Irreversible Electroporation

INDEPENDENT CARE HEALTH PLAN

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Policy Number: WI.PA-1266
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

There are no NCDs/LCDs/LCAs for irreversible electroporation.

Description

Irreversible electroporation (IRE), also known as **pulsed electric field ablation**, is a nonthermal ablative technique that uses high-voltage direct current delivered to a tumor via needle-like electrode probes. The current is applied in a series of microsecond pulses to create a high-intensity electric field around the target area that increases cell permeability resulting in permanent cell damage and, eventually, cell death. Like

other ablative techniques, IRE is a minimally invasive treatment. The procedure is usually performed under general anesthesia with ultrasound or computed tomography guidance and can be done either surgically or percutaneously.

The primary advantages of IRE are its imperviousness to the heat-sink effect (heat loss caused by local blood flow) and the theory that it, purportedly, causes less damage to surrounding healthy tissue than thermal ablation methods (eg, cryoablation, radiofrequency). Because of this, it has been investigated as a treatment option for tumors in areas with nearby blood vessels, ducts or other critical structures such as the kidneys, liver, lungs, pancreas and prostate.

There are currently two IRE devices approved by the U.S. Food & Drug Administration (FDA). While both the **NanoKnife** and the **Aliya** systems are approved for the ablation of soft tissue, neither device is specifically approved for use in tumor ablation.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Services that are not medically reasonable and necessary may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Treatment with **irreversible electroporation** will **not** be considered medically reasonable and necessary for any indication. A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Irreversible Electroporation
An independent technology assessment organization[2,3,4] found several studies regarding the use of IRE to treat liver, pancreatic and prostate cancers. The majority of the research has been conducted and published outside the US and, therefore, the results may not be generalizable to a US-based population. The available evidence regarding IRE for cancer treatment consists primarily of low-quality (eg, nonrandomized, retrospective, overlapping patient populations) studies. In many cases, these studies failed to compare IRE with more commonly used treatments (eg, radiofrequency ablation [RFA], radiation therapy) and, where comparisons are available, studies do not demonstrate the advantage of IRE. For example, two randomized controlled trials examining IRE for the treatment of liver cancer found no statistical difference between IRE and RFA in terms of overall survival and disease progression. Additional randomized trials are needed with larger, stratified patient populations and defined comparator groups to determine the clinical efficacy and utility of IRE as a cancer treatment.

The FDA has approved two IRE devices (NanoKnife[17], Aliya[16]) for the surgical ablation of soft tissue; however, neither device is specifically approved for tumor ablation. Additionally, there are no national oncologic organizations (eg, American Society of Clinical Oncology [ASCO], National Comprehensive Cancer Network [NCCN]) that offer recommendations for the use of IRE as a cancer treatment.[9,10]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	**Description**	**Comments**
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

References

1. ECRI Institute. Clinical Evidence Assessment. Aliya system (Galvanize Therapeutics Inc.) for treating early-stage non-small cell lung cancer. https://www.ecri.org. Published July 7, 2023.

2. ECRI Institute. Clinical Evidence Assessment. NanoKnife system (AngioDynamics, Inc.) for treating liver cancer. https://www.ecri.org. Published May 7, 2013. Updated April 6, 2023.

3. ECRI Institute. Clinical Evidence Assessment. NanoKnife system (AngioDynamics, Inc.) for treating pancreatic cancer. https://www.ecri.org. Published February 5, 2016. Updated April 12, 2023.

4. ECRI Institute. Clinical Evidence Assessment. NanoKnife system (AngioDynamics, Inc.) for treating prostate cancer. https://www.ecri.org. Published September 14, 2022.

5. Hayes, Inc. Evidence Analysis Research Brief. Aliya system (Galvanize Therapeutics Inc.) for pulsed electric field ablation of soft tissue. https://evidence.hayesinc.com. Published November 17, 2023.

6. Hayes, Inc. Health Technology Brief. NanoKnife system for irreversible electroporation treatment of locally advanced pancreatic cancer. https://evidence.hayesinc.com. Published September 1, 2016. Updated August 13, 2018.

7. Hayes, Inc. Health Technology Brief. NanoKnife system for irreversible electroporation treatment of primary and metastatic liver tumors. https://evidence.hayesinc.com. Published September 15, 2016. Updated September 18, 2018.

8. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Biliary tract cancers. https://www.nccn.org. Updated July 2, 2024.

9. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Hepatocellular carcinoma. https://www.nccn.org. Updated July 2, 2024.

10. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Pancreatic adenocarcinoma. https://www.nccn.org. Updated August 2, 2024.

11. UpToDate, Inc. Image-guided ablation of lung tumors. https://www.uptodate.com. Updated July 2024.

12. UpToDate, Inc. Image-guided ablation of skeletal metastases. https://www.uptodate.com. Updated July 2024.

13. UpToDate, Inc. Localized hepatocellular carcinoma: liver-directed therapies for nonsurgical candidates who are eligible for local ablation. https://www.uptodate.com. Updated July 2024.

14. UpToDate, Inc. Management of stage I and stage II non-small cell lung cancer. https://www.uptodate.com. Updated July 2024.

15. UpToDate, Inc. Radiofrequency ablation, cryoablation and other ablative techniques for renal cell carcinoma. https://www.uptodate.com. Updated July 2024.

16. US Food & Drug Administration (FDA). 510(k) summary: Aliya System. https://www.fda.gov. Published June 17, 2022.

17. US Food & Drug Administration (FDA). 510(k) summary: NanoKnife system. https://www.fda.gov. Published October 24, 2011.

Change Summary

09/24/2024 New Policy.