

Protocol

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

(70192)

Medical Benefit		Effective Date: 04/01/18	Next Review Date: 09/20
Preauthorization	No	Review Dates: 02/07, 02/08, 03/09, 01/10, 03/10, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 01/18, 09/18, 09/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With solid tumors (located in the breast, lung, pancreas, kidney or bone)	Interventions of interest are: <ul style="list-style-type: none">• Cryosurgical ablation	Comparators of interest are: <ul style="list-style-type: none">• Surgical resection• Other ablative techniques• No intervention	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Disease-specific survival• Quality of life• Treatment-related morbidity

DESCRIPTION

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) involves freezing of target tissues; this is most often performed by inserting a coolant-carrying probe into the tumor. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

SUMMARY OF EVIDENCE

For individuals who have solid tumors (located in areas of the breast, lung, pancreas, kidney, or bone) who receive cryosurgical ablation, the evidence includes nonrandomized comparative studies, case series, and systematic reviews of these nonrandomized studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is a lack of randomized controlled trials and high-quality comparative studies to determine the efficacy and comparative effectiveness of cryoablation. The largest amount of evidence assesses renal cell carcinoma in select patients (i.e., those with small tumors who are not surgical candidates, or those who have baseline renal insufficiency of such severity that standard surgical procedures would impair their kidney function). Cryoablation results in short-term tumor control and less morbidity than surgical resection, but long-term outcomes may be inferior to surgery. For other indications, there is less evidence, with single-arm series reporting high rates of local control. Due to the lack of prospective controlled trials, it is difficult to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2017 supports that the following indications provide a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with localized renal cell cancer when either of the following criteria is met:
 - No more than four cm in size when preservation of kidney function is necessary (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate <60 mL/min/m²), and standard surgical approach (i.e., resection of renal tissue) is likely to worsen kidney function substantially; or
 - When the patient is not considered a surgical candidate.
- Use of cryosurgical ablation to manage individuals with lung cancer when either of the following criteria is met:
 - Poor surgical candidates with early-stage non-small-cell lung cancer; or
 - Palliation of a central airway obstructing lesion.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with:
 - Malignant or benign tumors of the breast;
 - Pancreatic cancer; or
 - Bone cancer.

Thus, the above indication may be considered investigational.

Clinical input obtained in 2009 provided substantial support for cryoablation in patients with small renal cell cancers who were either poor surgical candidates or whose kidney function was likely to be impaired by surgery. Moreover, there was clinical support for cryoablation in patients who were either poor surgical candidates with early-stage non-small-cell lung cancer or who required palliation for a lesion obstructing the central airway. Contextual factors contributing to this support included the lack of treatment alternatives and the potential for reduced harm compared with surgery.

POLICY

Cryosurgical ablation may be considered **medically necessary** to treat localized renal cell carcinoma that is no more than four cm in size when either of the following criteria is met:

- Preservation of kidney function is necessary (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m²) and standard surgical approach (i.e., resection of renal tissue) is likely to worsen kidney function substantially; or
- The patient is not considered a surgical candidate.

Cryosurgical ablation may be considered **medically necessary** to treat lung cancer when either of the following criteria is met:

- The patient has early-stage non-small cell lung cancer and is a poor surgical candidate; or
- The patient requires palliation for a central airway obstructing lesion.

Cryosurgical ablation is considered **investigational** as a treatment for benign or malignant tumors of the breast, lung (other than defined above), pancreas or bone and other solid tumors or metastases outside the liver and prostate, and to treat renal cell carcinomas in patients who are surgical candidates.

BACKGROUND

BREAST TUMORS

Early-stage primary breast cancers are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach is balanced against the patient's desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient's age, hormone receptor status, and other factors. Adjuvant radiotherapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors. Treatment of metastatic disease includes surgery to remove the lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can present as a palpable mass or a mammographic abnormality. These benign tumors are frequently surgically excised to rule out a malignancy.

Lung Tumors

Early-stage lung tumors are typically treated surgically. Patients with early-stage lung cancer who are not surgical candidates may be candidates for radiotherapy with curative intent. Cryoablation is being investigated in patients who are medically inoperable, with small primary lung cancers or lung metastases. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment is rarely curative; rather, it seeks to retard tumor growth or palliate symptoms.

Pancreatic Cancer

Pancreatic cancer is a relatively rare solid tumor that occurs almost exclusively in adults, and it is largely considered incurable. Surgical resection of tumors contained entirely within the pancreas is currently the only potentially curative treatment. However, the nature of the cancer is such that few tumors are found at such an early and potentially curable stage. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment focuses on slowing tumor growth and palliation of symptoms.

Renal Cell Carcinoma

Localized renal cell carcinoma is treated with radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule because chemotherapy is relatively ineffective against metastatic renal cell carcinoma.

Cryosurgical Treatment

Cryosurgical treatment of various tumors including malignant and benign breast disease, lung cancer, pancreatic cancer, and renal cell carcinoma has been reported in the literature. The hypothesized advantages of cryosurgery include improved local control and benefits common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

REGULATORY STATUS

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration through

the 510(k) process for use in open, minimally invasive, or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery, and ear, nose, and throat. Examples include:

- Cryocare® Surgical System (Endocare);
- CryoGen Cryosurgical System (Cryosurgical);
- CryoHit® (Galil Medical) for the treatment of breast fibroadenoma;
- SeedNet™ System (Galil Medical); and
- Visica® System (Sanarus Medical).

Food and Drug Administration product code: GEH.

RELATED PROTOCOLS

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Whole Gland Cryoablation of Prostate Cancer

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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