

Policy: MP339

Section: Medical Benefit Policy

Subject: Irreversible Electroporation

### Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Irreversible Electroporation

### II. Purpose/Objective:

To provide a policy of coverage regarding Irreversible Electroporation

### III. Responsibility:

- A. Medical Directors
- B. Medical Management

### IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

#### **DESCRIPTION:**

Irreversible electroporation (IRE) also known as the NanoKnife® System, is a surgical method used to destroy soft tissue through non-thermal ablation. IRE employs direct-current electrical fields applied to soft tissue. When the high energy level electrical field is applied long enough, it permanently damages the tissue by creating small holes referred to as nanopores or micropores in the cell membranes of the tissue. These holes cause the cell to become more porous, which results in the death of the cell. IRE has been studied in the ablation of pancreatic adenocarcinoma, lung cancer, thyroid cancer, renal and liver lesions, prostate cancer and uveal melanoma.

#### **EXCLUSIONS:**

The Plan does NOT provide coverage for Irreversible Electroporation for any indication because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

#### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

#### **CODING ASSOCIATED WITH: Irreversible Electroporation**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

- 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
- 32999 Unlisted procedure, lungs and pleura
- 47399 Unlisted procedure, liver
- 48999 Unlisted procedure, pancreas
- 53899 Unlisted procedure, urinary system

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

#### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

#### **REFERENCES:**

Wendler JJ, Ganzer R, Hadaschik B, et al. Why we should not routinely apply irreversible electroporation as an alternative curative treatment modality for localized prostate cancer at this stage. *World J Urol* 2017;35(1):11-20. PMID:27147512.

Wendler JJ, Pech M, Fischbach F, et al. Initial assessment of the efficacy of irreversible electroporation in the focal treatment of localized renal cell carcinoma with delayed-interval kidney tumor resection (Irreversible Electroporation of Kidney Tumors Before Partial Nephrectomy [IRENE] Trial-An ablate-and resect pilot study). *Urology* 2018; 114:224-232. PMID:29305201

Canvasser NE, Sorokin I, Lay AH, et al. Irreversible electroporation of small renal masses: suboptimal oncologic efficacy in an early series. *World J Urol.* 2017;35(10):1549-1555

Zimmerman A, Grand D, Charpentier KP Irreversible electroporation of hepatocellular carcinoma: patient selection and perspectives. *J Hepatocell Carcinoma.* 2017;13(4):49-58

Scheffer HJ, Vroomen LG, de Jong MC, et al. Ablation of locally advanced pancreatic cancer with percutaneous irreversible electroporation: results of the phase I/II PANFIRE study. *Radiology.* 2017;282(2):585-597.

Moris D, Machairas N, Tsilmigras DI, et al. Systematic review of surgical and percutaneous irreversible electroporation in the treatment of locally advanced pancreatic cancer. *Ann Surg Oncol* 2019;26(6):1657-1668.

Narayanan G, Hosein PJ, Beulaygue IC, et al. Percutaneous image-guided irreversible electroporation for the treatment of unresectable, locally advanced pancreatic adenocarcinoma. *J Vasc Interv Radiol.* 2017;28(3):342-348

Scheffer HJ, Vroomen LG, Nielsen K, et al. Colorectal liver metastatic disease: efficacy of irreversible electroporation--a single arm phase II clinical trial (COLDFIRE-2 trial). *BMC Cancer* 2015;15: 772

Lyu T, Wang X, Su Z, et al. Irreversible electroporation in primary and metastatic hepatic malignancies: A review. *Medicine (Baltimore).* 2017;96 (17): e6386

Valerio M, Dickinson L, Ali A et al. Nanoknife® Electroporation Ablation Trial: A prospective development study investigating focal irreversible electroporation for localized prostate cancer. *J Urol* 2017;197 (3 Pt 1):647-654.

Dong S, Wang H, Zhao Y, Sun Y, Yao C. First human trial of high-frequency irreversible electroporation therapy for prostate cancer. *Technol Cancer Res Treat.* 2018; 1(17). PMID:30045668.

Blazevski A, Scheltema MJ, Yuen B, et al. Oncological and quality-of-life outcomes following focal irreversible electroporation as primary treatment for localized prostate cancer: A biopsy-monitored prospective cohort. *Eur Urol Oncol* 2019; S2588-9311 (19)30057-4

Ganzer R, Arthanareeswaran VKA, Ahmed HU, et al. Which technology to select for primary focal treatment of prostate cancer? European Section of Urotechnology (ESUT) position statement. *Prostate Cancer Prostatic Dis* 2018;21(2):175-186. PMID

National Comprehensive Cancer Network. NCCN Clinical practice guideline: Pancreatic adenocarcinoma. v1.2023

National Comprehensive Cancer Network. NCCN Clinical practice guideline. Kidney cancer. v4.2023

National Comprehensive Cancer Network. NCCN Clinical practice guideline. Hepatobiliary cancers. v1.2023

Hayes, Inc. Health Technology Assessment. NanoKnife® system for irreversible electroporation treatment of primary and metastatic liver tumors. Published September 15, 2016. Updated September 18, 2018.

Flak RV, Stender MT, Jensen TM, et al. Treatment of locally advanced pancreatic cancer with irreversible electroporation - a Danish single center study of safety and feasibility. *Scand J Gastroenterol.* 2019;54(2):252-258.

Giorgio A, Amendola F, Calvanese A, et al. Ultrasound-guided percutaneous irreversible electroporation of hepatic and abdominal tumors not eligible for surgery or thermal ablation: A western report on safety and efficacy. *J Ultrasound.* 2019;22(1):53-58.

Liu B, Clark J, Domes T, et al. Percutaneous irreversible electroporation for the treatment of small renal masses: The first Canadian case series. *Can Urol Assoc J.* 2019 Jan 21

Sugrue A, Vaidya V, Witt C, et al. Irreversible electroporation for catheter-based cardiac ablation: A systematic review of the preclinical experience. *J Interv Card Electrophysiol.* 2019 Jul 3

Charalambous P, Moris D, Karachaliou G-S, et al. The efficacy and safety of the open approach irreversible electroporation in the treatment of pancreatic cancer: A systematic review. *Eur J Surg Oncol.* 2020;46(9):1565-1572.

Belfiore MP, Reginelli A, Maggioletti N, et al. Preliminary results in unresectable cholangiocarcinoma treated by CT percutaneous irreversible electroporation: Feasibility, safety and efficacy. *Med Oncol.* 2020;37(5):45.

Månsson C, Nilsson A, Nygren P, Karlson BM. Ultrasound-guided percutaneous irreversible electroporation for treatment of locally recurrent pancreatic cancer after surgical resection. *Anticancer Res.* 2020; 40(5):2771-2775

Kwon JH, Chung MJ, Park JY, et al. Initial experience of irreversible electroporation for locally advanced pancreatic cancer in a Korean population. *Acta Radiol.* 2021; 62(2):164-171

Edhemovic I, Breclj E, Cemazar M, et al. Intraoperative electrochemotherapy of colorectal liver metastases: a prospective phase II study. *Eur J Surg Oncol.* 2020; 46(9):1628-1633.

Gupta P, Maralakunte M, Sagar S, et al. Efficacy and safety of irreversible electroporation for malignant liver tumors: a systematic review and meta-analysis. *European Radiology.* 2021;31(9):6511-6521.

U.S. National Library of Medicine. Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue (PRESERVE). Sponsored by AngioDynamics, Inc. Published July 22, 2021. Updated April 7, 2022

ECRI. NanoKnife System (AngioDynamics, Inc.) for Treating Pancreatic Cancer. Published 2/5/16. Updated 4/5/2022

ECRI. NanoKnife System (AngioDynamics, Inc.) for Treating Liver Cancer. Published 5/7/2013. Updated 3/30/2022

Hilton A, Kourounis G, Georgiades F, et al. Irreversible electroporation in renal tumours: A systematic review of safety and early oncological outcomes. *Urologia.* 2022;89(3):329-337.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 7/20

**Revised:**

**Reviewed:** 7/21, 7/22, 7/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.