This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address cryoablation, also known as cryotherapy or cryosurgery, that employs the application of a cryogenic substance to create extreme cold temperatures to freeze and destroy diseased tissues. The intracellular ice crystals formed during cryoablation damage mitochondria, dehydrate the cells, and degrade cell membranes. The full effects can take several days to weeks to appear but ultimately will result in cell death and tissue destruction. The destroyed tissue is then either removed or reabsorbed by the body. There are a number of variations of techniques for cryoablation.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

Cryoprobe and Contact Cryotherapy: uses metallic cryoprobe that is placed directly on the lesion
Dipstick: cryogen is poured into a separate container then dipped with a cotton swab and quickly applied to the lesion
Spray: uses a closed system device that discharges cryogen through a nozzle and trigger mechanism.
Cryoablation: typically, a standalone treatment for conditions such as cervical neoplasia and menorrhagia. May be used in conjunction with surgical resection or radiation therapy to treat tumors of various cancers.
Cryoretinopexy/Retinal Cryotherapy: cryotherapy is employed around the retinal tear to create a chorioretinal adhesion and is used for the treatment of retinal detachment.
Endoscopic Eradication Therapy (EET): combines endoscopic resection and thermal ablation to create a minimally invasive treatment for intramucosal esophageal cancer and dysplasia related to Barrett's esophagus

POLICY

Cryoablation of Malignant Skin Lesions

SECUR Health Plan considers cryoablation of malignant skin lesions as medically necessary when the following is met:

1. Low risk superficial or nodular basal cell carcinoma (BCC) in a member who is not a candidate for surgical resection or radiation therapy, or
2. Low risk cutaneous squamous cell carcinoma or Bowen disease in a member who is not a candidate for surgical resection, or

3. Symptomatic, cutaneous Kaposi sarcoma lesions measuring less than or equal to 1 cm.

Prostate Cancer
SECUR Health Plan utilizes NCD 230.9, Cryosurgery of Prostate, for cryoablation of prostate cancer medical necessity determinations.

Cryoablation
The table below depicts what will be considered medically necessary by SECUR Health Plan for cryoablation.

Indication	Criteria
Cervical intraepithelial neoplasia (CIN)	Will be considered reasonable and necessary when the following requirement(s) are met: • CIN grade 1; **OR** • CIN grades 2 or 3 in an individual for whom childbearing is not complete **And ALL of the following:** • Dysplasia encompasses less than 75% of the cervix; **AND** • Individual is not currently pregnant
Liver tumors – intrahepatic cholangiocarcinoma	Will be considered reasonable and necessary when the following requirement(s) are met: • Primary treatment in an individual requiring treatment of a single tumor that measures less than 3 cm in diameter; **OR**
	• Unresectable intrahepatic cholangiocarcinomas up to 5 cm in diameter (as primary treatment or to downstage for other curative treatments); **AND** • All hepatic tumors are amenable to ablation such that the tumor and a margin of normal tissue up to 1 cm can be treated
Liver tumors – metastatic	Will be considered reasonable and necessary when the following requirement(s) are met: • All hepatic tumors are amenable to ablation such that the tumor and a margin of normal tissue up to 1 cm can be treated

Lung tumors – malignant endobronchial obstruction	Will be considered reasonable and necessary when **ALL** of the following requirement(s) are met: • All lesions are intraluminal; **AND** • Individual is not a candidate for surgical resection (eg, unresectable disease) or declines surgery; **AND** • Individual is symptomatic (eg, reduced pulmonary function, shortness of breath); **AND** • Symptoms are not life-threatening (eg, requiring immediate relief) [5,49,53]
Lung tumors – metastatic	Will be considered reasonable and necessary when the following requirement(s) are met: • All original sites of disease have evidence of control or non-progression OR are amenable to local therapy (eg, cryoablation, radiation, surgical resection); **AND** • Tumor is less than 3 cm in diameter[46]
Lung tumors – non-small cell lung cancer (NSCLC)	Will be considered reasonable and necessary when the following requirement(s) are met: • Stage 1 non-small cell lung cancer;**AND** • Individual is not a candidate for surgical resection (eg, unresectable disease) or declines surgery; **AND** • Tumor is less than 3 cm in diameter

Menorrhagia (heavy menstrual bleeding)	Will be considered reasonable and necessary when **ALL** of the following requirement(s) are met: • Bleeding is due to benign causes; **AND** • Childbearing is complete; **AND** • Individual is premenopausal; **AND** • No large uterine fibroids or polyps (greater than 4 cm in diameter) are present; **AND** • Absence of **ALL** of the following contraindications: o Active gynecologic or urinary infection o Current pregnancy o Intrauterine device (IUD) currently in place o Known or suspected uterine cancer o Pre-malignant conditions of the endometrium (eg, adenomatous hyperplasia) o Previous endometrial ablation using any modality (eg, cryoablation, microwave, radiofrequency) o Prior surgery involving the uterus (eg, cesarean section, myomectomy, resection)
Renal cell carcinoma (RCC)	Will be considered reasonable and necessary when the following requirement(s) are met: • Biopsy-proven diagnosis or biopsy to be performed at the time of ablation **And ONE of the following:** • Localized tumor recurrence after nephrectomy; **OR** • Stage T1a tumor and **ALL** of the following: o Individual is not a candidate for surgical resection (eg, unresectable disease) or declines surgery; **AND**

	○ Tumor is less than or equal to 3 cm; **OR** • Stage T1b solid renal tumor in an individual who is not a candidate for surgical resection (eg, unresectable disease)
Retinal detachment or symptomatic retinal break	Will be considered reasonable and necessary with sufficient medical records to support the diagnosis.
Soft tissue sarcoma – desmoid tumors	Will be considered reasonable and necessary when the following criteria are met: • Desmoid tumor and **ONE** of the following: ○ Initial treatment of progressive, morbid or symptomatic disease; **OR** ○ Residual disease after surgical resection
Soft tissue sarcoma – intra-abdominal or retroperitoneal tumors	Will be considered reasonable and necessary when the following criteria are met: • Intra-abdominal or retroperitoneal disease and **ONE** of the following: ○ Palliative treatment of disseminated metastases; **OR** ○ Stage IV disease with limited bulk that is confined to a single organ
Soft tissue sarcoma – tumors of the extremities, head, neck, or trunk	Will be considered reasonable and necessary when the following criteria are met: • Disease of the extremities, head, neck or trunk and **ONE** of the following: ○ Oligometastatic synchronous Stage IV disease with limited tumor bulk; **OR** ○ Palliative treatment of disseminated metastases; **OR** ○ Recurrent, metastatic disease with limited tumor bulk that is confined to a single organ
Skeletal metastases	Will be considered reasonable and necessary when the following criteria are met: • Increased risk of fracture in weight-bearing bones; **OR** • Palliation of hormone secretion due to a metastatic hormone-producing tumor; **OR**

	• Painful musculoskeletal metastases[43]
Thyroid tumors	Will be considered reasonable and necessary when the following criteria are met: • Malignant metastases (distant or persistent) and **ONE** of the following: o Differentiated thyroid cancer (eg, papillary, follicular, oncocytic) not amenable to treatment with radioactive iodine (RAI)[13,45]; **OR** o Medullary thyroid cancer; **OR** • Malignant recurrent disease (locoregional or metastatic)[13,45]
Uveal melanoma	Will be considered reasonable and necessary when the following criteria are met: • Local control of extraocular extension with visible tumor or suspicion of gross disease in the orbit after enucleation; **OR** • Recurrent disease with extraocular involvement or orbital involvement in an individual with prior enucleation; **OR** • Subsequent treatment after particle beam radiotherapy if adequate response was not achieved from initial radiation

SECUR Health Plan considers cryoablation as not medically necessary for any of the following:

1. Breast cancer
2. Cutaneous melanoma
3. Pancreatic cancer
4. Primary bone tumors
5. Renal cysts

References:

1. American Academy of Dermatology (AAD). Guidelines for the management of cutaneous squamous cell carcinoma. https://www.aad.org. Published March 2018.
2. American Academy of Dermatology (AAD). Guidelines of care for the management of basal cell carcinoma. https://www.aad.org. Published March 2018.
3. American Academy of Ophthalmology (AAO). Preferred Practice Pattern. Posterior vitreous detachment, retinal breaks and lattice degeneration. https://www.aao.org. Published 2014. Updated October 2019.
4. American Association for the Study of Liver Diseases (AASLD). AASLD practice guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma. https://www.aasld.org. Published May 2023.
5. American College of Chest Physicians (ACCP). Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. https://www.accp.com. Published May 2013. Updated August 4, 2020.
6. American College of Gastroenterology (ACG). Diagnostic and management of Barrett's esophagus: an updated ACG guideline. https://gi.org. Published April 2022.
7. American College of Radiology (ACR). Appropriateness Criteria. Management of liver cancer. https://www.acr.org. Published 2022.
8. American Gastroenterological Association (AGA). AGA clinical guideline on endoscopic eradication therapy of Barrett's esophagus and related neoplasia. https://gastro.org. Published June 2024.
9. American Gastroenterological Association (AGA). AGA clinical practice update on endoscopic treatment of Barrett's esophagus with dysplasia and/or early cancer: expert review. https://gastro.org. Published February 2020.
10. American Radium Society (ARS). American Radium Society appropriate use criteria for the use of liver-directed therapies for management of non-surgical liver metastases: systematic review and guidelines. https://americanradiumsociety.org. Published July 2023.
11. American Society for Gastrointestinal Endoscopy (ASGE). Guideline. Endoscopic eradication therapy for patients with Barrett's esophagus-associated dysplasia and intramucosal cancer. https://www.asge.org. Published April 2018.
12. American Society of Breast Surgeons (ASBS). Consensus guideline on the use of transcutaneous and percutaneous ablation for the treatment of benign and malignant tumors of the breast. https://www.breastsurgeons.org. Published October 16, 2018.
13. American Thyroid Association (ATA). 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer. https://www.thyroid.org. Published 2016.
14. American Thyroid Association (ATA). Revised American Thyroid Association guidelines for the management of medullary thyroid carcinoma. https://www.thyroid.org. Published 2015.
15. American Urological Association (AUA). Renal mass and localized renal cancer: evaluation, management, and follow-up: AUA guideline. https://www.auanet.org. Published April 2017. Updated 2021.
16. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Destruction of malignant skin lesions (L33813). https://www.cms.gov. Published October 1, 2015. Updated October 24, 2019.
17. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Removal of benign and malignant skin lesions (L33445). https://www.cms.gov. Published October 1, 2015. Updated January 8, 2019.
18. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Cryosurgery of prostate (230.9). https://www.cms.gov. Published July 1, 2001.
19. ClinicalKey. McBride J, Atwell T, Charboneau W, et al. Minimally invasive treatment of metastatic pheochromocytoma and paraganglioma: efficacy and safety of radiofrequency ablation and cryoablation therapy. *Vasc Interv Radiol*. 2011;22(9): 1263-1270.
20. ECRI Institute. Clinical Evidence Assessment. C2 CryoBalloon ablation system (Pentax Medical, Inc.) for

treating barrett's esophagus or esophageal dysplasia. https://www.ecri.org. Published December 19, 2017. Updated August 31, 2022.
21. ECRI Institute. Clinical Evidence Assessment. Cryoablation for treating prostate cancer. https://www.ecri.org. Published October 14, 2021. Updated December 6, 2023.
22. ECRI Institute. Clinical Evidence Assessment. ICEfx cryoablation system (Boston Scientific Corp.) for treating renal cancer. https://www.ecri.org. Published September 15, 2023.
23. ECRI Institute. Clinical Evidence Assessment. truFreeze spray cryotherapy system (Steris Corp.) for Barrett's esophagus or esophageal cancer. https://www.ecri.org. Published May 20, 2014. Updated August 25, 2022.
24. Hayes, Inc. Evidence Analysis Research Brief. Cryoablation for treatment of non-small cell lung cancer. https://evidence.hayesinc.com. Published November 21, 2023.
25. Hayes, Inc. Evidence Analysis Research Brief. TruFreeze spray cryotherapy for treatment of Barrett's esophagus. https://evidence.hayesinc.com. Published May 9, 2022.
26. Hayes, Inc. Health Technology Assessment. Cryoablation for treatment of non-small cell lung cancer. https://evidence.hayesinc.com. Published December 10, 2015. Updated April 7, 2020.
27. Hayes, Inc. Health Technology Brief. Cryosurgical ablation for malignant endobronchial obstruction (EBO). https://evidence.hayesinc.com. Published November 24, 2008. Updated October 29, 2010.
28. Hayes, Inc. Medical Technology Directory. Comparative effectiveness review of cryoablation for primary treatment of localized prostate cancer. https://evidence.hayesinc.com. Published July 17, 2017. Updated September 13, 2021.
29. Hayes, Inc. Medical Technology Directory. Percutaneous cryoablation for the treatment of renal masses. https://evidence.hayesinc.com. Published June 9, 2014. Updated May 8, 2018.
30. National Cancer Institute (NCI). Skin cancer treatment (PDQ) – health professional version. https://www.cancer.gov. Updated March 11, 2024.
31. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Basal cell skin cancer. https://www.nccn.org. Updated March 1, 2024.
32. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Biliary tract cancers. https://www.nccn.org. Updated August 29, 2024.
33. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Bone cancer. https://www.nccn.org. Updated August 20, 2024.
34. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Colon cancer. https://www.nccn.org. Updated August 22, 2024.
35. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Esophageal and esophagogastric junction cancers. https://www.nccn.org. Updated July 30, 2024.
36. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Kaposi sarcoma. https://www.nccn.org. Updated November 7, 2023.
37. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Kidney cancer. https://www.nccn.org. Updated September 6, 2024.
38. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Melanoma: uveal. https://www.nccn.org. Updated May 23, 2024.
39. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Neuroendocrine and adrenal tumors. https://www.nccn.org. Updated August 1, 2024.
40. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. https://www.nccn.org. Updated September 9, 2024.
41. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Pancreatic adenocarcinoma. https://www.nccn.org. Updated August 2, 2024.
42. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Rectal cancer. https://www.nccn.org. Updated August 22, 2024.
43. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Soft

tissue sarcoma. https://www.nccn.org. Updated July 31, 2024.
44. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Squamous cell skin cancer. https://www.nccn.org. Updated November 9, 2023.
45. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Thyroid carcinoma. https://www.nccn.org. Updated August 19. 2024.
46. Society of Interventional Radiology (SIR). Society of Interventional Radiology multidisciplinary position statement on percutaneous ablation of non-small cell lung cancer and metastatic disease to the lungs. https://sirweb.org. Published August 2021.
47. Society of Interventional Radiology (SIR). Society of Interventional Radiology position statement on the role of percutaneous ablation in renal cell carcinoma. https://sirweb.org. Published February 2020.
48. Tariq R, Enslin S, Hayat M, et al. Efficacy of cryotherapy as a primary endoscopic ablation modality for dysplastic Barrett's esophagus and early esophageal neoplasia: a systematic review and meta- analysis. *Cancer Control*. 2020;27(1):1073274820976668.
49. UpToDate, Inc. Bronchoscopic cryotechniques in adults. https://www.uptodate.com. Updated August 2024.
50. UpToDate, Inc. Cervical intraepithelial neoplasia: ablative therapies. https://www.uptodate.com. Updated August 2024.
51. UpToDate, Inc. Cervical intraepithelial neoplasia: choosing excision versus ablation, and prognosis and follow-up after treatment. https://www.uptodate.com. Updated August 2024
52. UpToDate, Inc. Cervical intraepithelial neoplasia: terminology, incidence, pathogenesis and prevention. https://www.uptodate.com. Updated August 2024.
53. UpToDate, Inc. Clinical presentation, diagnostic evaluation and management of central airway obstruction in adults. https://www.uptodate.com. Updated August 2024.
54. UpToDate, Inc. Diabetic retinopathy: prevention and treatment. https://www.uptodate.com. Updated August 2024.
55. UpToDate, Inc. Endometrial ablation: non-resectoscopic techniques. https://www.uptodate.com. Updated August 2024.
56. UpToDate, Inc. Image-guided ablation of skeletal metastases. https://www.uptodate.com. Updated August 2024.
57. UpToDate, Inc. Minor dermatologic procedures. https://www.uptodate.com. Updated August 2024.
58. UpToDate, Inc. Overview of endometrial ablation. https://www.uptodate.com. Updated August 2024.
59. UpToDate, Inc. Radiofrequency ablation, cryoablation, and other ablative techniques for renal cell carcinoma. https://www.uptodate.com. Updated August 2024.
60. UpToDate, Inc. Retinal detachment. https://www.uptodate.com. Updated August 2024.
61. UpToDate, Inc. Simple and complex renal cysts in adults. https://www.uptodate.com. Updated August 2024.
62. UpToDate, Inc. Treatment and prognosis of basal cell carcinoma at low risk of recurrence. https://www.uptodate.com. Updated August 2024.
63. UpToDate, Inc. Treatment and prognosis of low-risk cutaneous squamous cell carcinoma (cSCC). https://www.uptodate.com. Updated August 2024.
64. US Food & Drug Administration (FDA). 501(k) summary: C2 CryoBalloon Ablation System. https://www.fda.gov. Published November 29, 2021.
65. US Food & Drug Administration (FDA). 501(k) summary: truFreeze System. https://www.fda.gov. Published August 18, 2022.
66. US Food & Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Cerene cryotherapy device. https://www.fda.gov. Published March 28, 2019.