

Cryoablation



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Disclaimer

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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NCD	Cryosurgery of prostate	230.9		
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Description

Cryoablation (also known as cryotherapy or cryosurgery) involves the internal or external use of liquid nitrogen or argon gas at extreme cold temperatures to destroy diseased tissue. For external uses, the liquid nitrogen is applied directly with a cotton swab or spray device. For internal purposes, either argon gas or liquid nitrogen is circulated through a cryoprobe that has been situated next to diseased tissue via image guidance, such as ultrasound, magnetic resonance imaging (MRI) or computed tomography (CT), which reportedly ensures less damage to nearby healthy tissue. Ice crystals form around the probe, which freezes the cells. Once the cells thaw, the body absorbs them. Cryoablation may be used to treat several types of cancer including, but may not be limited to, cervical, kidney, liver and prostate. Cryoablation has also been used in precancerous conditions to avoid the development of cancer (eg, cervical intraepithelial neoplasia [CIN]).

Cryoablation may be utilized for the treatment of cutaneous (superficial) basal cell carcinoma (BCC) and squamous cell carcinoma in situ (Bowen disease) in which surgery is contraindicated. Choice of treatment depends on factors such as anatomic location, risk factors for tumor recurrence, age and health status of the individual.

Cryoablation may purportedly be utilized for the treatment of cutaneous melanoma; however, data appears to be insufficient to support its use for this indication.

Other areas being studied for the use of cryoablation include, but may not be limited to, Barrett's esophagus, bone tumors, breast cancer, breast fibroadenomas, esophageal cancer, pulmonary tumors, non-small cell lung cancer (NSCLC) as well as thyroid cancer.

Cryotherapy is proposed for the use of ocular conditions such as retinal detachment. This treatment is designed to create scar tissue, which will seal the tear or help the retina reattach to the underlying tissue to keep it in the correct position.

Cryotherapy is being investigated for the treatment of uveal melanoma, retinopathy (eg, diabetic retinopathy, retinopathy of prematurity) or conjunctival lesions.

Cryoablation is also being investigated for the treatment of chronic rhinitis. The treatment is designed to destroy unwanted tissue and to purportedly interrupt nerve signals in the nose to reduce rhinitis symptoms (eg, ClariFix).

Cryoablation has also been used for noncancerous conditions such as atrial fibrillation, benign prostatic hyperplasia, benign skin lesions, chronic nerve pain, chronic spinal pain, plantar fasciitis, uterine fibroids and varicose veins.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Cryoablation will be considered medically reasonable and necessary when the following requirements are met:

- Cervical intraepithelial neoplasia ([CIN grade](#) 1, 2 or 3 in an individual who is not pregnant; **OR**
- Endometrial cryoablation for premenopausal women with menorrhagia (excessive bleeding) not related to uterine fibroids and whom childbearing is complete and are refractory to medical treatment; **OR**
- Localized, cutaneous (superficial) BCC in which surgery or radiation therapy is contraindicated;⁶⁰ **OR**
- Localized, cutaneous (superficial) squamous cell carcinoma in situ (Bowen disease) in which surgery is contraindicated;⁷² **OR**
- Malignant endobronchial obstruction in a symptomatic individual⁶⁸; **OR**
- Prostate cancer as a primary therapy in an individual with localized disease (eg, [TNM stage](#) T1-T3) who is not suitable for surgery or irradiation due to comorbidities^{22,26} **OR** as salvage therapy for recurrent cancer following failure of radiation therapy and who are either stage T2B or below or Gleason less than 9, PSA less than 8^{27,69}; **OR**
- Renal cell cancer in an individual with stage T1 renal lesions <3 cm who is not amenable to surgery^{26,66,96}; **OR**
- Retinal detachment⁸; **OR**
- Soft tissue sarcoma of the extremities or the trunk in a symptomatic individual with disseminated metastases⁷¹; **OR**
- Unresectable malignant primary or metastatic liver tumors⁶⁴

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

Cryoablation will not be considered medically reasonable and necessary:

- Bone tumors (primary)
- Conjunctival lesions
- Diabetic retinopathy
- Morton’s neuromas
- Peripheral neuropathy
- Pancreatic cancer
- Plantar fasciitis
- Thyroid cancer
- Uveal melanoma

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Cryoablation indications will not be considered medically reasonable and necessary:

- Barrett’s esophagus/Esophageal cancer; **OR**
- Breast cancer; **OR**
- Breast fibroadenomas; **OR**
- Chronic rhinitis (eg, ClariFix); **OR**
- Cutaneous melanoma; **OR**
- Pulmonary tumors (eg, NSCLC); **OR**

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Barrett’s Esophagus (BE)/Esophageal Cancer

A report of 2 systematic reviews of low-quality studies were of high risk of bias to support conclusions.³² Cryoablation differs from radiofrequency ablation (RFA) as it induces intracellular ice crystal formation, which reportedly causes no permanent change in protein structure. This may preserve the architecture of the extra-cellular collagen matrix.⁷⁹ However, the clinical advantages of cryoablation for the treatment of BE has not been fully established.¹ There are currently no randomized trials that address the efficacy of cryoablation for dysplastic BE.¹² The current literature is inadequate to recommend endoscopic eradication therapies utilizing cryotherapy for individuals with low-grade dysplasia or high-grade dysplasia with BE.¹⁵

Breast Cancer

According to the research, cryoablation is currently FDA approved for treatment of benign and malignant soft tissue. There are not specific techniques that are FDA approved for breast tumors. As the data emerges on its efficacy, it is advised to participate in registries and clinical trials that evaluates the use of this technology with and without surgical excision of a breast malignancy.²¹

Breast Fibroadenoma

Definitive conclusions regarding the efficacy and overall benefit for the use of cryoablation for breast fibroadenomas cannot be concluded due to the limitations of the available studies.⁴³

Chronic Rhinitis

Studies have shown symptom relief for chronic rhinitis at 1 year follow-up. However, whether results can be sustained in the long term cannot be determined. Available studies are needed.³⁰ There are no studies that compare cryoablation with other clinical treatments for the treatment of rhinitis.³⁷

Cutaneous Melanoma

The research supports the use of cryoablation for SC and BCC (see Coverage Determination); however, it should not be used to treat melanoma, including melanoma in situ.⁹³

Lung Cancer

The evidence supports the use of cryoablation for the treatment of endobronchial obstruction (see Coverage Determination) and suggested for use as treatment when surgical resection is not an option. However, additional studies are needed to assess safety and long-term efficacy of cryoablation as compared to other established treatments for lung cancer.³⁸ RFA is the most studies technique for non-small cell lung cancer (NSCLC), but other approaches are under development, which include microwave ablation, laser ablation and cryoablation.⁸⁵

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
17260	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.5 cm or less	
17261	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.6 to 1.0 cm	

17262	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 1.1 to 2.0 cm	
17263	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 2.1 to 3.0 cm	
17264	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 3.1 to 4.0 cm	
17266	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter over 4.0 cm	
17270	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less	
17271	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm	
17272	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm	
17273	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 2.1 to 3.0 cm	
17274	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm	
17276	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm	
17280	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less	
17281	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm	
17282	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm	

17283	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 2.1 to 3.0 cm	
17284	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 3.1 to 4.0 cm	
17286	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 4.0 cm	
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, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)	
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	
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical	
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed	
50541	Laparoscopy, surgical; ablation of renal cysts	

50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy	
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)	
57511	Cautery of cervix; cryocautery, initial or repeat	
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed	
67113	Repair of complex retinal detachment (eg, proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens	
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	
CPT® Category III Code(s)	Description	Comments
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	
HCPCS Code(s)	Description	Comments
C2618	Probe/needle, cryoablation	
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral	

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Appendix

Appendix A

CIN Grades

CIN 1	Abnormal cells are found on the surface of the cervix.
CIN 2	Moderately abnormal cells are found on the surface of the cervix.
CIN 3	Severely abnormal cells are found on the surface of the cervix.

Appendix B

TNM Staging System for Prostate Cancer⁶⁸

Primary tumor (T)	
Clinical T (cT)	
T category	T criteria
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
T1	Clinically inapparent tumor that is not palpable
T1a	Tumor incidental histologic finding in 5% or less of tissue resected
T1b	Tumor incidental histologic finding in more than 5% of tissue resected
T1c	Tumor identified by needle biopsy found in one or both sides, but not palpable
T2	Tumor is palpable and confined within prostate
T2a	Tumor involves one-half of one side or less
T2b	Tumor involves more than one-half of one side but not both sides

T2c	Tumor involves both sides
T3	Extraprostatic tumor that is not fixed or does not invade adjacent structures
T3a	Extraprostatic extension (unilateral or bilateral)
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall.
Pathological T (pT)	
T category	T criteria
T2	Organ confined
T3	Extraprostatic extension
T3a	Extraprostatic extension (unilateral or bilateral) or microscopic invasion of bladder neck
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall

Change Summary

- Click or tap to enter a date. New Policy.

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