Clinical Policy Title: Cryosurgery for tumors

Clinical Policy Number: 05.03.01

Effective Date: January 1, 2015
Initial Review Date: August 20, 2014
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Related policies:

CP# 05.02.09  Hyperthermia (treatment for cancer)
CP# 09.02.08  Cryoneurolysis

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of cryosurgery to be clinically proven and, therefore, medically necessary when the following criteria are met (Jiang 2017, Cazzato 2016, Gao 2016, Afsar 2015, Rose 2015, Tang 2014, Klatle 2014, Martin 2013):

- Liver tumors — Surgical excision is not possible based on the size, location, and number of nodules; and/or the presence of hepatic disease (e.g., cirrhosis).
- Prostate cancer — Disease is clinically organ-confined.
- Skin cancer — The tumor is of limited extent (e.g., localized squamous cell, basal cell carcinoma).
- Brain tumors — Cryosurgery is used as an assistive technique to surgical excision.
- Kidney tumors — Surgical excision is not possible and the tumor is less than 3 centimeters in diameter.
• Bone tumors — Cryosurgery is used in adjunct with curettage for locally aggressive, benign tumors.
• Breast tumors — Tumor is surgically inoperable and less than 1 centimeter in diameter.
• Retinoblastoma

Prestige Health Choice considers the use of cryosurgery to be investigational and, therefore, not medically necessary for the following conditions:

• Pharyngeal and laryngeal tumors.
• Bronchial tumors.
• Pancreatic tumors.
• Malignant bone tumors.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of cryosurgery are considered investigational and therefore not medically necessary.

Alternative covered services:

• Primary and specialty care provider evaluation and management.
• Chemotherapy.
• Radiotherapy.

Background

Cryosurgery is the process of surface application or injection of cryoprecipitant material via percutaneous probes into tumorous tissues to promote tumor cell death and necrosis for local palliation or cure. The circulating liquid nitrogen or pressurized argon in the probe causes formation of intracellular and extracellular ice, resulting in the destruction of cell membranes and intracellular structures, causing cell death. Cooling tissues to below -20 °C and repeated freeze-thaw cycles destroy tissue, helping to control tumor growth, relieve disease symptoms, and increase survival in patients with unresectable tumors. Cryosurgery can be effective in treating many conditions, including benign tumors and solid cancers.

Liver tumors:
Resection of liver tumors is based on the size, location, number of nodules, and the presence of concomitant liver disease (e.g., cirrhosis). Cryosurgery in the liver is most commonly used for metastatic tumors considered otherwise unresectable. Cryosurgery has also been used in combination with excision, excising some lesions and freezing others. A method of combining cryosurgery and excision is cryo-assisted excision, where a cryoprobe is inserted into a tumor, freezing to and adhering to the tissue, which then serves as a device for traction on the tumor to facilitate excision.

Common complications of hepatic cryosurgery include hemorrhage at probe-incision sites, coagulopathy from platelet deficiency, biliary fistula, pleural effusion, and renal failure. A complication rate between 20 percent and 30 percent is often cited for these procedures. Postoperative mortality is generally accepted as between 2 percent and 5 percent. Long-term survival rates vary greatly, with a median survival of more than two years a typical response. Adjunctive therapy such as chemotherapy or radiotherapy results in a distinct improvement in survival rate over cryotherapy alone.

Prostate cancer:

Cryosurgery for prostatic cancer emerged initially in the mid-1960s, and again with new technology in the 1990s. Techniques are similar to other cryosurgical methods, but use a temperature of -40 °C and have two freeze-thaw cycles.

While prostatic cryosurgery is promising, no randomized studies or long-term studies have been reported. Without such studies, it is difficult to assess the advantages and disadvantages of cryosurgery over other treatments for prostate cancer.

Skin cancer:

Cryosurgery for skin cancer applies a liquid nitrogen spray to basal and squamous cell carcinomas that are less than 2 cm in diameter. A cure rate of greater than 95 percent is typical. Recurrence, when it occurs, can be treated with cryosurgery again, leading to a 99 percent cure rate after five years in most hands.

Brain tumors:

Cryosurgery for intracranial tumors is frequently used as an assistive technique for surgical excision in the brain, spinal cord, and orbit. It also plays a role in control of residual tumor after incomplete excision; however, no studies report cryosurgery alone to be an effective method of tumor excision for cure.

Pharyngeal and laryngeal tumors:
Pharyngeal and laryngeal tumors are difficult to treat cryosurgically. Cryosurgery in this area carries a substantial risk of obstruction to the airway from edema and necrotic tissue. As such, the risks of asphyxiation have limited the application of cryosurgery to pharyngeal and laryngeal tumors.

**Bronchial tumors:**

Cryosurgery for bronchial tumors is considered to be of limited benefit and generally accompanies a combination of therapies, such as radiotherapy, photodynamic therapy, laser therapy, electrocautery ablation, or bronchoscopic and open surgical procedures. The verified benefits from cryosurgery alone are strictly palliative, resulting in relief of bronchial obstruction, reaeration of collapsed lungs, and amelioration of hemoptysis, cough, dyspnea, and pain.

**Pancreatic tumors:**

Few clinical trials of cryosurgery for pancreatic tumors exist. Canine studies suggest that cryosurgery should be tolerable, but insufficient data exists to prove its effectiveness in humans. When cryosurgery has been performed for pancreatic tumors, subjects report only palliative benefits (e.g., amelioration of pain). Success in palliation rates must be tempered with a significant occurrence of postoperative pancreatitis.

**Kidney tumors:**

Cryosurgery for kidney tumors has expanded since the 1990s. Candidates typically present with renal tumors in whom conservation of kidney function is a priority (e.g., solitary kidney). Clinical trials suggest that cryosurgery is an alternative to partial or hemi-nephrectomy in this setting; however, long-term studies are not yet available to verify this proposition.

**Bone tumors:**

Cryosurgery of bone tumors is performed as adjunctive treatment to curettage. Bone curettage alone is associated with high bony recurrence rates. Adjunctive cryosurgery may eliminate residual tumor cells, resulting in higher cure rates and reduced recurrence of locally aggressive tumors. Cryosurgery may induce certain palliative benefits, such as pain relief, as well. Cryosurgery is not recommended for treatment of malignant tumors of bone.

**Breast tumors:**

Studies are limited for the use of cryosurgery in treating breast tumors, with some limited success with small benign tumors less than 1 centimeter in diameter. While studies acknowledge the safety and effectiveness for cryosurgery on benign breast tumors, no long-term studies have compared it to excision.
Retinoblastoma:

Cryotherapy alone may be used as primary therapy for small peripheral retinoblastomas located anterior to the equator. Cryotherapy induces the tumor tissue to freeze rapidly, and a temperature to −90°C causes intracellular ice crystal formation, protein denaturation, pH changes and cell rupture, resulting in damage to the vascular endothelium with secondary thrombosis and infarction of the tumor tissue. Tumors are typically treated three times (triple freeze and thaw technique) per session transconjunctivally, with repeat sessions at monthly intervals. Ninety percent of tumors that are less than 3 mm in diameter are cured permanently. The complications are few and rarely serious, and include lid edema, transient conjunctival edema, and transient localized serous retinal detachments.

Other tumors:

Surgical excision remains the best option for tumor removal. In inoperable patients, cryosurgery may provide palliative benefits, especially in malignant tumors. With the resurgence of cryosurgery after technological advancements, further research and clinical trials could show significantly improved results in survival and recurrence rates.

Surgical excision, chemotherapy, or radiotherapy remain the best options for most malignant or benign tumors encountered in modern clinical practice. In inoperable patients, cryosurgery may provide palliative benefit and local control of tumor growth. Although technological advancements have fostered a resurgence of interest in cryosurgery, further research and clinical trials are needed to demonstrate any superiority in survival and recurrence rates over conventional therapies.

Searches

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 11, 2018. Search terms were: “cryosurgery,” “cryoablation,” and “tumor.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Tang (2014) described laparoscopic renal cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal masses in a systematic review and meta-analysis of comparative studies inclusive of nine trials including 1,197 participants. The authors compared safety and efficacy of laparoscopic renal cryoablation versus surgical excision and found comparable results with fewer complications from the cryoablation modality.

Klatle (2014) conducted a systematic review and meta-analysis of perioperative and oncologic outcomes of laparoscopic cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal tumors inclusive of 13 trials of an unspecified number of participants. The authors compared perioperative and oncologic outcomes of laparoscopic renal cryoablation versus laparoscopic (robot-assisted) partial nephrectomy and found cryoablation patients had shorter operative times, less blood loss, shorter stays, and fewer complications, but worse survival outcomes.

Martin (2013) performed a meta-analysis of cryoablation versus microwave ablation for small renal masses inclusive of 51 trials and 3,950 participants. The authors noted no difference in survival or in local/metastatic tumor progression.

Policy updates:

A narrative review (Cazzato 2016) outlined the medical evidence for percutaneous imaging-guided cryoablation (PICA) in small renal tumors, curative/palliative therapy of small primary/secondary lung tumors, palliation of painful bone metastases, and urologic treatment of organ-confined prostate cancer. There is growing evidence to support the use of percutaneous imaging-guided cryoablation for small hepatic tumors, and encouraging results have been obtained for breast tumors, extra-abdominal desmoid tumors, and management of higher-stage tumors and oligometastatic disease. However, the overall evidence base is weak, effectively restricting percutaneous imaging-guided cryoablation to cases where standard therapy and radiofrequency ablation are unsuitable.

Gao (2016) conducted a systematic review of seven studies inclusive of 1,252 patients diagnosed with localized prostate cancer comparing cryosurgery versus radiotherapy (RT) and/or radical prostatectomy (RP). The primary outcomes were overall survival (OS), disease-specific survival (DSS), and disease-free survival (DFS) of each intervention. Secondary events included complications caused by treatment which predominantly included urinary and sexual complications, mainly erectile dysfunction. With regard to cryosurgery versus radical prostatectomy, the data revealed a tendency for an advantage in OS in the cryosurgery group, but the differences were insignificant (p = 0.40, and p = 0.76 respectively). Disease-specific survival findings were similar (p = 0.48) in comparison of cryosurgery versus radiotherapy and
cryosurgery versus radical prostatectomy. Finally, there were no significant differences in DFS when comparing cryosurgery with radiotherapy (p = 0.35), but differences in DFS were significant in comparison of cryosurgery versus radical prostatectomy (p = 0.03). The authors concluded that cryosurgery is an efficient minimally invasive choice for clinically localized prostate cancer.

Afsar (2015), in a retrospective review of 1,031 dermatology patients undergoing cryosurgery, described this modality as an alternative treatment for many benign, premalignant, and malignant lesions of the skin. The most frequent indication for cryosurgery was common warts which were present in 535 patients (61.59 percent), followed by anogenital warts in 119 (11.54 percent), callosity in 81 (7.85 percent), actinic keratosis in 77 (7.46 percent), molluscum contagiosum in 35 (3.39 percent), and other benign or malignant skin lesions, among them tumors with well-circumscribed borders such as basal cell carcinoma, squamous cell carcinoma, Kaposi's sarcoma, and non-operable disseminated cutaneous metastases of malignant melanoma. No minor or major side effects were reported, and the authors suggested cryosurgery may be superior to other modalities with regard to results, degree of immediate functionality, and a substantially lower rate of complications.

Rose (2015), in a narrative review of cryosurgery for the treatment of benign conditions of the bones and soft tissues, as well as the palliation and durable treatment of musculoskeletal metastases, opined that this technology is not commonly indicated in the curative treatment of primary malignant bone or soft tissue sarcomas. While cryoablation has been reported in the treatment of primary bone and soft tissue malignancies, these lesions are rare enough that clinical experience with cryoablation as curative therapies has not been well established. The authors also noted that computed tomography (CT)-guided cryoablation has particular use in treating musculoskeletal neoplasms because of the ability to image the cryoprobe (which uses room temperature argon to provide cooling via rapid expansion, the so-called Joule-Thompson effect) and quantify in amount the lethal ice zone the probe creates around both bone and soft tissue structures.

During the past twelve months there has been further information published regarding percutaneous cryoablation compared with laparoscopic cryoablation.

A systematic review (Jiang 2017) was performed to obtain comprehensive evidence with regard to the feasibility and safety of percutaneous cryoablation compared with laparoscopic cryoablation. Patients undergoing percutaneous cryoablation were significantly older (P = 0.01). Patients with posterior tumors were significantly more likely to undergo percutaneous cryoablation than laparoscopic procedures (P = 0.0007), whereas patients with anterior tumors were significantly more likely to undergo laparoscopic cryoablation (P = 0.02). Percutaneous cryoablation was associated with shorter hospital stay (P < 0.0001) and higher incidence of perirenal hematoma (P < 0.0001).

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jiang (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Laparoscopic cryoablation vs. percutaneous cryoablation for treatment of small renal masses: a systematic review and meta-analysis. | • A systematic review was performed to obtain comprehensive evidence with regard to the feasibility and safety of percutaneous cryoablation compared with laparoscopic cryoablation.  
• Patients undergoing percutaneous cryoablation were significantly older (WMD = -0.16 years; \( P = 0.01 \)).  
• Patients with posterior tumors were significantly more likely to undergo percutaneous cryoablation than laparoscopic procedures (OR = 0.23; \( P = 0.0007 \)), whereas patients with anterior tumors were significantly more likely to undergo laparoscopic cryoablation (OR = 3.82; \( P = 0.02 \)).  
• Percutaneous cryoablation was associated with shorter hospital stay (WMD = 1.17 days; \( P < 0.0001 \)) and higher incidence of perirenal hematoma (OR = 0.18; \( P < 0.0001 \)). |
| Cazzato (2016) Percutaneous image-guided cryoablation: current applications and results in the oncologic field. | **Key points:**  
• PICA is a recently developed technique, which applies extreme hypothermia to destroy tumors under close imaging surveillance.  
• A narrative review noted a recent large increase in reports evaluating the utility of PICA in a wide range of patients and tumors, but systematic analysis of the literature is challenging due to the rapid pace of change and predominance of extensively heterogeneous level III studies.  
• The precise onco-therapeutic role of PICA has not been established. |
| Gao (2016) Cryosurgery would be an effective option for clinically localized prostate cancer: a meta-analysis and systematic review | **Key points:**  
• A systematic review of seven studies inclusive of 1,252 patients diagnosed with localized prostate cancer comparing cryosurgery versus RT and/or RP.  
• Complications caused by treatment were urinary and sexual complications, mainly erectile dysfunction.  
• Cryosurgery and RP data revealed a tendency for an advantage in OS in the cryosurgery group, but the differences were insignificant (RR 1.16, 95% CI 0.82–1.64, \( p = 0.40 \), and RR 1.05, 95% CI 0.75–1.48, \( p = 0.76 \), respectively).  
• DSS findings were similar (RR 1.15, 95% CI 0.78–1.72, \( p = 0.48 \)) in comparison of cryosurgery versus RT and cryosurgery versus RP.  
• No significant differences in DFS when comparing cryosurgery with RT (RR 0.69, 95% CI 0.32–1.49, \( p = 0.35 \)) were apparent, but differences in DFS were significant in comparison of cryosurgery versus RP (RR 0.85, 95% CI 0.73–0.99, \( p = 0.03 \)).  
• The authors concluded that cryosurgery is an efficient minimally invasive choice for clinically localized prostate cancer, with comparable OS, DSS, and DFS as RT and RP. |
| Afsar (2015) Clinical practice trends in cryosurgery: a retrospective study of cutaneous lesions | **Key points:**  
• A retrospective review of 1,031 dermatology patients undergoing cryosurgery.  
• The most frequent indication for cryosurgery was common warts which were present in 535 patients (61.59%), followed by anogenital warts in 119 (11.54%), callosity in 81 (7.85%), actinic keratosis in 77 (7.46%), molluscum contagiosum in 35 (3.39%), and... |
other benign or malignant skin lesions.

- No minor or major side effects were reported.
- Authors suggested cryosurgery may be superior to other modalities with regard to results, degree of immediate functionality, and a substantially lower rate of complications.

**Key points:**
- Narrative review of cryosurgery for the treatment of benign conditions of the bones and soft tissues.
- Primary bone and soft tissue malignancies are rare enough that clinical experience with cryoablation has not been well established.
- CT-guided cryoablation has particular use in treating musculoskeletal neoplasms because of its ability to image the ice zone the cryoprobe creates around bone and soft tissue.

**Tang (2014)**
Laparoscopic renal cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal masses: a systematic review and meta-analysis of comparative studies

**Key points:**
- Meta-analysis of cryotherapy for small kidney masses.
- 9 trials, 1,197 participants, safety and efficacy compared.
- Laparoscopic renal cryoablation vs. surgical excision.
- Comparable safety and renal function, fewer complications.

**Klatte (2014)**
Systematic review and meta-analysis of perioperative and oncologic outcomes of laparoscopic cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal tumors

**Key points:**
- Meta-analysis of cryotherapy for small kidney tumors.
- 13 trials, perioperative and oncologic outcomes compared.
- Laparoscopic renal cryoablation vs. laparoscopic (robot-assisted) partial nephrectomy.
- Cryoablation patients had shorter operative time, less blood loss, shorter stays, fewer complications — but worse oncology outcomes.

**Martin (2013)**
Meta-analysis of cryoablation versus microwave ablation for small renal masses: is there a difference in outcome?

**Key points:**
- Meta-analysis of cryotherapy for small kidney masses.
- 51 trials, 3,950 participants.
- Cryoablation vs. microwave ablation.
- No difference in survival, local/metastatic tumor progression.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

100-3 National Coverage Determination (NCD) for cryosurgery of Prostate (230.9). Effective July 2001. CMS Medicare Coverage Database website.
Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tr>
<td>17000</td>
<td>Destruction, e.g., cryosurgery, premalignant lesion; first lesion.</td>
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<tr>
<td>17003</td>
<td>Add on code, second through 14 lesions.</td>
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<td>17004</td>
<td>Destruction, e.g., cryosurgery, premalignant lesion, 15 or more.</td>
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<td>17110</td>
<td>Destruction, e.g., cryosurgery, benign lesion; up to 14 lesions.</td>
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<td>Destruction, e.g., cryosurgery, benign lesion; 15 or more lesions.</td>
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<td>19105</td>
<td>Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma.</td>
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<td>47371</td>
<td>Laparoscopy, cryosurgical ablation of one or more liver tumors.</td>
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<td>Cryosurgical ablation, open, of one or more liver tumors.</td>
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<td>50250</td>
<td>Cryosurgical ablation, open, one or more renal mass lesion(s).</td>
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<tr>
<td>55873</td>
<td>Cryosurgical ablation of the prostate.</td>
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