Priority Health

# MEDICAL POLICY No. 91599-R4

# IRREVERSIBLE ELECTROPORATION(IRE)/NANOKNIFE

**Effective Date: June 1, 2024**

**Review Dates: 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24**

**Date Of Origin: April 11, 2012**

**Status: Current**

## Summary of Changes

Deletion: Removed redundant statement "IRE/NanoKnife® does not have FDA approval for use in cancer, and no randomized trials or large comparative studies to evaluate the device for cancer indications have been completed."

## I. POLICY/CRITERIA

Irreversible electroporation (IRE) or NanoKnife® use for ablation of cancer is considered experimental and investigational due to insufficient evidence in the peer-reviewed literature.

## II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

## III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***

- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

## IV. DESCRIPTION

In electroporation, direct-current electrical fields are applied to soft tissue, creating nanoscale defects in the cell membranes. In reversible electroporation, which is being used in conjunction with chemotherapeutic drugs for cancer treatment (electrochemotherapy), the defects are temporary. In irreversible electroporation, electrical fields are delivered at an energy level and duration that causes cell death in the targeted tissue. Because irreversible electroporation does not require the use of drugs, it has been proposed as advantageous in immunocompromised patients compared with electrochemotherapy.

Use of the NanoKnife® System for cancer treatment is currently controversial because the technology is not approved by the FDA specifically for this indication, and no randomized trials or large comparative studies have been performed that evaluate the device for cancer treatment.

A prospective registry (Cannon, 2013) of patients undergoing IRE for hepatic tumors over a 2-year period analyzed factors included patient and tumor characteristics, treatment related complications, and local recurrence free survival (LRFS) for ablated lesions. LRFS was calculated according to Kaplan-Meier, with secondary analyses stratified by procedural approach (laparotomy, laparoscopy, and percutaneous) and tumor histology. Forty-four patients undergoing 48 total IRE procedures, 20 colorectal metastasis, 14 hepatocellular, and 10 other metastasis. Initial success was achieved in 46 (100%) treatments. Five patients had 9 adverse events, with all complications resolving within 30 days. LRFS at 3, 6, and 12 months was 97.4%, 94.6%, and 59.5%. There was a trend toward higher recurrence rates for tumors over 4 cm (HR 3.236, 95% CI: 0.585-17.891; P = 0.178). The authors conclude that IRE appears to be a safe treatment for hepatic tumors in proximity to vital structures. Further prospective evaluation is needed to determine the optimal effectiveness of IRE in relation to size and technique for IRE of the liver.

The FDA granted the original 510(k) clearance for the technology to Oncobionics Inc. in November 2006 for the surgical ablation of soft tissue. In mid-2008,

AngioDynamics Inc. completed acquisition of Oncobionics and began marketing the technology as the NanoKnife® System. In January 2011, the FDA issued a warning letter to AngioDynamics for inappropriate marketing of the NanoKnife for unapproved clinical indications. In January 2012, AngioDynamics issued a recall of Ablation Zone Estimator software, which is used in the NanoKnife® System, after the FDA stated that the software would require a separate regulatory submission. The company halted shipment of NanoKnife® systems in the United States, and current U.S. users were contacted to remove the software.

The NanoKnife System has received FDA clearance for the surgical ablation of soft tissue. It has not received clearance for the therapy or treatment of any specific disease or condition

## V. CODING INFORMATION

**ICD-10 Diagnosis Codes:**
*All diagnoses are not covered*

**CPT/HCPCS Codes:**
*Not Covered*
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

## VI. REFERENCES

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