

LCD for Ablative Therapy (L30312)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402

Contractor Type

Carrier - FI - MAC

LCD Information

LCD ID Number

L30312

LCD Title

Ablative Therapy

Contractor's Determination Number

GSURG-033

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CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Primary Geographic Jurisdiction

Wisconsin

Oversight Region

Region V

Original Determination Effective Date

For services performed on or after 09/15/2009

Original Determination Ending Date

Revision Effective Date

For services performed on or after 03/01/2010

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Ablative procedures have been in the armamentarium of tumor therapy for many years. Recent technological advances have allowed the use of ablative procedures in virtually any organ system.

Radiofrequency ablation (RFA), which can be performed laparoscopically or percutaneously, involves the passage of high-frequency electrical current into the tumor mass. Guided by images from intraoperative computed tomography (CT) or ultrasound (US), the surgeon inserts a small electrode into the tumor. Applying a high-frequency electrical current generates heat within the renal mass and ablates tissue around the electrode. 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.

Tumor ablation destroys the tumor without surgically removing it by placing ablation probes at precise locations. Therefore, it should be performed in conjunction with computed tomography scan, ultrasound or magnetic resonance guidance to ensure proper placement.

This LCD does not address cardiac ablative procedures or endometrial ablative procedures. For all indications the cryosurgical, radiofrequency ablation (RFA), or any other ablative device used must be FDA-approved for the indications used.

A. Liver Tumors

Cryosurgery (Cryoablation) and Radiofrequency Ablation for Treatment of Liver Tumors

Cryosurgery is a means for surgical destruction of diseased tissue utilizing sub-zero temperatures. It has been used for years in many medical fields including dermatology, neurosurgery, proctology, gynecology, and otolaryngology. In the past two decades, much work has been done in applying this modality to the treatment of liver tumors, both primary and metastatic. The biggest breakthrough in the field of cryosurgery for liver tumors has been the application of intraoperative ultrasound both to detect small lesions and to monitor the cryosurgical destruction process in order to assure complete ablation of the desired lesion with a margin of normal tissue. In the treatment of liver tumors, cryosurgical destruction is often used in addition to surgical resection.

In 2000, the FDA approved the use of radiofrequency induced tumor ablation (RFA) for hepatic tumors. WPS believes 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 are considered safe and effective in the following clinical scenarios:

- a. Primary hepatocellular carcinoma when conventional surgical resection is felt to be contraindicated or when ablation is used as an adjunct to surgical resection; and
- 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:
 - The primary cancer site must be effectively controlled.
 - 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 carcinomas metastatic to the liver, the following qualifying conditions for coverage 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 concern; any extrahepatic disease should be minimal and well-controlled.
- c. The open laparotomy approach or percutaneous approach may be used.
- d. The patient must have no more than 3 liver metastases, except in rare instances (such as multiple neuroendocrine liver metastases).
- e. No lesion should be larger than 7 cm. in size.

Note:

- 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.

B. Bone Tumors:

Percutaneous RFA of osteoid osteomas has become the preferred method of therapy for these benign lesions. RFA and cryotherapy have both been shown to be safe and effective in the palliation of metastatic bone tumors.

C. Renal Tumors:

Although open partial nephrectomy has been the gold standard for excision of renal tumors, minimally invasive approaches offer excellent results with lower morbidity and sparing renal function. The ablative techniques, cryoablation and radiofrequency ablation, have been relatively safe. At present, RF ablation is probably better suited for peripheral, exophytic masses in which higher blood flow and the collecting system are not problems.

Indications:

1. Solid renal masses less than or equal to 3 cm. 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, patients undergo periodic evaluations by CT or magnetic resonance imaging (MRI) to monitor for regrowth of the ablated mass); and;

2. Lesions in solitary kidney or patients with increased surgical risk/renal insufficiency; and

Examples:

- a. selected patients with small and incidentally detected renal cortical lesions
- b. in patients with a genetic predisposition to multiple tumors, or
- c. in patients with a solitary kidney, or
- d. when bilateral tumour growth is present.
- e. are poor surgical candidates due to poor renal function (e.g., RCC detected in an anatomical or functional solitary kidney when resection would result in the need for dialysis) and/or
- f. comorbid disease, and
- g. patients at high risk for the development of additional RCC in the future in whom the least invasive nephron-sparing approach is desirable (e.g., patients with hereditary diseases; patients with synchronous RCC).

3. A limit of 3 or less lesions; and

4. Biopsy proven or image documentation consistent with renal cell cancer, i.e. characteristics that are suspicious for malignancy.

A substantial percentage of patients referred for percutaneous ablation of renal tumors had benign masses. If CT or MRI alone cannot be used to diagnose a benign entity, patients 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 patients who need treatment and determining which of those may be most suitable for ablative therapy.

Limitations:

1. Small centrally located lesions or lesions adjacent to the renal hilum should not be considered.
2. Due to risk of tumor spillage from cyst contents with puncture from a cryoprobe, not indicated for primarily cystic lesions.

D. Breast Tumors:

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 by WPS Medicare.

E. Lung Tumors:

Radio frequency Ablation

The literature for pulmonary nodule ablation consists of several small studies of heterogeneous patients with short-term follow-up. All studies commented on a promising technology with further studies needing to be performed. There is no breakdown as to indications or durability of treatment for primary, metastatic, or multiple lesions treated percutaneously. Per the FDA, lack of safety and efficacy data precludes specific approval of ablation devices in lung cancer. Therefore, percutaneous ablation of pulmonary lesions remains an investigational modality. At this time this procedure will not be covered outside of a Medicare-approved clinical trial.

Cryotherapy

Endobronchial cryosurgery is a palliative technique, with the aim of alleviating symptoms and improving the patient's performance status. Patients 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.

F. Uterine leiomyoma, Percutaneous:

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. We have determined that RFA of uterine leiomyomata is not proven effective and thus not covered by Medicare.

This contractor will consider the ablation by any method of tumors not specifically mentioned above to be investigational and not covered by Medicare.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
83x	Special facility or ASC surgery-ambulatory surgical center (Discontinued for Hospitals Subject to Outpatient PPS; hospitals must use 13X for ASC claims submitted for OPPS payment -- eff. 7/00)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)
999x	Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: Providers are reminded that not all the CPT/HCPCS codes listed can be billed with all TOB and RC codes listed. CPT/HCPCS codes are required to be billed with specific TOB and RC codes.

Providers are encouraged to refer to the CMS Internet – Only Manual (IOM) Pub. 100.4, Claims Processing Manual, for further guidance.

036X	Operating room services-general classification
071X	Recovery room-general classification

CPT/HCPCS Codes

Group 1

The following codes, when used as described below, are considered not proven effective and will be denied as such:

19105	ABLATION, CRYOSURGICAL, OF FIBROADENOMA, INCLUDING ULTRASOUND GUIDANCE, EACH FIBROADENOMA
19499	UNLISTED PROCEDURE, BREAST
32999	UNLISTED PROCEDURE, LUNGS AND PLEURA
0071T	FOCUSED ULTRASOUND ABLATION OF UTERINE LEIOMYOMATA, INCLUDING MR GUIDANCE; TOTAL LEIOMYOMATA VOLUME LESS THAN 200 CC OF TISSUE
0072T	FOCUSED ULTRASOUND ABLATION OF UTERINE LEIOMYOMATA, INCLUDING MR GUIDANCE; TOTAL LEIOMYOMATA VOLUME GREATER OR EQUAL TO 200 CC OF TISSUE

Group II

The following codes, when used as described below, are covered services.

20982	ABLATION, BONE TUMOR(S) (EG, OSTEOID OSTEOMA, METASTASIS) RADIOFREQUENCY, PERCUTANEOUS, INCLUDING COMPUTED TOMOGRAPHIC GUIDANCE
20999	UNLISTED PROCEDURE, MUSCULOSKELETAL SYSTEM, GENERAL
47370	LAPAROSCOPY, SURGICAL, ABLATION OF 1 OR MORE LIVER TUMOR(S); RADIOFREQUENCY
47371	LAPAROSCOPY, SURGICAL, ABLATION OF 1 OR MORE LIVER TUMOR(S); CRYOSURGICAL
47380	ABLATION, OPEN, OF 1 OR MORE LIVER TUMOR(S); RADIOFREQUENCY

47381	ABLATION, OPEN, OF 1 OR MORE LIVER TUMOR(S); CRYOSURGICAL
47382	ABLATION, 1 OR MORE LIVER TUMOR(S), PERCUTANEOUS, RADIOFREQUENCY
50250	ABLATION, OPEN, 1 OR MORE RENAL MASS LESION(S), CRYOSURGICAL, INCLUDING INTRAOPERATIVE ULTRASOUND, IF PERFORMED
50542	LAPAROSCOPY, SURGICAL; ABLATION OF RENAL MASS LESION(S)
50592	ABLATION, 1 OR MORE RENAL TUMOR(S), PERCUTANEOUS, UNILATERAL, RADIOFREQUENCY
50593	ABLATION, RENAL TUMOR(S), UNILATERAL, PERCUTANEOUS, CRYOTHERAPY
76940	ULTRASOUND GUIDANCE FOR, AND MONITORING OF, PARENCHYMAL TISSUE ABLATION
77013	COMPUTED TOMOGRAPHY GUIDANCE FOR, AND MONITORING OF, PARENCHYMAL TISSUE ABLATION
77022	MAGNETIC RESONANCE GUIDANCE FOR, AND MONITORING OF, PARENCHYMAL TISSUE ABLATION

ICD-9 Codes that Support Medical Necessity

ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.

For use with Group II CPT Codes above

CPT codes: 47370, 47371, 47380, 47381, 47382

152.2 - 152.9	MALIGNANT NEOPLASM OF ILEUM - MALIGNANT NEOPLASM OF SMALL INTESTINE UNSPECIFIED SITE
153.0 - 153.9	MALIGNANT NEOPLASM OF HEPATIC FLEXURE - MALIGNANT NEOPLASM OF COLON UNSPECIFIED SITE
154.0 - 154.8	MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION - MALIGNANT NEOPLASM OF OTHER SITES OF RECTUM RECTOSIGMOID JUNCTION AND ANUS
155.0	MALIGNANT NEOPLASM OF LIVER PRIMARY
156.0	MALIGNANT NEOPLASM OF GALLBLADDER
156.1	

MALIGNANT NEOPLASM OF EXTRAHEPATIC BILE DUCTS

197.7 MALIGNANT NEOPLASM OF LIVER SECONDARY

235.3 NEOPLASM OF UNCERTAIN BEHAVIOR OF LIVER AND BILIARY PASSAGES

239.0 NEOPLASM OF UNSPECIFIED NATURE OF DIGESTIVE SYSTEM

259.2 CARCINOID SYNDROME

CPT codes: 50250, 50542, 50592, 50593

189.0 MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS

198.0 SECONDARY MALIGNANT NEOPLASM OF KIDNEY

233.9 CARCINOMA IN SITU OF OTHER AND UNSPECIFIED URINARY ORGANS

CPT code: 20982

198.5 SECONDARY MALIGNANT NEOPLASM OF BONE AND BONE MARROW

213.0 - 213.9 BENIGN NEOPLASM OF BONES OF SKULL AND FACE - BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE SITE UNSPECIFIED

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements

Documentation Requirements

1. Criteria listed in “Indications and Limitations of Coverage” must be met for Medicare reimbursement.
2. If cryosurgery or RFA is performed in addition to surgical resection, specific CPT codes must be submitted to reflect this along with the pertinent modifiers. The operative report must specify both surgical resection and cryosurgery or RITA ablation were performed.
3. There must be a written report of the procedure performed in the patient’s medical records and copies of the medical records must be made available upon Medicare request. When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act. When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.
4. For liver procedures: In rare instances (such as multiple neuroendocrine liver metastases) more than 3 liver metastases might be appropriately treated with ablation or a combination of ablation and surgical excision. In such cases, the claim should be re-submitted for review with a detailed letter of explanation of the clinical situation necessitating treatment of more than 3 metastases. In addition, a detailed operation note should be submitted with the claim in this situation.
5. The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

Appendices

Utilization Guidelines

Reasons for Denial

1. All other indications not listed in the “Indications and Limitations of Coverage” section of this policy;
2. The service is not medically necessary;
3. The medical record does not verify that the service described by the HCPCS code was provided;
4. The service does not follow the guidelines of this policy.
5. Services performed using other than FDA-approved equipment will be denied as non-covered.
6. CPT codes should only be billed once per day. Additional billing of these services on the same date of service will deny as not medically necessary.

Sources of Information and Basis for Decision

Liver

Cryosurgery:

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Iannitti, David, et al; Radiofrequency Ablation. *Arch Surg.* 2002; 137; 422-427

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RITA Medical Systems Website – <http://www.ritamedical.com/medscape.htm>

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Solbiati et. Al., "percutaneous radiofrequency ablation of hepatic metastases from colorectal cancer: Long-term results in 117 patients", *Radiology*, Vol 221, No 1, October 2001, pp 159-166

Kidney

Trabulsi et. Al., "New approaches to the minimally invasive treatment of kidney tumors", *The Cancer Journal*, Vol 11 no 1, Jan/Feb 2005, pp 57-63

Deane and Clayman, "Review of minimally invasive renal therapies: Needle-based and extracorporeal", *Urology*, Vol 68, July 2006, pp 26-37

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*Gervais DA, McGovern FJ, Arellano RS, McDougal, WS, Mueller, P. Renal cell carcinoma: clinical experience and technical success with radio-frequency ablation of 42 tumors. *Radiology* 2003 Feb; 226(2):417-24.

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- de Baere et. Al., “Midterm local efficacy and survival after radiofrequency ablation of lung tumors with minimum follow-up of 1 year”, Radiology, Vol 240, No 2, August 2006, pp 587-596
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Medical consultants

Other Medicare contractor policies

Advisory Committee Meeting Notes

Meeting Date:

Wisconsin: 01/16/2009

Illinois: 01/28/2009

Michigan: 01/07/2009

Minnesota: 01/22/2009

J-5 MAC (IA,KS,MO, NE) 02/12/2009

Start Date of Comment Period

02/12/2009

End Date of Comment Period

03/29/2009

Start Date of Notice Period

03/01/2010

Revision History Number

12

Revision History Explanation

03/01/2010, Added CPT code 47382 to the list of covered codes. It was inadvertently omitted from the original document

7/24/2009 Revisions to Draft LCD and removal of Coding And Billing Article completely. Released to Final.

06/29/09 Removed contractor 05392 as it is combining with WMO as one contractor number effective 8/1/09
bw

11/15/2009 - The description for CPT/HCPCS code 47370 was changed in group 2

11/15/2009 - The description for CPT/HCPCS code 47371 was changed in group 2

11/15/2009 - The description for CPT/HCPCS code 47380 was changed in group 2

11/15/2009 - The description for CPT/HCPCS code 47381 was changed in group 2

03/01/2010, Added CPT code 47382 to the list of covered codes. It was inadvertently omitted from the original document; 09/15/2009

Reason for Change

Last Reviewed On Date

02/05/2010

Related Documents

This LCD has no Related Documents.

LCD Attachments

All Versions

Updated on 02/05/2010 with effective dates 03/01/2010 - N/A

Updated on 11/15/2009 with effective dates 09/15/2009 - N/A

Updated on 07/24/2009 with effective dates 09/15/2009 - N/A