

02-40000-26

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Reviewed: 05/23/24

Revised: 06/15/24

Subject: Irreversible Electroporation (IRE)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursements	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Irreversible electroporation (IRE) describes a process that uses application of brief, controlled, high-voltage direct current impulses to create multiple holes in cell membranes. This process irreversibly damages the cell's homeostasis mechanism, leading to instant cell death. IRE is most frequently performed in the liver, kidney, lung, prostate, and pancreas, and is also being used to treat metastatic disease in the liver.

The Nanoknife® Oncobionic System is a low-energy direct current thermal ablation system, which received initial Food and Drug Administration (FDA) 510K clearance in 2006, as a tissue ablation system indicated for surgical ablation of soft tissue, including cardiac and smooth muscle. Subsequent FDA clearance clarified the approved indications to "the surgical ablation of soft tissue". It has not received clearance for the therapy or treatment of any specific disease or condition.

Summary and Analysis of Evidence: Meijerink et al (2021) investigated the efficacy and safety of IRE for colorectal liver metastases (CRLMs) unsuitable for resection or thermal ablation because of proximity to critical structures and for further systemically administered treatments. A total of 51 participants (median age, 67 years [interquartile range, 62-75 years]; 37 men) underwent IRE. Of these 51 participants, 50 with a total of 76 CRLMs (median tumor size, 2.2 cm; range, 0.5-5.4 cm) were successfully treated in 62 procedures; in one participant, treatment was stopped prematurely because of pulse-induced cardiac arrhythmia. With a per-participant 1-year LTP-free survival of 68% (95% CI: 59, 84) according to competing risk analysis, the primary end point was met. Local control following repeat procedures was achieved in 74% of participants (37 of 50). Median overall survival from first IRE was 2.7 years (95% CI: 1.6, 3.8). The authors concluded that IRE was effective and relatively safe for colorectal liver metastases 5.0 cm or smaller that were unsuitable for partial hepatectomy, thermal ablation, or further systemic treatment. The reported results were limited by the lack of control group and blinding, as well as the use of concurrent procedures with IRE. In addition, the predefined threshold in the sample

size calculation was chosen arbitrarily. Yang et al (2020) conducted a prospective trial for using IRE through surgical approaches for locally advanced pancreatic cancer (LAPC) in 11 medical centres in Asia, from 2012 to 2017. All related and treatment outcomes were analysed from a prospective database. 74 patients were enrolled. Thirty complications occurred in thirteen (17.6%) patients without mortality. The progression-free survival (PFS) rate at one year, three years, and five years were 69.1%, 48.7%, and 28.8%, and the overall survival (OS) rate at one year, three years, and five years were 97.2%, 53%, and 31.2%. The authors concluded that the study showed that combined induction chemotherapy and surgical IRE for LAPC is safe. For well-selected patients, IRE can achieve encouraging survival outcomes. However, the complication rate of 17.6% was not insignificant. Entry into this trial was limited to individuals who had responded to initial induction chemotherapy. Results may not apply to other individuals. Further prospective, randomized trials are warranted to fully understand the risks and benefits of IRE. Verloh et al (2019) compared the frequency of adverse events of thermal microwave (MWA) and radiofrequency ablation (RFA) with non-thermal irreversible electroporation (IRE) in percutaneous ablation of hepatocellular carcinoma (HCC). 117 MWA/RFA and 47 IRE procedures (one tumor treated per procedure; 144 men and 20 women; median age, 66 years) were analyzed regarding adverse events, duration of hospital and intensive care unit (ICU) stays and occurrence of a post-ablation syndrome. 70.1% of the RFA/MWA and 63.8% of the IRE procedures were performed without complications. Shortcomings of this study included the retrospective nature, lack of randomization, and lack of blinding.

POSITION STATEMENT:

Irreversible electroporation (IRE), including the use of the NanoKnife® system, is considered **experimental or investigational** for all indications, including, but not limited to, ablation of soft tissue or of solid organs, such as the liver and pancreas.

There is insufficient clinical peer reviewed literature demonstrating the safety, efficacy, and the effects of irreversible electroporation (IRE), on long-term health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous (Investigational)
0601T	Ablation, irreversible electroporation; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open (Investigational)

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Electroporation: a cell is subjected to a powerful electrical field using high-voltage direct current (up to 3 kV); this creates multiple holes in the cell membrane and irreversibly damages the cell's homeostasis mechanism, leading to instant cell death.

RELATED GUIDELINES:

[Radiofrequency Ablation of Liver Tumors, 02-40000-23](#)

[Radiofrequency Ablation of Solid Tumors Other Than Liver Tumors, 02-99221-13](#)

OTHER:

Index terms:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

IRE

NanoKnife®

Oncobionic System

Soft tissue ablation

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/23/24.

GUIDELINE UPDATE INFORMATION:

02/15/16	New Medical Coverage Guideline.
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03/15/17	Scheduled review. Maintained position statement. Updated references.
03/15/18	Scheduled review. Position statement maintained; updated references.
04/15/19	Scheduled review. Position statement maintained; updated references.
04/15/20	Scheduled review. Maintained position statement and updated references.
07/01/20	Quarterly CPT/HCPCS coding update. Added codes 0600T, 0601T.
01/01/21	Annual CPT/HCPCS coding update. Revised 0601T.
06/15/21	Scheduled review. Maintained position statement and updated references.
12/15/21	Revision. Updated references and maintained position statement.
06/15/23	Scheduled review. Maintained position statement and updated references.
06/15/24	Scheduled review. Revised description. Maintained position statement and updated references.