The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if the medically necessary criteria of this Protocol will not be met, and you feel the service is medically necessary; supporting documentation must be submitted to Utilization Management.** 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.

**Description**

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

**Background**

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). Potential complications of cryosurgery include those caused by hypothermic damage to normal tissue adjacent to the tumor, structural damage along the probe track, and secondary tumors, if cancerous cells are seeded during probe removal.

Cryosurgical treatment of various tumors including renal cell carcinomas, malignant and benign breast disease, pancreatic cancer, and lung cancer has been reported in the literature.

**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 radiation therapy 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 primary lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can either 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 radiation treatment 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. This is rarely curative but rather 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 is almost always fatal. 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. This is rarely curative but rather seeks to retard tumor growth or palliate symptoms.

Renal cell carcinoma. Localized renal cell carcinoma (RCC) is treated by radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic RCC.

**Regulatory Status**

There are several cryoablation devices cleared for marketing by the U.S. Food and Drug Administration (FDA) 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 by Endocare;
- CryoGen Cryosurgical System by Cryosurgical, Inc.;
- CryoHit® by Galil Medical for the treatment of breast fibroadenoma;
- SeedNet™ System by Galil Medical; and
- Visica® System by Sanarus Medical.

**Related Protocols:**

- Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- Cryoablation of Prostate Cancer
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

**Corporate Medical Guideline**

Cryosurgical ablation may be considered *medically necessary* to treat localized renal cell carcinoma that is no more than 4 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 60mL/min per m²) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; or
- Patient is not considered a surgical candidate.

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

**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.


