Occipital Nerve Stimulation (ONS)

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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

Occipital nerve stimulation (ONS) is a neurostimulation technique being investigated as a potential treatment of several conditions, including but not limited to, migraine headaches, hemicrania continua (aka, vascular headache), craniofacial pain, cluster headaches, and chronic, intractable pain of the trunk or limbs.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	For ***removal of an ONS device only,*** as well as ***revision/replacement*** of *not medically necessary devices, see guidance in the Medicare Benefit Policy Manual.*

	General Exclusions From Coverage. Note: Even if initial placement of the device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in select circumstances for the removal of the device. A procedure or device that does not meet medical necessity criteria is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage.	Chapter 16 - General Exclusions From Coverage §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare[1]
	Revision/replacement requests of previously placed medically necessary devices. Replacement of previously placed medically necessary devices or their components that are non-functioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty.[1]	Chapter 15 – Covered Medical and Other Health Services §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement[2]
National Coverage Determinations (NCDs)*	See References[,3,4]	
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles.	***Peripheral Nerve Stimulation***	**LCD L37360** The U.S. Food and Drug Administration (FDA) has not cleared any occipital nerve stimulation device for treatment of headache.

Billing and coding guidelines for ***Peripheral Nerve Stimulation***	Article **A55531**

**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For initial placement:

- Description of the planned treatment, including the indication being treated, symptoms, prior attempted therapies, and the type of electrical stimulation;
- Name of stimulation device. *(Note, occipital nerve stimulators that have not yet been FDA-approved will not be covered.)*

For replacement:

- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty or that the component excluded from the warranty.

For revisions and removal only (without replacement):

- Revisions to previously placed medically necessary devices and removals do not require additional documentation.

REGULATORY STATUS

Occipital nerve stimulation (ONS) devices consist of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

The U.S. Food and Drug Administration (FDA) has not yet cleared any occipital nerve stimulation device for treatment of headache.

The Synergy™ IPG (implantable pulse generator) device from Medtronic received marketing clearance in 1999 for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature.

The Genesis™ neuromodulation system (St. Jude Medical) is approved by the FDA for spinal cord stimulation and has received CE mark approval in Europe for the treatment of chronic migraines.

Medical devices that are not approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Therefore, ONS devices that have not received FDA approval are non-covered, unless they are used in the context of an FDA-approved investigational (IDE) trial.[2] For other types of peripheral nerve stimulators used in occipital nerve stimulation, see criteria provided above for coverage guidance.

CROSS REFERENCES

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

Auricular Electrostimulation, Medicine, Policy No. M-146

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

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty
2. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 – Coverage of Medical Devices
3. NCD for Electrical Nerve Stimulators (160.7) *(This reference can be found on the Medicare Coverage Database website)*
4. NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1). *(This reference can be found on the Medicare Coverage Database website)*

CODING

Codes	Number	Description
CPT	61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
	61886	With connection to two or more electrode arrays
	64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

Codes	Number	Description
	64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
	64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
	64999	Unlisted procedure, nervous system
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve,, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming
	95971	; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95972	; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each *(Code non-covered by Medicare – see L8679)*
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

Codes	Number	Description
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator

***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.*