Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP187

Section: Medical Benefit Policy

Subject: Cryoablation

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Cryoablation

II. Purpose/Objective:

To provide a policy of coverage regarding Cryoablation

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.

- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Cryosurgery or cryoablation is a technique involving the use of extremely low temperatures to destroy tumors that are left in place to be reabsorbed. It is a focal therapy that allows treatment of specific lesions with preservation of normal tissue.

INDICATIONS:
The following indications have been evaluated by the Geisinger Technology Assessment Committee and are considered to be medically necessary.

I. *Cryoablation* for the treatment of hepatic tumors may be considered medically necessary for patients with unresectable primary liver cancer or unresectable metastatic liver tumors with no evidence of extrahepatic disease.

II. *Cryoablation* for the treatment of Prostate Cancer may be considered medically necessary if **ANY** of the following criteria are met:
1. Member with T1 prostate cancer; **or**
2. Member with T2 prostate cancer; **or**
3. Member with T3 prostate cancer when regional lymph nodes have been evaluated and determined to be cancer free; **or**
4. As a salvage therapy for recurrent prostate cancer following failure of radiation therapies when the member has a prostate-specific antigen (PSA) of less than 8ng/mL, a Gleason score less than 9, or a disease state of T2B or below.

Primary Tumor Stages

Tx	Primary tumor cannot be assessed	**T2b**	Tumor involves more than half a lobe but not both lobes
T0	No evidence of primary tumor	**T3**	Tumor extends through the prostatic capsule
T1	Clinically inapparent tumor not palpable or visible by imaging	**T3a**	Unilateral extracapsular extension
T1a	Tumor incidental histologic finding in <5% of tissue resected via transurethral resection (TURP)	**T3b**	Bilateral extracapsular extension
T1b	Tumor incidental histologic finding in >5% of tissue resected via (TURP)	**T3c**	Tumor invades the seminal vesicle(s)
T1c	Tumor identified by needle biopsy	**T4**	Tumor is fixed or invades adjacent structures other than the seminal vesicles
T2	Tumor palpable but confined within the prostate	**T4a**	Tumor invades any of the bladder neck, external sphincter or rectum
T2a	Tumor involves half a lobe or less	**T4b**	Tumor invades levator muscles and/or is fixed to the pelvic wall
T2b	Tumor involves more than half a lobe but not both lobes		

From: The Prostate Cancer Research Institute (PCRI)

III. *Cryoablation* for the treatment of renal tumors may be considered medically necessary when **ALL** of the following criteria are met;
1. Member has a solitary kidney or in need of nephron-sparing procedure to preserve renal function; **AND**
2. Tumor is less than 4 cm in size; **AND**
3. Member presents with concomitant co-morbidities which increase the risk of renal insufficiency (i.e. Diabetes, Morbid Obesity, etc.)

*Note; Renal insufficiency is defined as glomerular filtration rate is less than or equal to 60/ml/min/m^2

IV. Cryoablation for the treatment of low-risk superficial basal cell carcinoma, and squamous cell carcinoma in situ (Bowen disease), may be considered medically necessary when surgery or radiation is contraindicated or impractical.

V. Cryoablation for the treatment of soft tissue sarcoma of the extremities may be considered medically necessary in symptomatic members with disseminated metastases.

VI. Cryoablation for the treatment of malignant endobronchial obstruction is considered medically necessary

VII. Cryoablation may be considered medically necessary to treat lung cancer when either of the following criteria is met:
The member has early-stage non-small cell lung cancer and is a poor surgical candidate;
or
The member requires palliation for a central airway obstructing lesion.

VIII. Cryoablation for the treatment of atrial fibrillation in association with other cardiac surgery may be considered medically necessary.

IX. Cryoablation for the treatment of cervical intraepithelial neoplasia is considered medically necessary.

X. Cryoablation for the treatment of colon cancer with oligometastases to the lungs and/or liver is considered medically necessary

XI. Cryoablation in the treatment of Grade I intracompartmental bone cancer as an adjuvant to intralesional curettage is considered medically necessary

XII. Cryoablation for the treatment of knee pain secondary to osteoarthritis is considered medically necessary**. (Please see MP329 Genicular Nerve Ablation)**

XIII. Cryoablation for the treatment of nerve pain is considered medically necessary.

EXCLUSIONS:
Cryoablation of benign or malignant breast lesions because it is considered **experimental, investigational or unproven** and therefore **NOT COVERED.** The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.
For the Medicaid Business Segment cryoablation of breast fibroadenoma may be considered as a program exception.

Cryoablation for the treatment of plantar fasciitis or plantar fibroma because it is considered **experimental, investigational or unproven** and therefore **NOT COVERED.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

CODING ASSOCIATED with: Cryoablation
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.

19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
20983	ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation
31641	Bronchoscopy (rigid or flexible); with destruction of tumor or relief of stenosis by any

	method other than excision (e.g., laser therapy, cryotherapy)
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation
47371	Laparoscopy, surgical, ablation of one or more liver tumor(s); cryosurgical
47381	Ablation, open, of one or more liver tumor(s); cryosurgical
47383	ablation, 1 or more liver tumor(s), percutaneous, cryoablation
50250	Ablation, open, one or more renal mass lesions(s), cryosurgical, including intraoperative ultrasound, if performed.
50542	Laparoscopy, surgical; ablation of renal mass lesion(s)
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)
57511	Cautery of cervix; cryocautery, initial or repeat
76942	Ultrasonic guidance for needle placement (e.g. biopsy, aspiration, injection, locailization device), imaging supervision and interpretation.
76940	Ultrasound guidance for, and monitoring of, visceral tissue ablation.
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)
0581T	ABLATION, MALIGNANT BREAST TUMOR(S), PERCUTANEOUS, CRYOTHERAPY, INCLUDING IMAGING GUIDANCE WHEN PERFORMED, UNILATERAL

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 08/09/06

Revised: 9/07 (add'l exclusion added); 10/10 (indications added), 10/11(added T stages, and defined renal insufficiency); 10/15 (added indications), 10/16, 9/17 (Added Medicaid Exception); 9/20 (add indications); 9/21 (add nerve pain indication); 9/22 (add lung CA indication)

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