

IRREVERSIBLE ELECTROPORATION(IRE)/NANOKNIFE

Effective Date: April 25, 2012
Date Of Origin: April 11, 2012

Review Dates: 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18
Status: Current

I. POLICY/CRITERIA

Irreversible electroporation (IRE) or NanoKnife[®] use for ablation of cancer is considered experimental and investigational and is not a covered benefit.

IRE/NanoKnife[®] does not have FDA approval for use in cancer, and no randomized trials or large comparative studies have been performed to evaluate the device for cancer indications.

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

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); 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. 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 has halted shipment of NanoKnife[®] systems in the United States, and current U.S. users will be contacted to remove the software. AngioDynamics expects to resume shipments in the United States by the end of May 2012.

Although the company intends to pursue FDA approval for cancer treatment, the time frame for a regulatory submission is not yet known. Because the device is approved for surgical ablation, off-label use for cancer treatment is expected to continue, even in the absence of evidence, because the NanoKnife[®] offers a noninvasive alternative to chemotherapy, radiation therapy, and surgical and minimally invasive ablative treatments.

V. CODING INFORMATION

ICD-10 Diagnosis Codes:

All diagnoses are not covered

CPT/HCPCS Codes:

Unlisted codes must be submitted with explanatory notes

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

VI. REFERENCES

NanoKnife[®] System, Hayes Prognosis Overview, February 2012.

Bagla S, Papadouris D. Percutaneous irreversible electroporation of surgically unresectable pancreatic cancer: a case report. *J Vasc Interv Radiol.* 2012 Jan; 23(1):142-5.

Ablation of Soft tissue using Irreversible electroporation (IRE), Anthem Blue Cross Medical Policy
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Irreversible Electroporation (IRE), Medical Policy SURG.00126, Anthem Blue Cross,
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Pilot Study of Irreversible Electroporation (IRE) to Treat Early-Stage Primary Liver Cancer (HCC) @ <http://clinicaltrials.gov/ct2/show/NCT01078415>

NanoKnife[®] Low Energy Direct Current (LEDC) System in Subjects with Locally Advanced Unresectable Pancreatic Cancer, Phase II
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Irreversible Electroporation (NanoKnife[®]), Clinical Policy Bulletin 0828, Aetna,
@ http://www.aetna.com/cpb/medical/data/800_899/0828.html (Retrieved April 8, 2014; April 7, 2015; March 30, 2016; April 5, 2017; March 28, 2018).

Hayes, Inc. NanoKnife[®] System (AngioDynamics Inc.) for Irreversible Electroporation Treatment of Pancreatic Cancer, June 2014 and annual update reviews

Hayes, Inc. NanoKnife[®] System (AngioDynamics Inc.) for Irreversible Electroporation Treatment of Primary and Metastatic Liver Tumors, June 2014 and annual update reviews

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