to the brain. The stimulation system is placed adjacent to the nerve, a process commonly known as remote selective targeting. The nerve is stimulated by implanting a small lead wire with ultrasound guidance to target a specific nerve. The lead is connected to a small, wearable stimulator. The wearer can adjust the level of stimulation using Bluetooth technology.

C. Definitions

- **Acute Pain** – Pain lasting 4 weeks or less.
- **Chronic Pain** – A distressing feeling often caused by intense or damaging stimuli (pain) lasting more than 3 months, which is considered beyond normal healing time.
- **Minimally Invasive** – Procedures involving entry into the living body through a small incision to lessen recovery time, level of pain, and risk of infection.
- **Sub-Acute Pain** – Pain lasting between four (4) and twelve (12) weeks.

D. Policy

I. Any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition which CareSource determines in its sole discretion to be experimental or investigational is not covered by CareSource.

II. Peripheral nerve stimulators are considered experimental and investigational and are unproven for all indications for the reduction of acute, sub-acute, and chronic pain.

III. Peripheral nerve stimulators are not covered. This includes, but is not limited to:
   A. SPRINT PNS System
   B. Nalu Neurostimulation System
   C. StimRouter Neuromodulation System
   D. Moventis PNS
   E. StimQ PNS System.

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E. Conditions of Coverage
NA

F. Related Policies/Rules
Medical Necessity Determinations
Experimental and/or Investigational Item or Service

G. Review/Revision History

	DATE	ACTION
Date Issued	10/01/2022	
Date Revised	07/29/2022 02/15/2023	Converted from administrative policy (AD-1201) to medical policy. Annual review. Updated definitions.
Date Effective	06/01/2023	
Date Archived	04/30/2024	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Hayes, Inc. Percutaneous peripheral nerve stimulation for treatment of chronic pain. Retrieved February 6, 2023 from www.evidence.hayesinc.com.
2. Hayes, Inc. Peripheral nerve stimulation for treatment of chronic pain. Retrieved February 6, 2023 from www.evidence.hayesinc.com.
3. Hayes, Inc. SPRINT PNS system (SPR therapeutics) for chronic pain. Retrieved February 6, 2023 from www.evidence.hayesinc.com.
4. Helm S, Shirsat N, Calodney A, et al. Peripheral Nerve Stimulation for Chronic Pain: A Systematic Review of Effectiveness and Safety. Pain Ther. 2021;10(2):985-1002. doi:10.1007/s40122-021-00306-4.
5. Mauck WD. Peripheral Nerve Stimulation. Mayo Clinic Connect. Retrieved February 6, 2023 from www.mayoclinic.org.
6. Renew JR. Peripheral Nerve Stimulation. UpToDate. Retrieved February 6, 2023 from www.uptodate.com.
7. United States Food and Drug Administration (FDA). 510(k) Premarket Notification. Retrieved February 6, 2023 from www.accessdata.fda.gov.

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