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Medicare Advantage Policy Manual **Policy ID:** M-SUR242

Irreversible Electroporation

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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 they may also 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

Irreversible electroporation produces high-frequency electric pulses to create an electric current that permanently damages cell membranes causing cell death due to the inability to maintain homeostasis. Irreversible electroporation produces no thermal effect and appears to preserve vessels, nerves and the extracellular matrix.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: The Medicare references in this policy represent the guidance available at publication; please see the Medicare Coverage Database for the latest guidance. This policy includes links to external webpages that are not maintained by the health plan.

This policy does not address the use of irreversible electroporation for tumors other than liver and prostate.

CMS Coverage Manuals

None

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Medical Policy Manual

Medicare coverage guidance is not available for irreversible electroporation. Therefore, the health plan's medical policy is applicable.

Irreversible Electroporation, Surgery, Policy No. 242 *(see "NOTE" below)*

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

The NanoKnife System is a software-controlled low-energy direct-current generator that includes single electrode probes and an optional probe spacer. Voltage is applied between pairs of probes in a series of pulses with adjustable waveform. The NanoKnife SystemTM (Angiodynamics) was originally cleared through the 510(k) process (K102329) in 2011 for the surgical ablation of soft tissue. In 2024, the indication for NanoKnife was expanded to surgical ablation of soft tissue, including prostate tissue.

FDA approval indicates a drug or device has been evaluated for safety and efficacy but does not guarantee coverage. CMS and Medicare contractors evaluate services for medical necessity for Medicare plans under §1862(a)(1)(A).

CROSS REFERENCES

1. Radiofrequency Ablation (RFA) of Tumors Other Than the Liver, Surgery, Policy No. M-SUR92

2. Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS), and High Intensity Focused Ultrasound (HIFU) Ablation, and Transurethral Ultrasound Ablation (TULSA), Surgery, Policy No. M-SUR139
3. Focal Laser Ablation of Prostate Cancer, Surgery, Policy No. M-SUR222

REFERENCES

None

CODING

NOTE: Not all policies have a coding note, but for those that do, the applicable coding note would be placed here.

Codes	Number	Description
CPT	47384	Ablation, irreversible electroporation, liver, 1 or more tumors, including imaging guidance, percutaneous
	55877	Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous
HCPCS	None	