

## DRAFT Medical Coverage Policy | Irreversible Electroporation (IRE) of Tumors Other Than Liver



**EFFECTIVE DATE:** 06|01|2026

**POLICY LAST REVIEWED:** 02|18|2026

### OVERVIEW

Irreversible electroporation (IRE) produces high-frequency electric pulses to create an electric current that permanently damages cell membranes causing cell death due to the inability to maintain homeostasis. IRE produces no thermal effect and appears to preserve vessels, nerves and the extracellular matrix.

This policy does not address IRE for tumors of the liver. Refer to the Related Policies section for details.

### MEDICAL CRITERIA

Not applicable

### PRIOR AUTHORIZATION

#### Medicare Advantage Plans and Commercial Products

#### CPT Code 0601T Only

Prior Authorization is required for Medicare Advantage Plans and is recommended for Commercial Products for CPT code 0601T, as this code is not specific to tumor location (e.g. liver, pancreas, kidney, lung, prostate).

### POLICY STATEMENT

#### Medicare Advantage Plans and Commercial Products

Irreversible electroporation (IRE) for treatment of primary or metastatic solid tumors including, but not limited to, tumors of the pancreas, kidney, lung or prostate is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable surgical benefits/coverage.

### BACKGROUND

#### Irreversible Electroporation (IRE)

Electroporation generates high-frequent electric pulses between two or more electrodes which produces an electric current that damages the cell membrane and allows molecules to pass into the cell passively. Electroporation can be temporary (reversible electroporation) or permanent (irreversible electroporation [IRE]). In IRE the cell membrane is permanently damaged causing cell death due to the inability to maintain homeostasis. IRE achieves its action with no thermal effect. IRE appears to preserve vessels, nerves and the extracellular matrix.

#### Pancreatic Cancer

Pancreatic ductal adenocarcinoma has a poor prognosis. The National Cancer Institute estimates that in 2025, there will be over 67,000 new cases of pancreatic cancer in the U.S. and over 51,000 pancreatic cancer deaths. Pancreatic cancer is the third-leading cause of cancer death in men and women. Risk factors for developing pancreatic cancer include: cigarette smoking, obesity, alcohol use, diabetes, pancreatitis and hereditary factors.

Surgical resection is considered the only curative therapy although the majority of cases of pancreatic cancer are unresectable. Locally advanced pancreatic cancer accounts for 30% of newly diagnosed cases of pancreatic cancer and is usually unresectable due to local involvement of adjacent vessels. The 5-year overall survival rate is < 5% for locally advanced, unresectable disease.

The NCCN recommended treatment for patients with locally advanced pancreatic adenocarcinoma includes systemic therapy with fluorouracil + leucovorin + irinotecan + oxaliplatin (FOLFIRINOX)-based or gemcitabine-based therapy, potentially with radiation therapy, with the goal of shrinking the tumor enough for surgical resection. Individuals who are unable to undergo surgery may continue systemic therapy. Depending on the kind of cancer and the genetic makeup some individuals may be candidates for immunotherapy or poly adenosine diphosphate-ribose polymerase (PARP) inhibitors.

Thermal (radiofrequency and microwave) ablation therapies are not commonly used due to the increased risk of trauma to the adjacent major anatomical structures. IRE is being considered as an adjunct to systemic therapy because it may not cause thermal injury to nearby sensitive structures such as the superior mesenteric and portal veins, superior mesenteric and celiac arteries, bile duct adjacent nerves, or gastrointestinal structures.

### **Kidney Tumors**

The National Cancer Institute estimates that there will be over 80,000 new cases of kidney cancer and over 14,000 kidney cancer related deaths in 2025. At diagnosis, approximately 65% of disease is localized disease.

Kidney cancer is approximately 2-fold more common in males compared to females. Mortality rates are 2-fold higher for kidney cancers in Native American people compared to White people. There are many risk factors for kidney cancer such as smoking, hypertension, obesity, chronic kidney disease, exposure to analgesics, chemotherapy and certain toxic compounds, and kidney stones.

Surgery is curative for most patients with localized kidney cancer and is therefore the preferred treatment. NCCN guidelines for kidney cancer recommend partial or radical nephrectomy for T1 kidney cancer, or ablation or active surveillance in select patients. The guidelines say that thermal ablation is an option for the management of clinical stage T1 renal lesion that are  $\leq 3$  cm and is an option for clinical T1b masses in select patients who not eligible for surgery. However, the guidelines caution that randomized phase III trials of ablative techniques with surgical resection have not been performed.

### **Lung Tumors**

The National Cancer Institute estimates that there will be over 226,000 new cases of lung cancer and over 124,000 lung cancer deaths in 2025. Lung cancer is the second most commonly diagnosed cancer and the leading cause of cancer death in both men and women.

Cigarette smoking is the leading risk factor for lung cancer, accounting for 80% to 90% of lung cancer deaths in the US. Other risk factors include radon exposure and radiation therapy to the chest. Black men are approximately 12% more likely to develop lung cancer than White men and Black women are approximately 16% less likely to develop lung cancer than White women. Women have historically had a lower risk than men, but the gap is closing.

The standard for treatment of stage I non-small cell lung cancer (NSCLC) in operable patients is surgical resection with lobectomy and systematic lymph node evaluation. However, a significant number of patients with stage I lung cancer are considered medically inoperable or high-risk surgical candidates. NCCN guidelines state that local ablative therapy with image-guided thermal ablation includes radiofrequency ablation, microwave ablation, and cryoablation, and may be considered for those patients who are deemed "high risk" (medically inoperable due to comorbidities) and is an option for the management of NSCLC lesions < 3 cm. The guidelines also state that in the setting of progression at a limited number of sites

(oligoprogression), local ablative therapy may extend the duration of benefit of the current line of systemic therapy.

### **Prostate Cancer**

The National Cancer Institute estimates that there will be over 313,000 new cases of prostate cancer and over 35,000 prostate cancer deaths in 2025. The 5-year relative survival rate for prostate cancer is 97.9%. The most common risk factor for developing prostate cancer is increasing age. Black men are more likely to get prostate cancer compared to men of other races or ethnicities. Black men are also more than twice as likely to die from prostate cancer compared to men of other races. Genetic factors can also be a risk factor for prostate cancer, especially if a first-degree relative has had prostate cancer.

The standard for treatment of low-risk or favorable intermediate-risk prostate cancer includes active surveillance, radiation therapy, or radical prostatectomy. In patients with regional prostate cancer or higher risk groups, androgen deprivation therapy is recommended, generally in combination with radiation therapy or abiraterone. NCCN guidelines state that ablative therapy (either focal or whole gland ablative therapy) is an experimental and emerging technology for the initial treatment of localized prostate cancer that lacks randomized controlled trial evidence with long-term follow-up showing its superiority or noninferiority to current recommended management strategies. Focal therapy meets the criteria as an alternative therapy, or a non-standard treatment for initial treatment. External beam radiotherapy, brachytherapy, and cryotherapy ablation are currently US Food and Drug Administration (FDA) approved or cleared for initial treatment of prostate cancer, but randomized evidence to the superiority in long-term cancer control and/or quality of life are lacking when delivered as focal rather than whole gland therapy. Other device categories, including IRE, are noted as not currently FDA approved or cleared for the treatment of prostate cancer as focal or whole gland therapy and should only be used in the context of a clinical trial.

NCCN guidelines recommend the use of local therapy as secondary treatment in the case of biopsy-proven recurrence in the prostate after radiation therapy without distant metastatic disease. Local therapy options for patients with recurrence in the prostate include cryotherapy, IRE, high-intensity focused ultrasound, reirradiation (ie, brachytherapy, stereotactic body radiotherapy), and prostatectomy plus pelvic lymph node dissection.

### **Regulatory Status**

The NanoKnife System™ (Angiodynamics) was originally cleared through the 510(k) process (K102329) In 2011 for the surgical ablation of soft tissue. In 2024, the indication for NanoKnife was expanded to surgical ablation of soft tissue, including prostate tissue.

For individuals with locally advanced pancreatic cancer who receive IRE, the evidence includes single-arm studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, and quality of life. Thermal ablation therapies are not commonly used to treat pancreatic cancer due to the increased risk of trauma to the adjacent major anatomical structures. Irreversible electroporation may be an alternative that does not cause thermal injury to nearby sensitive structures. However, there is a lack of consensus on the optimal IRE treatment protocol. Studies of IRE for pancreatic tumors are single-arm. There are insufficient data to determine whether survival is improved with chemotherapy followed by IRE compared to chemotherapy alone. Two randomized controlled trials are underway. Prospective, single arm studies suggest a high complication rate. There are no studies reporting functional or quality of life outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals being treated with locoregional therapy for tumors in the kidneys who receive IRE, the evidence includes single-arm studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, and quality of life. Studies of IRE for kidney tumors are single-arm. Only one study has included more than 10 participants. No comparative data are available.

Therefore, there are no data to determine how survival or adverse events compare to other methods for locoregional therapy. There are no studies reporting functional or quality of life outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals being treated with locoregional therapy for tumors in the lungs who receive IRE, the evidence includes single-arm studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, and quality of life. Irreversible electroporation may be an option for locoregional therapy that is less damaging to nearby broncho vascular structures. Studies of IRE for lung tumors are single-arm. The ALICE study was a prospective, single-arm study conducted at 2 centers that was stopped early (n=23) due to failing to meet expected efficacy at an interim analysis based on high recurrence rates of 61% at a median follow-up of 1 year. No comparative data are available. Therefore, there are no data to determine how survival or adverse events compare to other methods for locoregional therapy. There are no studies reporting functional or quality of life outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals being treated with locoregional therapy for tumors in the prostate who receive IRE, the evidence includes systematic reviews of observational studies and prospective nonrandomized trials. Relevant outcomes are overall survival, disease-specific survival, symptoms, morbid events, functional outcomes, and quality of life. Irreversible electroporation is suggested as an option in clinical guidelines for secondary treatment of biopsy-proven recurrence of prostate cancer after radiation. Studies included in systematic reviews for IRE as initial therapy were too heterogeneous to conduct any pooled analyses. Across those studies, reports of biopsy-proven recurrence post-IRE ranged from 0% to 38.9%. Similarly, studies included in the systematic review for IRE as salvage therapy were also too dissimilar to conduct meta-analyses. Rates of local oncological control post-IRE varied from 67% to 77%, although the definition of control also varied across studies. In the PRESERVE study, 71% of patients had negative in-field biopsies at 12 months, which aligned with results from observational studies across systematic review. The small sample sizes, heterogeneity across studies and study populations, and observational study designs all preclude conclusions of efficacy compared to other standard treatments. No subgroup analyses have been conducted across various severities of prostate cancer. Additionally, the short follow-up times are insufficient to establish long-term oncological effects. No comparative data with guideline-recommended standard of care are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **CODING**

### **Medicare Advantage Plans and Commercial Products**

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 55877** Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous (New Code Effective 1/1/2026)
- 0600T** Ablation, irreversible electroporation; 1 or more tumors per organ, other than liver or prostate, including imaging guidance, when performed, percutaneous (Text Revised Effective 1/1/2026)

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when filed for IRE of tumors other than liver. Refer to the Related Policies section for details:

- 0601T** Ablation, irreversible electroporation; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open

## **RELATED POLICIES**

Prior Authorization of Services, Treatments or Procedures

## **PUBLISHED**

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