Ablative Therapy

Origination: February 17, 2016
Review Date: March 16, 2016
Next Review: March, 2018

DESCRIPTION OF PROCEDURE OR SERVICE

Radiofrequency ablation (RFA) is a procedure in which a probe is inserted into the center of a tumor, guided by intraoperative computed tomography (CT) or ultrasound (US), and heated locally by a high frequency, alternating current that flows from electrodes. The local heat treats the tissue adjacent to the probe, resulting in a 3- to 5-cm sphere of dead tissue. The cells killed by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it occurs at the edge and, in some cases, may be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure. Although heat is generated in the tissue around the electrode, rather than in the electrode itself, some RFA systems circulate chilled water or saline through the electrode during thermoablation to minimize charring of renal tissue and increase the heat-generating capacity of the targeted tissue.

Cryotherapy, also called cryosurgery, cryoablation or targeted cryoablation therapy, is a minimally invasive treatment that uses extreme cold to freeze and destroy diseased tissue, including cancer cells. Although cryotherapy and cryoablation can be used interchangeably, the term "cryosurgery" is reserved best for cryotherapy performed using an open, surgical approach. In cryotherapy, liquid nitrogen or argon gas is applied to diseased cells located outside or inside the body. Physicians use image-guidance techniques such as ultrasound, computed tomography (CT) or magnetic resonance (MR) to help guide these freezing substances to treatment sites located inside the body.

POLICY STATEMENT

Coverage will be provided for Ablative Therapy when it is determined to be medically necessary and when the medical criteria and guidelines shown below are met.

Refer to the Oral Anticancer Medications medical policy for information on coverage of antiemetic medications used in conjunction with oral anticancer medications.

BENEFIT APPLICATION

Please refer to the member’s individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions for will be made in accordance with:
The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

A. Preauthorization by the Plan is required;

B. Liver Tumors:

In 2000, the FDA approved the use of radiofrequency induced tumor ablation (RFA) for hepatic tumors. Per LCD L34527, the indications for RFA are the same as for cryosurgery.

1. Cryosurgery and RFA in the treatment of certain selected primary and secondary liver tumors will be covered for the following indications, items a-d:
   a. Primary hepatocellular carcinoma when conventional surgical resection is felt to be contraindicated or when ablation is used as an adjunct to surgical resection.
   b. Primary carcinoma of the colon, small intestine, gall bladder, ovary, and neuroendocrine system, or other sites metastasized to the liver.
   c. Metastatic tumors with the following qualifying conditions:
      i. The primary cancer site must be effectively controlled.
      ii. The metastatic lesions must be limited to the liver and not present in other organs.
   d. The cryosurgical device and RFA device used must be FDA approved for the indications used.

2. In the case of metastatic carcinomas to the liver, the following criteria, items a-f must be met:
   a. The primary cancer site must be effectively controlled;
   b. The metastatic lesions must be liver-dominant in terms of symptoms and clinical indications.
   c. Any extrahepatic disease should be minimal and well-controlled.
   d. The open laparotomy approach or percutaneous approach may be used.
   e. The member must have no more than 3 liver metastases, except in rare instances (such as multiple neuroendocrine liver metastases).
   f. No lesion should be larger than 7 cm. in size.

C. Bone Tumors:

1. RFA and cryotherapy have both been shown to be safe and effective in the palliation of metastatic bone tumors.

D. Renal Tumors:
1. RFA or cryotherapy will be covered for the following indications:
   a. Solid renal masses less than or equal to 3cm.
   b. Larger masses would be appropriate in conjunction with vascular or chemical ablation. The larger masses can be devascularized shrinking them to an effective size for treatment. The scanned mass could still be larger than 3cm - (RFA of a renal mass may require multiple cycles of current application with the electrode placed at different sites within the mass. For renal tumors larger than 3 centimeters (cm), re-treatment may be required on a subsequent day with multiple cycles of renal tissue ablation on each day of treatment. In the months following RFA, members undergo periodic evaluations by CT or magnetic resonance imaging (MRI) to monitor for regrowth of the ablated mass).
   c. Lesions in solitary kidney.
   d. Members with increased surgical risk/renal insufficiency due to the following:
      i. Small and incidentally detected renal cortical lesions,
      ii. A genetic predisposition to multiple tumors,
      iii. A solitary kidney,
      iv. Bilateral tumor growth present,
      v. Poor renal function (e.g., Renal cell carcinoma (RCC) detected in an anatomical or functional solitary kidney when resection would result in the need for dialysis),
      vi. High risk of development of additional RCC in the future in whom the least invasive nephron-sparing approach is desirable (e.g., members with hereditary diseases; members with synchronous RCC), and/or
      vii. Comorbid disease.
   e. A limit of 3 or less lesions.
   f. Biopsy proven or image documentation consistent with renal cell cancer, i.e. characteristics that are suspicious for malignancy.

NOTE: A substantial percentage of members referred for percutaneous ablation of renal tumors had benign masses. If CT or MRI alone cannot be used to diagnose a benign entity, members may need to undergo a biopsy before the treatment session. Better techniques for subtyping renal tumors (eg serologic, genetic and/or radiographic) are required to aid in selecting members who need treatment and determining which of those may be most suitable for ablative therapy. *Sometimes benign lesions of the kidney are indistinguishable from cancer. This is the case with oncocytomas. Thus they are managed like a cancer.

E. Lung Tumors:
   1. Radio frequency Ablation - Effective 08/01/2015 RFA for lung tumors is an approved therapy for non-small cell lung cancer (NSCLC), primary and metastatic lung cancer.
WHEN COVERAGE WILL NOT BE APPROVED
1. When the criteria listed above are not met, requests will be reviewed by the Medical Director.
2. Primary carcinomas of the breast, lung, stomach, pancreas, adenocarcinoma of unknown origin and other primary cancers which are widely disseminated at the same time liver metastases are present are not appropriate for cryosurgical ablation.
3. Small centrally located lesions adjacent to the renal tumor hilum will not be considered for coverage.
4. Due to risk of tumor spillage from cyst contents with puncture from a cryoprobe, it is not indicated for primary cystic lesions.
5. There is ongoing research into the use of ablation in both benign and malignant breast tumors. At present the research is too preliminary to determine the role of ablation in breast treatment. Ablation of breast lesions is not yet proven effective and therefore is not covered.
6. Endobronchial cryosurgery is a palliative technique, with the aim of alleviating symptoms and improving the member’s performance status. Members with lung cancers can develop endobronchial lesions that obstruct the major airways, causing symptoms such as dyspnea, cough, hemoptysis and postobstructive pneumonia. Future randomized trials, comparing the results of endobronchial cryosurgery with other forms of palliative treatment for lung cancer are needed. At this time this procedure will not be covered outside of a Medicare-approved clinical trial.
7. The use of RFA in symptomatic uterine leiomyomata is being studied in several centers. The issue of durability of the therapy, repeat procedures, and efficacy superior to other acceptable methods of therapy has not been determined. RFA of uterine leiomyomata is not proven effective and is not covered by Medicare.

NOTE: The LCD considers ablation by any method of tumors not specifically mentioned above, to be investigational and not covered by Medicare with the exception of cryosurgery of the prostate which is addressed in the NCD Manual, Chapter 1, Part 4, Section 230.9 – Cryosurgery of Prostate.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION
This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: 20982, 20983, 32998, 47370, 47371, 47380, 47381, 47382, 47383, 50250, 50542, 50592, 50593, 76940, 77013, 77022.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.
SPECIAL NOTES
There are no CPT codes specific to microwave ablation.

According to a 2012 American Medical Association publication (*Clinical Examples in Radiology*, Vol. 8, Issue 3; Summer 2012), “microwave is part of the radiofrequency spectrum, and simply uses a different part of the radiofrequency spectrum to develop heat energy to destroy abnormal tissue.” Therefore, they instruct that microwave ablation should be reported using the CPT codes for radiofrequency ablation – 47382 (liver).

References:
1. Medicare Local Coverage Determination for Ablative Therapy – Wisconsin Physician Service (L34527); Effective Date 03/01/2016; viewed via [www.cmg.gov/medicare-coverage-database](http://www.cmg.gov/medicare-coverage-database) 03/08/16.
2. BCBSA – Microwave Tumor Ablation – MPRM 7.01.133, referencing AMA publication instructing microwave ablation should report the same CPT code as radiofrequency ablation; last review 10/2015, viewed 03/08/16. Cryosurgery of Prostate is addressed in CMS Pub 100-03 Medicare National Coverage Determination (NCD) Manual, Chapter 1- Coverage Determinations, Part 4, Section 230.9 – Cryosurgery of Prostate. Accessed via CMS.gov – Internet-Only Manuals 02/26/16.

Policy Implementation/Update Information:
Revision Date: February 18, 2016; new policy.

Approval Dates:
Medical Coverage Policy Committee:
Policy Owner: Jennifer Davis, RN, MHA
Medical Policy Coordinator