

Radiofrequency Ablation and Cryosurgery of Primary or Metastatic Liver Tumors

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| Approved By: | Highmark Health Options – Market Leadership |
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| Products: | Medicaid |
| Application: | All participating hospitals and providers |
| Page Number(s): | 1 of 5 |

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Radiofrequency ablation – A procedure in which a probe is inserted into the center of a tumor 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 3-5 cm sphere of dead tissue. The cells killed by RFA are not removed but are gradually replaced by fibrosis and scar tissue. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

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

PROCEDURES

RFA of primary or metastatic hepatocellular carcinoma (HCC) may be considered medically necessary in individuals who are not surgical candidates when ANY of following are met:

- There are no more than three (3) nodules and all tumor foci can be adequately treated; or
- As a bridge to transplant when ALL of the following criteria have been met:
 - Preserved liver function defined as Child-Pugh Class A or B; and
 - Single tumors less than or equal to 6.5 cm in diameter, or no more than three (3) lesions less than or equal to 4.5 cm in diameter, and total tumor diameter less than or equal to 8 cm ; and
 - No evidence of extra-hepatic metastases; and
 - No evidence of severe renal function impairment; and
 - No evidence of portal vein occlusion; or
- Primary or metastatic treatment of hepatic metastases 5 cm or less in diameter from colorectal cancer in the absence of extrahepatic metastatic disease when all tumor foci can be adequately treated; or
- Treatment of hepatic metastases from neuroendocrine tumors in individuals with symptomatic disease when systemic therapy has failed to control symptoms; or
- As a repeat procedure when at least six (6) months have elapsed since the prior surgical resection or ablation.

RFA for hepatic metastasis is considered experimental/investigational for the following:

- Hepatic metastases from colorectal cancer or neuroendocrine tumors that do not meet the criteria above; and
- Hepatic metastases from other types of cancer with the exception of colorectal cancer or neuroendocrine tumors.

RFA of liver tumors is considered experimental/investigational for all other indications because the safety/and or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Cryosurgery of the liver, using a Federal Food and Drug Administration approved cryosurgical device, may be considered medically necessary for select individuals with unresectable liver tumors or for individuals whose liver tumors are not totally resectable when ALL of the following criteria are met:

- Proven primary or secondary malignant tumor by biopsy, tumor markers, MRI, CT scan or ultrasound; and
- The lesion(s) must be unresectable, whether on the basis of size, location, (proximity to major structures) bilobar involvement, or underlying liver disease (such as cirrhosis); and
- For individuals with metastatic disease there must be no residual tumor at the primary site; and
- There must be no evidence of extrahepatic malignancy; and
- All visible tumors (visible by imaging study including intraoperative ultrasound) must be eradicable; and
- Lesion measures no more than 4 cm in diameter; and
- Lesions must be either a primary hepatocellular carcinoma or hepatic metastases from either primary colorectal cancer or neuroendocrine cancer.

The following uses of cryosurgery of the liver are considered experimental/investigational:

- When policy criteria have not been met; or

- Metastatic lesions of the liver are from tumor primaries other than colorectal or neuroendocrine cancer.

The use of cryosurgery for liver tumors is considered experimental/investigational for all other indications because the safety and/or effectiveness of this service cannot be established by the available peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/Investigational (E/I) services are not covered regardless of place of service.

RFA and Cryosurgery of Primary or Metastatic Liver Tumors is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

| CPT codes | Description |
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| 47370 | Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency. |
| 47380 | Ablation, open, of 1 or more liver tumor(s); radiofrequency. |
| 47382 | Ablation, one or more liver tumor(s), percutaneous, radiofrequency. |
| 76940 | Ultrasound guidance for, and monitoring of, parenchymal tissue ablation. |
| 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, one or more liver tumor(s), percutaneous, cryoablation. |

Covered Diagnosis Codes for Procedure Codes: 47370, 47380, 47382, 47371, 47381, 47383

| Code | Description |
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| C22.0 | Liver cell carcinoma. |
| C22.2 | Hepatoblastoma. |
| C22.3 | Angiosarcoma of liver. |
| C22.4 | Other sarcomas of liver. |
| C22.7 | Other specified carcinomas of liver. |
| C22.8 | Malignant neoplasm of liver, primary, unspecified as to type. |
| C22.9 | Malignant neoplasm of liver, not specified as primary or secondary. |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct. |
| C7B.1 | Secondary merkel cell carcinoma. |

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| D01.5 | Carcinoma in situ of liver, gallbladder and bile ducts. |
| D37.6 | Neoplasm of uncertain behavior of liver, gallbladder and bile ducts. |

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

| <Date> | <Event> |
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