**Policy Name:** Irreversible Electroporation (NanoKnife® System)

**Effective Date:** 12/21/2020

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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Irreversible electroporation (i.e. NanoKnife® system) is considered investigative and unproven and therefore **NOT COVERED** for all indications, including but not limited to ablation of soft tissue or of solid organs, such as the liver, pancreas, and kidney. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

**Description**

The NanoKnife® System (AngioDynamics, Inc., Latham, NY, USA) is intended for surgical ablation of soft tissue through irreversible electroporation (IRE). During the procedure, two or more electrodes (up to six) are placed around the tumor to be ablated, and a series of high-voltage, direct-current microsecond pulses create an electric field to induce cell electroporation. This purportedly increases permeability of the cells and causes permanent cell damage and cell death. The ablated tissue is eliminated naturally in a few weeks. This minimally invasive procedure is performed under general anesthesia with ultrasound or computed tomography guidance. The system consists of a low-energy, direct-current generator; touchscreen monitor; keyboard and trackpad for data entry; double foot pedal to activate system; wheels; and needle-like electrode probes. It can be used during open or laparoscopic surgery or percutaneous procedures.

It is proposed that this technique causes less damage to tissue compared with thermal or radiation procedures. The reported benefit of this type of minimally invasive ablation procedure is that it can be used in areas where precision and preservation of the surrounding tissue, blood vessels, and nerves is paramount. This conservation of critical structures is thought to lead to fewer adverse effects. It does require the use of general anesthesia and complete neuromuscular blockade (paralysis) due to the muscle contractions brought about by the strong electric fields created by IRE and the direct stimulation of the neuromuscular junction. It is performed by an interventional radiologist along with an anesthesiologist.

**FDA Approval**

FDA granted 510(k) marketing clearance for the NanoKnife® System in June 2019 (K183385) and granted 510(k) clearance to the original NanoKnife® System (formerly the Oncobionic System) in October 2011 (K102329). The predicate devices are the Oncobionic System (K080202) and the Oncobionic System (K080376). The labeled indication reads: “The NanoKnife® System with six outputs is indicated for the surgical ablation of soft tissue.” The NanoKnife® system has no labeled indications to treat any specific disease or condition.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
- 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

Original Effective Date: 12/21/2020

Re-Review Date(s):

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