

Medical Coverage Policy | Cryosurgical Ablation of Primary or Metastatic Liver Tumors



EFFECTIVE DATE: 02 | 17 | 2015

POLICY LAST UPDATED: 11 | 02 | 2022

OVERVIEW

Cryosurgical ablation involves the freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgical ablation can be performed as an open surgical technique or percutaneously or laparoscopically, typically with ultrasound guidance.

MEDICAL CRITERIA

Not applicable.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Cryosurgical ablation of either primary or metastatic tumors in the liver is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Cryosurgical ablation of either primary or metastatic tumors in the liver is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable not medically necessary benefits/not covered coverage.

BACKGROUND

Cryosurgical ablation (CSA) involves the freezing of target tissues, often by inserting a probe through which coolant is circulated into the tumor. CSA can be performed as an open surgical technique or percutaneously or laparoscopically, typically with ultrasound guidance. For individuals who have unresectable primary hepatocellular carcinoma amenable to locoregional therapy who receive CSA, the evidence includes 1 randomized controlled trial (RCT), several nonrandomized comparative studies, and multiple noncomparative studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The available RCT comparing cryoablation with radiofrequency ablation demonstrated lower rates of local tumor progression with cryoablation, but no differences in survival outcomes between groups. Although this trial provided suggestive evidence that cryoablation is comparable with radiofrequency ablation, trial limitations would suggest findings need to be replicated. Additional comparative evidence is needed to permit conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable liver metastases from neuroendocrine tumors amenable to locoregional therapy who receive CSA, the evidence includes a Cochrane review and case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, and treatment-related mortality and morbidity. The available evidence base is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable liver metastases from colorectal cancer amenable to locoregional therapy who have CSA, the evidence includes 1 RCT, a number of nonrandomized comparative and noncomparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The available RCT comparing surgical resection with cryoablation was judged at high risk of bias. Some nonrandomized comparative studies have reported improved survival outcomes for patients managed with cryotherapy compared with those managed with resection alone; however, these studies were subject to bias in the selection of patients for treatments. Additional controlled studies are needed to permit conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary Commercial Products:

- 47371** Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
- 47381** Ablation, open, 1 or more liver tumor(s); cryosurgical
- 47383** Ablation, 1 or more liver tumor(s), percutaneous, cryoablation

RELATED POLICIES

Not Applicable

PUBLISHED

Provider Update, January 2023
Provider Update, December 2021
Provider Update, November 2020
Provider Update, January 2020
Provider Update, November/December 2018

REFERENCES:

1. Singh SK, Singh R. Liver cancer incidence and mortality: Disparities based on age, ethnicity, health and nutrition, molecular factors, and geography. *Cancer Health Disparities*. Mar 2020; 4: e1-e10. PMID34164612
2. Sohn RL, Carlin AM, Steffes C, et al. The extent of cryosurgery increases the complication rate after hepatic cryoablation. *Am Surg*. Apr 2003; 69(4): 317-22; discussion 322-3. PMID 12716090
3. Wang C, Wang H, Yang W, et al. Multicenter randomized controlled trial of percutaneous cryoablation versus radiofrequency ablation in hepatocellular carcinoma. *Hepatology*. May 2015; 61(5): 1579-90. PMID 25284802
4. Wang Y, Li W, Man W, et al. Comparison of Efficacy and Safety of TACE Combined with Microwave Ablation and TACE Combined with Cryoablation in the Treatment of Large Hepatocellular Carcinoma. *Comput Intell Neurosci*. 2022; 2022: 9783113. PMID 35795769
5. Luo J, Dong Z, Xie H, et al. Efficacy and safety of percutaneous cryoablation for elderly patients with small hepatocellular carcinoma: A prospective multicenter study. *Liver Int*. Apr 2022; 42(4): 918-929. PMID 35065003
6. Chen L, Ren Y, Sun T, et al. The efficacy of radiofrequency ablation versus cryoablation in the treatment of single hepatocellular carcinoma: A population-based study. *Cancer Med*. Jun 2021; 10(11): 3715-3725. PMID 33960697
7. Cha SY, Kang TW, Min JH, et al. RF Ablation Versus Cryoablation for Small Perivascular Hepatocellular Carcinoma: Propensity Score Analyses of Mid-Term Outcomes. *Cardiovasc Intervent Radiol*. Mar 2020;43(3): 434-444. PMID 31844951
8. Ko SE, Lee MW, Rhim H, et al. Comparison of procedure-related complications between percutaneous cryoablation and radiofrequency ablation for treating periductal hepatocellular carcinoma. *Int J Hyperthermia*. Nov 17 2020; 37(1): 1354-1361. PMID 33297809

9. Wei J, Cui W, Fan W, et al. Unresectable Hepatocellular Carcinoma: Transcatheter Arterial Chemoembolization Combined With Microwave Ablation vs. Combined With Cryoablation. *Front Oncol.* 2020; 10: 1285. PMID 32850395
10. Ei S, Hibi T, Tanabe M, et al. Cryoablation provides superior local control of primary hepatocellular carcinomas of 2 cm compared with radiofrequency ablation and microwave coagulation therapy: an underestimated tool in the toolbox. *Ann Surg Oncol.* Apr 2015; 22(4): 1294-300. PMID 25287439
11. Dunne RM, Shyn PB, Sung JC, et al. Percutaneous treatment of hepatocellular carcinoma in patients with cirrhosis: a comparison of the safety of cryoablation and radiofrequency ablation. *Eur J Radiol.* Apr 2014;83(4): 632-8. PMID 24529593
12. Awad T, Thorlund K, Gluud C. Cryotherapy for hepatocellular carcinoma. *Cochrane Database Syst Rev.* Oct 07 2009; (4): CD007611. PMID 19821432
13. Adam R, Hagopian EJ, Linhares M, et al. A comparison of percutaneous cryosurgery and percutaneous radiofrequency for unresectable hepatic malignancies. *Arch Surg.* Dec 2002; 137(12): 1332-9; discussion1340. PMID 12470093
14. Yang Y, Wang C, Lu Y, et al. Outcomes of ultrasound-guided percutaneous argon-helium cryoablation of hepatocellular carcinoma. *J Hepatobiliary Pancreat Sci.* Nov 2012; 19(6): 674-84. PMID 22187145
15. Rong G, Bai W, Dong Z, et al. Long-term outcomes of percutaneous cryoablation for patients with hepatocellular carcinoma within Milan criteria. *PLoS One.* 2015; 10(4): e0123065. PMID 25849963
16. Zhou L, Yang YP, Feng YY, et al. Efficacy of argon-helium cryosurgical ablation on primary hepatocellular carcinoma: a pilot clinical study. *Ai Zheng.* Jan 2009; 28(1): 45-8. PMID 19448416
17. Wang C, Lu Y, Chen Y, et al. Prognostic factors and recurrence of hepatitis B-related hepatocellular carcinoma after argon-helium cryoablation: a prospective study. *Clin Exp Metastasis.* 2009; 26(7): 839-48. PMID 19784786
18. Jaeck D, Oussoultzoglou E, Bachellier P, et al. Hepatic metastases of gastroentero pancreatic neuroendocrine tumors: safe hepatic surgery. *World J Surg.* Jun 2001; 25(6): 689-92. PMID 11376398
19. Gurusamy KS, Ramamoorthy R, Sharma D, et al. Liver resection versus other treatments for neuroendocrine tumours in patients with resectable liver metastases. *Cochrane Database Syst Rev.* Apr 15 2009; (2): CD007060. PMID 19370671
20. Saxena A, Chua TC, Chu F, et al. Optimizing the surgical effort in patients with advanced neuroendocrine neoplasm hepatic metastases: a critical analysis of 40 patients treated by hepatic resection and cryoablation. *Am J Clin Oncol.* Oct 2012; 35(5): 439-45. PMID 21654315
21. Chung MH, Pisegna J, Spirt M, et al. Hepatic cytoreduction followed by a novel long-acting somatostatin analog: a paradigm for intractable neuroendocrine tumors metastatic to the liver. *Surgery.* Dec 2001;130(6): 954-62. PMID 11742323
22. Al-Asfoor A, Fedorowicz Z, Lodge M. Resection versus no intervention or other surgical interventions for colorectal cancer liver metastases. *Cochrane Database Syst Rev.* Apr 16 2008; (2): CD006039. PMID18425932
23. Korpan NN. Hepatic cryosurgery for liver metastases. Long-term follow-up. *Ann Surg.* Feb 1997; 225(2):193-201. PMID 9065296
24. Bala MM, Riemsma RP, Wolff R, et al. Cryotherapy for liver metastases. *Cochrane Database Syst Rev.* Jun 05 2013; (6): CD009058. PMID 23740609
25. Gurusamy KS, Ramamoorthy R, Imber C, et al. Surgical resection versus non-surgical treatment for hepatic node positive patients with colorectal liver metastases. *Cochrane Database Syst Rev.* Jan 20 2010;(1): CD006797. PMID 20091607
26. Pathak S, Jones R, Tang JM, et al. Ablative therapies for colorectal liver metastases: a systematic review. *Colorectal Dis.* Sep 2011; 13(9): e252-65. PMID 21689362
27. Ruers TJ, Joosten JJ, Wiering B, et al. Comparison between local ablative therapy and chemotherapy for non-resectable colorectal liver metastases: a prospective study. *Ann Surg Oncol.* Mar 2007; 14(3): 1161-9. PMID 17195903
28. Niu R, Yan TD, Zhu JC, et al. Recurrence and survival outcomes after hepatic resection with or without cryotherapy for liver metastases from colorectal carcinoma. *Ann Surg Oncol.* Jul 2007; 14(7): 2078-87. PMID 17473951

29. Joosten J, Jager G, Oyen W, et al. Cryosurgery and radiofrequency ablation for unresectable colorectal liver metastases. *Eur J Surg Oncol*. Dec 2005; 31(10): 1152-9. PMID 16126363
30. Ng KM, Chua TC, Saxena A, et al. Two decades of experience with hepatic cryotherapy for advanced colorectal metastases. *Ann Surg Oncol*. Apr 2012; 19(4): 1276-83. PMID 21913018
31. Seifert JK, Springer A, Baier P, et al. Liver resection or cryotherapy for colorectal liver metastases: a prospective case control study. *Int J Colorectal Dis*. Nov 2005; 20(6): 507-20. PMID 15973545
32. Kornprat P, Jarnagin WR, DeMatteo RP, et al. Role of intraoperative thermoablation combined with resection in the treatment of hepatic metastasis from colorectal cancer. *Arch Surg*. Nov 2007; 142(11):1087-92. PMID 18025338
33. Xu KC, Niu LZ, He WB, et al. Percutaneous cryosurgery for the treatment of hepatic colorectal metastases. *World J Gastroenterol*. Mar 07 2008; 14(9): 1430-6. PMID 18322961
34. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology:Hepatobiliary Cancers. Version 2.2022.https://www.nccn.org/professionals/physician_gls/PDF/hepatobiliary.pdf. Accessed July 25, 2022.
35. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology:Neuroendocrine and Adrenal Tumors. Version 1.2022.https://www.nccn.org/professionals/physician_gls/PDF/neuroendocrine.pdf. Accessed July 25, 2022.
36. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology:Colon Cancer. Version 1.2022.https://www.nccn.org/professionals/physician_gls/PDF/colon.pdf. Accessed July 25, 2022.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

