Subcutaneous Tibial Nerve Stimulation

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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

Subcutaneous tibial nerve stimulation (STNS) of the posterior tibial nerve is a technique of electrical neuromodulation for the treatment of urgency urinary incontinence in patients who have failed behavioral and/or pharmacologic therapies. The posterior tibial nerve contains mixed sensory motor nerve fibers that originate from L4 through S3, which modulate the innervation to the bladder, urinary sphincter and pelvic floor. The specific mechanism of action of neuromodulation is unclear, although theories include improved blood flow and change in neurochemical balance along the neurons. Neuromodulation may have a direct effect on the detrusor or a central effect on the micturition centers of the brain.

MEDICARE ADVANTAGE POLICY CRITERIA

Notes:

- Stimulation of the sacral nerve as a treatment of incontinence is discussed in a separate Medical Policy (see Cross References).
- This policy does not address percutaneous (non-implanted) posterior tibial nerve stimulation (PTNS) for treatment of non-neurogenic urinary dysfunction including overactive bladder, which may be considered medically necessary.

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for subcutaneous tibial nerve stimulation as a treatment of bladder dysfunction. Therefore, the health plan's medical policy is applicable.* Subcutaneous Tibial Nerve Stimulation, Medicine, Policy No. 154 *(see "NOTE" below)*

POLICY GUIDELINES

REGULATORY STATUS

The eCoin® Peripheral Neurostimulator (Valencia Technologies, Inc.), an implantable STNS device, received U.S. FDA premarket approval for the treatment of urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation.

The Revi™ System, previously referred to as the RENOVA iStim, (BlueWind Medical) received U.S. FDA PMA for the treatment of urinary incontinence with or without urinary urgency in August of 2023.

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, CMS 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

Sacral Nerve Stimulation (Neuromodulation) for Pelvic Floor Dysfunction, Surgery, Policy No. M-134

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

REFERENCES

1. NCD for Bladder Stimulators (Pacemakers) (230.16) *(This reference can be found on the Medicare Coverage Database website)*

CODING

NOTE: CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553, 64555, 64561, 64590) are not appropriate since PTNS uses percutaneously temporarily inserted needles and wires rather than percutaneously implanted electrodes that are left in place.

Codes	Number	Description
CPT	0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
	0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
	0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
	0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial
	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.*