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Department of Origin: Integrated Healthcare Services	**Effective Date:** 06/06/23
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 06/06/23
Clinical Policy Document: Cryoablation/Cryosurgery for Oncology Indications	**Replaces Effective Clinical Policy Dated:** 06/09/22
Reference #: MC/I007	**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 - VIII

I. Endobronchial obstruction of malignant origin with central airway occlusion.[3,4,5,6]

II. Hepatic lesions[7,8] – must satisfy all of the following: A - E

   A. Member is not a candidate for open surgical resection; and

   B. Primary hepatocellular origin or colorectal cancer metastases; and

   C. Presence of isolated liver disease (members with nodal or extra-hepatic systemic metastases are not considered candidates for these procedures); and

   D. Preoperative imaging indicate that all liver tumors will potentially be destroyed by cryosurgery or cryoablation; and

   E. Hepatic lesions must have both of the following: 1 and 2
      1. Less than or equal to 4 cm in diameter; and

      2. Occupying less than or equal to 50% of the liver parenchyma

III. 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.

IV. 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.

V. Renal mass or renal cell carcinoma [17,18, **19, 25**] – must satisfy one of the following: A - D

A. Tumor is less than or equal to 4cm/ stage T1a disease;

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).

VI. 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.

VII. 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.

VIII. Desmoid tumors (aggressive fibromatosis)[24] - 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

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/m^2

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)

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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PO Box 59052
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Fax: 763.847.4010
customerservice@preferredone.com

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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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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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