

**Contractor Name**

Wisconsin Physicians Service (WPS)

**Contractor Number**

00951, 00952, 00953, 00954

**Contractor Type**

Carrier

**LCD Database ID Number**

Wisconsin	L16817
Illinois	L16818
Michigan	L16819
Minnesota	L16820

**LCD Version Number**

**LCD Title**

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

**Contractor's Determination Number**

GSURG-033

**AMA CPT/ ADA CDT Copyright Statement**

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**CMS National Coverage Policy**

**Primary Geographic Jurisdiction**

Wisconsin, Illinois, Michigan, Minnesota

**Oversight Region**

Region V

**CMS Consortium**

Midwest

**Original Determination Effective Date**

Wisconsin:	10/01/1998
Illinois:	11/05/1997
Michigan:	11/05/1997
Minnesota:	01/01/1998

**Revision Effective Date**

\*01/01/2008

**Indications and Limitations of Coverage and/or Medical Necessity**

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.

- A. Cryosurgery and RFA in the treatment of certain selected primary and secondary liver tumors are considered safe and effective in the following clinical scenarios:
1. Primary hepatocellular carcinoma when conventional surgical resection is felt to be contraindicated or when ablation is used as an adjunct to surgical resection; and
  2. Primary carcinoma of the colon, small intestine, gall bladder, ovary, and neuroendocrine system, or other sites metastasized to the liver.
  3. \*Metastatic tumors with the following qualifying conditions:
    - a) The primary cancer site must be effectively controlled.
    - b) The metastatic lesions must be limited to the liver and not present in other organs.
  4. The cryosurgical device and RFA device used must be FDA approved for the indications used.
- B. In the case of carcinomas metastatic to the liver, the following qualifying conditions for coverage must be met:
1. The primary cancer site must be effectively controlled;
  2. \*The metastatic lesions must be liver-dominant in terms of symptoms and clinical concern; any extrahepatic disease should be minimal and well-controlled.
  3. \*The open laparotomy approach or percutaneous approach may be used.
  4. The patient must have no more than 3 liver metastases, except in rare instances (such as multiple neuroendocrine liver metastases).
  5. 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.**

**Coverage Topic**

Ambulatory Surgical Centers  
Hospital Care Inpatient

**CPT/HCPCS Codes**

47370	Laparoscopy, surgical, ablation of one or more liver tumor(s): radiofrequency
47371	Laparoscopy, surgical ablation of one or more liver tumor(s); cryosurgical
47380	Ablation, open, of one or more liver tumor(s); radiofrequency
47381	Ablation, open, of one or more liver tumor(s); cryosurgical
47382	Ablation, one or more liver tumor(s), percutaneous, radiofrequency
76940	Ultrasound guidance and monitoring of, parenchymal tissue ablation

- \*77013 Computed tomographic guidance for, and monitoring of parenchymal tissue ablation
- 77022 Magnetic resonance guidance for, and monitoring of parenchymal tissue ablation

**Does the CPT 30% Rule Apply**

No

**ICD-9 Codes that Support Medical Necessity**

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

NA

**Diagnoses that Support Medical Necessity**

NA.

**ICD-9 Codes that DO NOT Support Medical Necessity**

NA

**Diagnoses that DO NOT Support Medical Necessity**

NA

**Documentation Requirements**

1. Documentation supporting the medical necessity of cryosurgical or RFA treatments of liver tumors should be legible, maintained in the patient's medical record, and must be made available to Medicare upon request.
2. Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

**Utilization Guidelines**

1. Code 76940 should be billed only once per operative session regardless of the specialty billing for this code.
2. Code 76940 should be reported when intraoperative ultrasound guidance and monitoring is done with laparoscopic or open ablation.
3. Codes 77013 and 77022 may be medically indicated for tissue ablation of tumor sites other than the liver that are not addressed in this policy.

**Sources of Information and Basis for Decision**

**Cryosurgery:**

1. Kane, R.A. Ultrasound-Guided Hepatic Cryosurgery for Tumor Ablation. *Seminars in Interventional Radiology*; 1993, Vol. 10, No 2:132-142.
2. New Technology - Surgery Issues Carrier Medical Directors Clinical Work Group.
3. Onik, G.M. et al Cryosurgery of Liver Cancer. *Seminars in Surgical Oncology*; 1993, Vol. 9:309-317.
4. Ravikumar, T.S. et al. A 5-Year Study of Cryosurgery in the Treatment of Liver Tumors. *Archives of Surgery* ; 1991, Vol. 126:1520-1524.
5. Steele, Glenn, Jr. Cryoablation in Hepatic Surgery. *Seminars in Liver Disease: May 1994 Vol. 14, No 2; 120-125*.

6. Stone, Michael D. et al. 1990. Surgical Therapy for Recurrent Liver Metastases from Colorectal Cancer. *Archives of Surgery* Vol. 125:718-722.
7. Zhou, X., Tang, Z. et al. 1993. The Role of Cryosurgery in the Treatment of Hepatic Cancer *Cancer Research Clinical Oncology* 120:100-102.

**Radiofrequency Ablation (RFA):**

- 1 Berber, Eren, Pelley, Robert, et al. Predictors of Survival After Radiofrequency Thermal Ablation of Colorectal Cancer Metastases to the Liver: A Prospective Study. *Journal of Clinical Oncology*, March 2005, Vol. 23, No 7, 1358-1364
- 2 Bleicher RJ., Allegra DP., Nora, DT., Wood, TF., Foshag, L.J., Bilchik, AJ., Radiofrequency ablation in 447 complex unresectable liver tumors: Lessons learned. *Annals of Surgery Oncology* 2003: 10:52-58.
3. Curley, S.A., Izzo, F., et al. Radiofrequency ablation of hepatocellular cancer in 110 patients with cirrhosis. *Annals of Surgery*, September 2000, Vol. 232, No. 3: 381-391
4. Curley, S.A., Marra, Paola, et al. Early and Late Complications After Radiofrequency Ablation of Malignant Liver Tumors in 608 Patients. *Annals of Surgery* 2004, Vol. 239, No 4; 450-458
5. Goldberg, S.N., Gazelle G.S., et al. Treatment of intrahepatic malignancy with radiofrequency ablation: radiologic-pathologic correlation. *Cancer*, June 1, 2000, Vol. 88, No. 11: 2452-2463
- 6 Iannitti, David, et al; Radiofrequency Ablation. *Arch Surg*. 2002: 137; 422-427
7. Noridian Draft Local Coverage Determination
8. Radio Therapeutics Website – <http://www.radiotherapeutics.com/>
9. RITA Medical Systems Website – <http://www.ritamedical.com/medscape.htm>
- 10 Siperstein, A., Garland, A., et al. Laparoscopic radiofrequency ablation of primary and metastatic liver tumors: Technical considerations. *Surgical Endoscopy*, April 2000, Vol. 14, No.4: 400-405

**Advisory Committee Meeting Notes**

Available upon request

Meeting Date:

Wisconsin:	02/02/2007, 03/05/1998
Illinois:	01/17/2007, 06/17/1997
Michigan:	01/03/2007, 06/17/1997
Minnesota:	01/25/2007, 08/20/1997

**Start Date of Comment Period**

Wisconsin:	02/02/2007; 03/06/1998
Illinois:	02/02/2007; 06/18/1997
Michigan:	02/02/2007; 06/18/1997
Minnesota:	02/02/2007; 08/21/1997

**End Date of Comment Period**

Wisconsin: 03/20/2007, 04/21/1998  
 Illinois: 03/20/2007, 08/03/1997  
 Michigan: 03/20/2007, 08/03/1997  
 Minnesota: 03/20/2007, 10/06/1997

**Start Date of Notice Period (Published)**

Wisconsin, \*01/01/2008, Article; 08/01/2007; 05/01/2007; 11/01/2006, Article; 09/01/2005, Article; 12/01/2001; 09/01/2001; 09/01/1998  
 Illinois: \*01/01/2008, Article; 08/01/2007; 05/01/2007; 11/01/2006, Article; 09/01/2005, Article; 12/01/2001; 09/01/2001; 02/01/2001; 10/15/1997  
 Michigan: \*01/01/2008, Article; 08/01/2007; 05/01/2007; 11/01/2006, Article; 09/01/2005, Article; 12/01/2001; 09/01/2001; 02/01/2001; 10/15/1997  
 Minnesota: \*01/01/2008, Article; 08/01/2007; 05/01/2007; 11/01/2006, Article; 09/01/2005, Article; 12/01/2001; 09/01/2001; 01/01/1998

**Revision History Number/Explanation**

Wisconsin: \*01/01/2008, CPT code 77013 description change (seven); 09/16/2007, replaces LCD Cryosurgery for Liver Tumors (six); 11/01/2006, CPT code 76986 deleted and replaced with CPT code 76940 (five); 09/01/2005, removed CPT code 49200 (four); 05/01/2004, LCD Reformat, (three); 01/01/2002, code update, (two); 09/01/2001, (one).  
 Illinois: \*01/01/2008, CPT code 77013 description change (seven); 09/16/2007, replaces LCD Cryosurgery for Liver Tumors (six); 11/01/2006, CPT code 76986 deleted and replaced with CPT code 76940 (five); 09/01/2005, removed CPT code 49200 (four); 05/01/2004, LCD Reformat, (three); 01/01/2002, code update, (two); 09/01/2001, (one).  
 Michigan: \*01/01/2008, CPT code 77013 description change (seven); 09/16/2007, replaces LCD Cryosurgery for Liver Tumors (six); 11/01/2006, CPT code 76986 deleted and replaced with CPT code 76940 (five); 09/01/2005, removed CPT code 49200 (four); 05/01/2004, LCD Reformat, (three); 01/01/2002, code update, (two); 09/01/2001, (one).  
 Minnesota: \*01/01/2008, CPT code 77013 description change (seven); 09/16/2007, replaces LCD Cryosurgery for Liver Tumors (six); 11/01/2006, CPT code 76986 deleted and replaced with CPT code 76940 (five); 09/01/2005, removed CPT code 49200 (four); 05/01/2004, LCD Reformat, (three); 01/01/2002, code update, (two); 09/01/2001, (one).

**Last Reviewed On**

01/01/2008

**Notes**

Effective 09/16/2007, Cryosurgery (Cryoablation) and Radiofrequency Ablation for Treatment of Liver Tumors replaces all previous policies titled Cryosurgery for Liver Tumors. This LCD was returned to CAC January and February 2007, for discussion and the inclusion of CPT codes 47370, 47380, 47382, 77013 and 77022. Multiple comments and references were received from CAC members and other esteemed physicians specializing in tumor ablation, confirming that ablation therapy may be medically indicated for cancers that have metastasized to the liver from multiple origins. Therefore, based on the evidence submitted, in order to assure access to those Medicare beneficiaries in need of medically indicated tumor ablation, WPS has removed the ICD-9-CM list from this LCD.

Quad State revision 01/01/2002; GSURG-033 replaces MN policy GSURG 97-14

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See companion document, [Coding and Billing Guidelines for Cryosurgery \(Cryoablation\) and Radiofrequency Ablation for Treatment of Liver Tumors \(GSURG-033\)](#)

\* - An asterisk indicates a revision to that section of the policy.

**Does this LCD contain a "Least Costly Alternative" Provision?**

No

This policy does not reflect the sole opinion of the carrier or Carrier Medical Director. Although the final decision rests with the carrier, this policy was developed in cooperation with carrier advisory groups, which includes representatives from relative medical specialties.