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Medicare Advantage Policy Manual **Policy ID:** M-SUR236

Ablation of Peripheral Nerves to Treat Pain

Published: 02/01/2025

Next Review: 09/2025

Last Review: 12/2024 ***Medicare Link(s) Revised:*** *01/01/2025*

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

Radiofrequency ablation (RFA) and cryoneurolysis or cryoablation of nerves have been proposed as treatments for several different types of pain. Ablation has been used to treat a number of clinical pain syndromes such as knee pain and plantar fasciitis.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	*Medicare coverage guidance is not available for ablation of peripheral nerves to treat pain. Therefore, the health plan's medical policy is applicable.* Radiofrequency Ablation of Peripheral Nerves to Treat Pain, Surgery, Policy No. 236

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

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in Table 2.

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). One of the indications is specifically for "creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (> 50% reduction in pain) to a diagnostic genicular nerve block."

Radiofrequency and Cryoneurolysis Devices

Device	Manufacturer	Clearance	Date	FDA Product Code
SInergy®/Bayless Pain Management Probe	Kimberly-Clark/Baylis	K053082	2005	GXD
NeuroTherm® NT 2000	NeuroTherm	K111576	2011	GXD
iovera°	Pacira (formerly Myoscience)	K133453	2014	GXH

Device	Manufacturer	Clearance	Date	FDA Product Code
COOLIEF® Cooled Radiofrequency Kit	Avanos (formerly Halyard Health)	K163236	2016	GXI
COOLIEF® Cooled RF Probe	Avanos (formerly Halyard Health)	K163461	2017	GXI
Rulo(TM) Radiofrequency Lesion Probe	Epimed International	K190256	2019	GXI
Intracept Intraosseous Nerve Ablation System	Relievant Medsystems, Inc	K222281	2022	GXI
Apex 6 Radiofrequency Lesion Generator	RF Innovations, Inc	K220122	2023	GXD
CryoICE Cryo2	Atricure, Inc	K142203	2014	GXH, GEH
CryoICE Cryoablation Probe	Atricure, Inc	K152337	2016	GEH, OCL
CryoSPHERE and CryoSPHERE Max	Atricure, Inc	K233170	2023	GXH

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

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve, Surgery, Policy No. M-225

REFERENCES

None

CODING

NOTE: See Billing and Coding: Cryoneurolysis Instructions (Article A59753)

Codes	Number	Description
CPT	0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve
	0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
	0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)
	64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
	64999	Unlisted procedure, nervous system

HCPCS	C9808	Nerve cryoablation probe (e.g., cryoice, cryosphere, cryosphere max, cryoice cryosphere, cryoice cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
	C9809	Cryoablation needle (e.g., iovera system), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)

***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.*