BlueCross BlueShield
of Alabama

<u>Name of Blue Advantage Policy:</u>
Irreversible Electroporation (IRE)

Policy #: 612 Latest Review Date: October 2019
Category: Surgery Policy Grade: B

BACKGROUND:

***Blue Advantage** medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **irreversible electroporation (IRE)** as a **non-covered benefit** and is considered **investigational for all indications**, including but not limited to, the surgical ablation of soft tissue and/or solid organs.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Irreversible electroporation (IRE) is a non-invasive ablation technique that uses non-thermal energy (i.e., electrical pulses) to disrupt cellular homeostasis leading to cell death. Because the device is non-thermal, it is proposed to allow the ability to ablate tumors in locations previously contraindicated for thermal ablation such as tumors located near blood vessels.

IRE uses electrical currents delivered through thin needles to treat tumors. The needles are placed in certain locations around the tumor. The electrical pulses disrupt the cell membrane which triggers cancer cells to die and destroys the tumor. Because the electrical pulses are contained between the electrodes placed around the tumor, damage to surrounding tissue, vessels, etc., is contained to the tumor.

KEY POINTS:

A literature review was conducted through October 11, 2019. The published evidence to date on irreversible electroporation consists of smaller studies with only short term follow up; however, there are clinical trials in progress.

Summary

Irreversible electroporation is an emerging technology aimed at focal therapy of tumors. Based on the small studies available, there is not adequate evidence for proof of effectiveness. Larger studies with long term outcomes are needed to determine the net health outcomes related to this procedure.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2013, NICE guidelines regarding renal, primary liver, primary lung, lung metastases, and pancreatic cancer state that current evidence on the safety and efficacy of irreversible electroporation is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. In particular, studies should report the effect of the procedure on local tumour control and patient survival."

In 2016, NICE guidelines regarding prostate cancer states that,"Current evidence on the safety and efficacy of irreversible electroporation for treating prostate cancer is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Studies should include randomised controlled trials comparing the procedure with current standards of care. They should report details of patient selection and short- and long-term outcomes, including patient-reported outcomes and the effect on any future prostate surgery."

In 2017, NICE guidelines reaffirmed the guidelines for pancreatic cancer.

The NCCN does not address IRE for the treatment of prostate, pancreatic or hepatobiliary cancer.

U.S. Preventive Services Task Force Recommendations
Not Applicable.

KEY WORDS:

Nanoknife, Irreversible Electroporation, IRE, SmartTarget

APPROVED BY GOVERNING BODIES:

In 2011, the Nanoknife System received FDA 510k clearance for the surgical ablation of soft tissue. The FDA further clarified in 2011, that it has not been cleared for treatment for a specific disease or condition.

In May 2017, the SmartTarget received FDA 510k clearance for treatment of the prostate. The device is "intended as an accessory for image guided interventional and diagnostic procedures involving the prostate gland…..Example procedures include, but are not limited to: needle biopsy in which tissue samples are removed from the prostate…..irreversible electroporation…"

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

CURRENT CODING:
CPT Codes:

0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous **(Effective 07/01/2020)**
0601T	Ablation, irreversible electroporation; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open **(Effective 01/01/2021)**

Prior to 7/1/2020, there were no specific codes for IRE. Procedures would likely come in on an unlisted code related to the specific body area being treated.

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

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Policy History:

Adopted for Blue Advantage, September 2015
Available for comment September 29 through November 12, 2015
Medical Policy Group, February 2018
Medical Policy Group, October 2019
Medical Policy Group, August 2020: Added CPT codes 0600T and 0601T.
Medical Policy Group, November 2020: 2021 Annual Coding Update. Revised CPT code 0601T to state, "ablation, irreversible electroporation; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open."

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.