

Department of Origin: Integrated Healthcare Services	Effective Date: 06/05/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 06/04/24
Clinical Policy Document: Cryoablation/Cryosurgery for Oncology Indications	Replaces Effective Clinical Policy Dated: 06/06/23
Reference #: MC/1007	Page: 1 of 5

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria – Must satisfy any of the following: I – VII

- I. Endobronchial obstruction of malignant origin with central airway occlusion.^{3,4,5,6}
- II. Hepatic metastases from neuroendocrine tumors^{9,10} – must satisfy all of the following: A - C
 - A. Member is a poor candidate for surgical resection (eg, due to location of the tumor/s and/or comorbid conditions); and
 - B. Symptoms are refractory to systemic therapy; and
 - C. All tumor foci can be adequately treated by cryoablation.
- III. Prostate cancer^{11,12,13,14,15,16} – must satisfy any of the following: A - C
 - A. Primary therapy – must satisfy both of the following: 1 and 2
 - 1. As an alternative to surgery or radiation therapy; and
 - 2. Prostate cancer is localized (clinical stage T1 or T2 [organ confined] or T3 [locally advanced]).
 - B. Salvage therapy after failure of radiation therapy as primary therapy – must satisfy all the following: 1 - 3
 - 1. Presence of *biochemical failure*; and
 - 2. Prostate-specific antigen (PSA) of less than 10ng/ml; and
 - 3. Life expectancy is greater than 10 years.
 - C. Palliative therapy for relief of lower urinary tract symptoms.
- IV. Renal mass or renal cell carcinoma^{17,18,19,24} – must satisfy one of the following: A - D
 - A. Tumor is less than or equal to 4cm/ stage T1a disease; or

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- B. Member is a poor candidate for surgery (eg, presence of renal insufficiency or a solitary kidney); or
 - C. Stage IV oligometastatic disease; or
 - D. Hereditary renal cell carcinoma from any of the following syndromes Birt-Hogg-Dube syndrome (BHDS), hereditary papillary renal carcinoma (HPRC), tuberous sclerosis complex (TSC), or von Hippel-Lindau (VHL).
- V. Bone metastases from renal cell carcinoma^{18,22,23} – must satisfy all of the following: A – C
- A. Member is a poor candidate for surgery; and
 - B. Located in multi-metastatic sites (lung, bone, or brain); and
 - C. One of the following: 1 or 2
 - 1. Member initially presented with primary renal cell carcinoma; or
 - 2. Member developed multi-metastases after a prolonged disease-free interval from nephrectomy.
- VI. Soft tissue sarcoma^{20,21} – must satisfy both of the following: A and B
- A. Located in the superficial trunk, extremity(ies), head, or neck; and
 - B. The tumor is classified as *Stage IV* - must satisfy any of the following: 1 or 2
 - 1. Primary tumor management or local recurrence where the disease is confined to a single organ with limited tumor bulk that is amenable to local therapy; or
 - 2. Palliative treatment for disseminated metastatic disease.
- VII. Desmoid tumors (aggressive fibromatosis)²⁰ - must satisfy both of the following: A and B
- A. Progressive, morbid, or symptomatic disease; and
 - B. Located in the abdominal wall, trunk, pelvis, extremity(ies), head, neck, or intrathoracic.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description.

The following are considered investigative (see Investigative List): I - II

- I. Cryoablation for peripheral nerve damage in the lower extremity (includes use of iovera[®] system for knee osteoarthritis [OA]) - CPT 64640
- II. Cryoablation/cryosurgery for numerous indications

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DEFINITIONS:

Biochemical Failure:¹¹

Prostate specific antigen (PSA) rise by 2ng/mL or more above the nadir PSA is the standard definition for biochemical failure after external beam radiation therapy (EBRT) with or without hormone (androgen) therapy.

Renal insufficiency:

Glomerular filtration rate of less than or equal to 60 ml/min/m²

Stage IV (Soft Tissue Sarcoma):²⁰

Any Primary Tumor (T) stage, any Regional Lymph Nodes (N) stage, with or without distant metastasis (M) and any Histologic Grade (G)

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Prior Authorization: Yes, per network provider agreement.

CODING:

CPT®

- 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)
- 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
- 50593 Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
- 55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

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REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. National Comprehensive Cancer Network (NCCN) Guidelines. Non-Small Cell Lung Cancer. NSCL-D. Version 5.2024, 04/23/24. Accessed 05-01-24.
4. National Institutes for Health and Clinical Excellence (NICE). Cryotherapy for malignant endobronchial obstruction. 2005. Retrieved from <https://www.nice.org.uk/guidance/ipg142>.
5. Colt HG. Bronchoscopic cryotechniques in adults. (Topic: 4407, Version 38.0; last updated: 12-07-23) In: Finlay G, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2020. www.uptodate.com. Accessed 05-01-24.
6. Thomas CF, Jett JR, Strosberg JR. Lung neuroendocrine (carcinoid) tumors: Treatment and prognosis. (Topic: 85914, Version: 39.0; last updated: 12-20-22) In: Savarese DMF, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2021. www.uptodate.com. Accessed 05-01-24.
7. National Comprehensive Cancer Network (NCCN) Guidelines. Hepatocellular Carcinoma. HCC-G. Version 1.2024, 04-09-24) Accessed 05-01-24.
8. Curley SA, Stuart KE, Schwartz JM, Carithers RL. Localized hepatocellular carcinoma: Liver-directed therapies for nonsurgical candidates who are eligible for local ablation. (Topic: 2487, Version: 58.0; last updated: 09-16-22) In: Savarese DMF, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2020. www.uptodate.com. Accessed 05-01-24.
9. National Comprehensive Cancer Network (NCCN) Guidelines. Neuroendocrine and Adrenal Tumors. NE-I, MS-15. Version 1.2023, 08/02/23. Accessed 05-01-24.
10. Chan JA, Kulka M, Clancy TE. Metastatic gastroenteropancreatic neuroendocrine tumors: local options to control tumor growth and symptoms of hormone hypersecretion. (Topic: 16105, Version: 56.0; last updated: 08-31-22) In: Savarese DMF, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2019. www.uptodate.com. Accessed 05-01-24.
11. National Comprehensive Cancer Network (NCCN) Guidelines. Prostate Cancer. PROS-K, MS-35-36. Version 3.2024, 03/08/24) Accessed 05-01-24.

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12. Pisters LL, Spiess PE. Cryotherapy and other ablative techniques for the initial treatment of prostate cancer. (Topic: 6930, Version: 45.0; last updated: 11-23-22) In: Savarese DMF, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2020. www.uptodate.com. Accessed 05-01-24.
13. Moul JW. Rising serum PSA after radiation therapy for localized prostate cancer: Salvage local therapy. (Topic: 6932, Version: 39.0; last updated: 07-05-22) In: Savarese DMF, eds. *UpToDate*. Waltham, Mass.: UpToDate; 2021. www.uptodate.com. Accessed 05-01-24.
14. Chin JF, Al-Zahrani AA, Autran-Gomez AM, Williams AK, Bauman G. Extended follow-up oncologic outcome of randomized trial between cryoablation and external beam therapy for locally advanced prostate cancer (T2c-T3b). *J Urol*. 2012 Oct;188(4):1170-5. doi: 10.1016/j.juro.2012.06.014
15. Finley DS, Beddegrun AS. Salvage cryotherapy for radiation-recurrent prostate cancer: outcomes and complications. *Curr Urol Rep*. 2011 Jun;12(3):209-15. doi: 10.1007/s11934-011-0182-4
16. Ng CK, Moussa M, Downey DB, Chin JL. Salvage cryoablation of the prostate: follow-up and analysis of predictive factors for outcome. *J Urol*. 2007 Oct;178(4 Pt 1):1253-7; discussion 1257.
17. National Comprehensive Cancer Network (NCCN) Guidelines. Kidney Cancer. KID-1, KID-3, KID-A, ST-1, HERED-RCC-C. Version 3.2024, 03/11/24 Accessed 05-01-24.
18. Hines A, Goldberg, SN. Radiofrequency ablation, cryoablation, and other ablative techniques for renal cell carcinoma. (Topic: 3001, Version: 30.0; last updated: 02-01-24) In: Shah S, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2020. www.uptodate.com. Accessed 05-01-24.
19. National Institute for Health and Clinical Excellence (NICE). Percutaneous cryotherapy for renal cancer. Interventional Procedure Guidance 402. London, UK: NICE; July 2011. Available at: <https://www.nice.org.uk/guidance/ipg402>.
20. National Comprehensive Cancer Network (NCCN). Soft Tissue Sarcoma. DESM-4, SARC-F, EXTSARC-5, EXTSARC-6. Version 1.2024, 04/26/24. Accessed 05-01-24.
21. Raut CP, George S, Demetri GD. Surgical treatment and other localized therapy for metastatic soft tissue sarcoma. (Topic: 7738, Version: 35.0; last updated: 10-10-23) In: Shah S, Collins KA, eds. *UpToDate*. Waltham, Mass.: UpToDate; 2021. www.uptodate.com. Accessed 05-01-24.
22. Gardner CS, Ensor JE, Huang SY, et al. Cryoablation of Bone Metastases from Renal Cell Carcinoma for Local Tumor Control. *J Bone Joint Surg Am* 2017 Nov 15;99(22):1916-1926.
23. Jennings JW, Prologo JD, Garnon J, et al. Cryoablation for Palliation of Painful Bone Metastases: The MOTION Multicenter Study. *Radiol Imaging Cancer* 2021 Feb 12;3(2):e200101.
24. Pierorazio PM, Campbell SC. Diagnostic approach, differential diagnosis, and management of a small renal mass. (Topic: 2970, Version: 44.0; last updated: 09-07-23) In: Shah S, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2023. www.uptodate.com. Accessed 05-01-24.

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Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

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Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ ໂດຍບໍ່ເສັຽຄ່າ, ຈະມີມີ້ພ້ອມໃຫ້ທ່ານ. ໂທສ 1-800-332-6501 (TTY: 711).