



## Hepatic Neoplasm Treatment

### **I. Policy**

University Health Alliance (UHA) will reimburse for treatment of hepatic neoplasm outside of systemic chemotherapy alone when determined to be medically necessary and within the medical criteria guidelines (subject to limitations and exclusions) indicated below.

### **II. Background**

Liver tumors (primary or metastatic) represent some of the most complex intra-abdominal malignancies. The association of hepatocellular carcinoma with Hepatitis B and C (and the high seroprevalence of these diseases) as well as the frequency of isolated hepatic metastases from other primary tumors make the case for a comprehensive and integrated approach clear. Issues related to hepatic reserve, number, and location of tumors and their biologic behavior (all in the context of the patient's general constitution and the presence or absence of systemic disease) are important in treatment planning.

Hepatic resection, radiofrequency ablation, cryotherapy, chemoembolization, and microsphere radiocolloid infusion/embolization have all been employed in the treatment of liver tumors. Selection of a preferred therapeutic course can be complicated. Oncologic, anatomic, and distinct physiologic considerations mandate a broad and seasoned understanding of these disease entities and their preferred treatment.

### **III. Criteria/Guidelines**

- A. UHA requires prior authorization whenever liver tumors are considered for treatment outside of systemic chemotherapy alone.
  1. Routine treatment criteria must be met (as outlined in Milliman Care Guidelines).
  2. There must be documented evidence that the UHA member has been evaluated by a surgeon with formal training in hepatic surgery (i.e., hepatic transplantation or formal hepatobiliary fellowship completion).
    - a. This evaluation can occur in second opinion consultation or in a formal tumor board presentation. In the latter case, the patient must be given an understanding of the opinions rendered and be offered a second opinion with the hepatic surgeon.
    - b. This applies to patients considered for operative, radiologic, chemical, thermal, and all ablative therapies excluding systemic chemotherapy so as to advance the goal of enhanced informed consent in this area of multiple treatment alternatives.
- B. The following types of treatment are covered for the conditions indicated:
  1. Percutaneous Ethanol Injection:
    - a. UHA considers percutaneous ethanol injection (PEI) medically necessary for the treatment of hepatocellular cancers (HCC) without extra-hepatic spread.
    - b. There is inadequate information to document the effectiveness of PEI as an alternative to surgical resection for the treatment of hepatic metastases.
    - c. UHA considers combined radiofrequency ablation and PEI experimental and investigational for the treatment of HCC because of insufficient evidence in the peer-reviewed literature.
  2. Chemoembolization:

- a. UHA considers hepatic chemoembolization (CE) medically necessary for any of the following:
    - i. For treatment of neuroendocrine cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver.
      - CE is considered medically necessary only in persons who have failed systemic therapy with octreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea); or
    - ii. For unresectable, primary HCC; or
    - iii. For liver-only metastasis from uveal (ocular) melanoma; or
    - iv. Preoperative hepatic artery chemoembolization followed by orthotopic liver transplantation for HCC.
  - b. UHA considers CE experimental and investigational for other indications including palliative treatment of liver metastases from other non-neuroendocrine primaries (e.g., breast cancer, colon cancer, melanoma, rhabdomyosarcoma, or unknown primaries) because there is inadequate evidence in the medical literature of the effectiveness of CE for these indications.
3. Intra-Hepatic Chemotherapy:
- a. UHA considers intra-hepatic chemotherapy (infusion) medically necessary for members with liver metastases from colorectal cancer.
  - b. UHA does not consider intra hepatic chemotherapy medically necessary for other indications, including treatment of liver primaries or metastases from other primaries besides colorectal cancer, “one-shot” arterial chemotherapy for liver metastases from colorectal cancer, and transarterially administered gene therapy because of insufficient evidence in the peer reviewed literature.
  - c. UHA does not consider “one-shot” arterial chemotherapy as meeting criteria for medical necessity for members with liver metastases from colorectal cancer because of insufficient evidence in the peer-reviewed literature.
  - d. UHA does not consider transarterially administered gene therapy as meeting criteria for medical necessity for primary and secondary liver malignancies because of insufficient evidence in the peer-reviewed literature.
4. Intra-Hepatic Microspheres:
- a. UHA considers intra-hepatic microspheres (e.g., TheraSphere, MDS Nordion Inc.; SIR-Spheres, Sirtex Medical Inc.) medically necessary for any of the following:
    - i. For symptomatic treatment of neuroendocrine cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver.
      - For carcinoid tumors, intra-hepatic microspheres are considered medically necessary only in persons who have failed systemic therapy with octreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea); or
    - ii. For unresectable, primary HCC; or
    - iii. For unresectable liver tumors from primary colorectal cancer; or
    - iv. Pre-operative use as a bridge to orthotopic liver transplantation for HCC.
5. UHA considers cryosurgery, microwave, or radiofrequency ablation medically necessary for members with isolated colorectal cancer liver metastases or isolated hepatocellular cancer who are not candidates for surgical resection when all criteria specified below are met.

Particular emphasis should be placed on criteria B and C, which ensure that cryosurgery, microwave, or radiofrequency ablation is performed with curative intent:

- a. Member must either have hepatic metastases from a colorectal primary cancer or have a hepatocellular cancer; and
  - b. Members must have isolated liver disease. Members with nodal or extra-hepatic systemic metastases are not considered candidates for these procedures; and
  - c. All tumors in the liver, as determined by pre-operative imaging, would be potentially destroyed by cryotherapy, microwave, or radiofrequency ablation; and
  - d. Because open surgical resection is the preferred treatment, members must be unacceptable open surgical candidates due to the location or extent of the liver disease or due to co-morbid conditions such that the member is unable to tolerate an open surgical resection; and
  - e. Liver lesions must be 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma.
6. UHA considers ablation medically necessary for unresectable neuroendocrine tumors metastatic to the liver.
  7. UHA does not consider cryosurgery, microwave, or radiofrequency ablation of hepatic lesions medically necessary when criteria within this policy are not met.
    - a. Additionally, cryosurgical, microwave or radiofrequency ablation as a palliative treatment of either hepatic metastases from colorectal cancer or hepatocellular cancer does not meet criteria for medical necessity because the effectiveness of these approaches for these indications has not been established.
  8. UHA considers combinational treatment of radiofrequency ablation and transcatheter arterial chemoembolization for the treatment of unresectable hepatocellular carcinoma medically necessary where criteria for radiofrequency ablation for hepatocellular carcinomas above are met.
    - a. Combinational treatment of high-intensity focused ultrasound (HIFU) and transcatheter arterial chemo-embolization for the treatment of hepatoblastoma does not meet criteria for medical necessity because the effectiveness of this approach has not been established.
    - b. Radiofrequency ablation does not meet criteria for medical necessity for the treatment of giant hepatic hemangioma because the effectiveness of this approach has not been established.
  9. Surgical excision by anatomic or nonanatomic resection is covered when all hepatic tumor (primary or secondary) can be extirpated with clear margins in one or two stages. Isolated and respectable pulmonary metastases or the need for neoadjuvant chemotherapy are not strict contraindications to resectional therapy.

#### **IV. Limitations/Exclusions**

- A. Indications or conditions not listed in this policy that are not supported by medical literature to meet criteria for medical necessity are not covered.

**NOTE:**

*This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.*

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member's individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

## V. Administrative Guidelines

- A. UHA will require prior authorization whenever liver tumors are considered for treatment outside of systemic chemotherapy alone.
- B. All of the following documentation must be submitted:
  1. Clinical notes describing symptoms and physical findings; and
  2. Documentation of evidence that the UHA member has been evaluated by a surgeon with formal training in hepatic surgery, as noted in guidelines above.
- C. To request prior authorization, please submit via UHA's online portal. If a login has not been established, you may contact UHA at 808-532-4000 to establish one.
- D. This policy may apply to the following codes. Inclusion of a code in the table below does not guarantee that it will be reimbursed.

### Ablation of Hepatic Lesions

CPT codes covered if selection criteria are met:

CPT Code	Description
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

Other CPT codes related to the CPB:

CPT Code	Description
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

Other HCPCS codes related to the CPB:

HCPCS Code	Description
C1886	Catheter, extravascular tissue ablation, any modality (insertable)

### Liver and Other Neoplasms - Treatment Approaches

CPT codes covered if selection criteria are met:

CPT Code	Description
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family
36260	Insertion of implantable intra-arterial infusion pump (e.g., for chemotherapy of liver)
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary or intracranial, any method, including radiological supervision and interpretation, initial treatment day
37212	Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day

37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation
47120	Hepatectomy, resection of liver; partial lobectomy
47122	Hepatectomy, resection of liver; trisegmentectomy
47125	Hepatectomy, resection of liver; total left lobectomy
47130	Hepatectomy, resection of liver; total right lobectomy
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to code for primary procedure)
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care)
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
77799	Unlisted procedure, clinical brachytherapy
96446	Chemotherapy administration into the peritoneal cavity via indwelling port or catheter

**Other CPT codes related to the CPB:**

CPT Code	Description
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)

**HCPCS codes covered if selection criteria are met:**

HCPCS Code	Description
Q3001	Radioelements for brachytherapy, any type, each
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

**Other HCPCS codes related to the CPB:**

HCPCS Code	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, nondepot form for subcutaneous or intravenous injection, 25 mg

## **VI. Policy History**

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