Liver Diagnostic Tests and Tumor Treatment

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon* ☐ *Washington*

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Hepatic fibrosis is the excessive accumulation of fibrotic connective tissue resulting from prolonged inflammation and progressive scarring of the liver due to a sustained wound-healing response to alcohol or nonalcohol-induced liver injury (nonalcoholic liver disease. Hepatic tumors share a close association with liver fibrosis with a high percentage of tumors develop in fibrotic livers.

Hepatic tumors can arise either as primary liver cancer (e.g., hepatocellular carcinoma) or by metastasis to the liver from other primary cancer sites. Local therapy for hepatic metastasis may be indicated when there is no extrahepatic disease. Surgical resection, radiofrequency ablation and liver transplantation may be options for patients with limited disease. For patients with more advanced hepatocellular carcinoma recommended options may include-trans-arterial chemoembolization. Locoregional therapies are proposed as a treatment for unresectable hepatic tumors, both as primary treatment, palliative treatment, and as a bridge to liver transplant. In the case of liver transplants, the intent is to reduce tumor progression while awaiting transplantation and to preserve a member's candidacy for liver transplant during the wait time for a donor organ.

Enhanced Liver Fibrosis (ELF) Test

The Enhanced Liver Fibrosis Test is a blood based analysis of 3 biomarkers (hyaluronic acid, procollagen III amino terminal peptide, and tissue inhibitor of metalloproteinase 1

Treatment Options for Locoregional Therapy:

Chemoembolization/Embolization

Transcatheter Arterial Chemoembolization (TACE) is a non-surgical procedure performed by interventional radiologists and interventional neuroradiologists. It involves injection of anti-cancer drugs and selective occlusion of blood vessels feeding a tumor, in effect trapping the drug and blocking blood flow to the tumor.

Transcatheter Arterial Embolization (TAE) is a non-surgical procedure performed by interventional radiologists and interventional neuroradiologists. It involves blocking the blood supply to a tumor using gelatin or small beads.

Radioembolization

Radioembolization is a form of radiation therapy done by interventional radiologists to treat liver cancer. Radioactive particles (microspheres) are delivered through the bloodstream to the liver tumor via the hepatic artery. Radioactivity decreases gradually over a two-week period and response to treatment is assessed at 30 days. Treatment may be repeated.

Percutaneous Ethanol Injection

Using a needle, percutaneous ethanol injection (PEI) delivers an injection of 95 percent ethanol directly into a tumor. Multiple treatment sessions may be performed in order to achieve tumor destruction.

Cryosurgical Ablation

Cryosurgical ablation destroys cells by freezing target tissues, most often by inserting a probe into the tumor through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

Radiofrequency Ablation

Radiofrequency ablation (RFA) destroys cells (cancerous and normal) by applying a heat-generating rapidly alternating radiofrequency current through probes inserted into the tumor. The cells ablated by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it may be retreated. RFA can be performed as an open surgical procedure, laparoscopically, or percutaneously with ultrasound or computed tomography (CT) guidance.

Microwave Ablation

Microwave ablation (MWA) is a technique in which the use of microwave energy induces a high-speed alternating electric field which causes water molecule rotation and the creation of heat. MWA uses ultrasound, computed tomography (CT), or magnetic resonance imaging (MRI) to guide placement of a needle-like probe into a tumor. This results in thermal coagulation and localized tissue necrosis. Multiple antennas may also be used simultaneously to ablate multiple tumors. MWA can be performed surgically, percutaneously, or laparoscopically and is most often performed by a specially trained interventional radiologist

Criteria

Commercial

Prior authorization is required

I. Enhanced Liver Fibrosis (ELF) Test

PacificSource considers Enhanced Liver Fibrosis (ELF) Test medically necessary for the detection and prognosis of liver fibrosis in persons with chronic liver diseases when **BOTH** the following criteria is met.

- **A.** Performance of the Enhanced Liver Fibrosis test is not more than twice per year
- **B.** Performance of Enhanced Liver Fibrosis test is not within 6 months following a liver biopsy (or other test for liver fibrosis)

II. Chemoembolization/ Embolization- Transcatheter Arterial Chemoembolization (TACE) or Transcatheter Arterial Embolization (TAE)

PacificSource considers Transcatheter Arterial Chemoembolization or Transcatheter Arterial Embolization for hepatic malignancy medically necessary for the following indications:

- **A.** Hepatic tumors for palliative treatment when other treatments have failed to control liver tumor related symptoms
- **B.** Hepatocellular carcinoma as a primary treatment for either surgically unresectable primary hepatocellular carcinoma or as a bridge to liver transplantation when **ALL** of the following criteria is met:
  1. Preserved liver function defined as Childs-Turcotte-Pugh Class A or B
  2. Three (3) or fewer encapsulated nodules and each nodule is less than or equal to 5 centimeters in diameter
  3. No evidence of extra-hepatic metastases
  4. No evidence of severe renal function impairment
  5. No evidence of portal vein occlusion
- **C.** Neuroendocrine Cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver when **ALL** of the following criteria is met:
  1. Liver tumor related symptoms persist despite systemic therapy
  2. Tumor(s) are not eligible of surgical resection

II. Radioembolization

PacificSource considers Radioembolization with TheraSpheres or SIR-Spheres medically necessary for the following indications:

- **A.** Unresectable Tumors when **ONE** of the following criteria is met:
  1. Unresectable primary hepatocellular liver cancer
  2. Unresectable metastatic liver (hepatocellular) tumors from primary colorectal cancer
  3. Unresectable cholangiocarcinoma

B. Bridge to liver transplant or downstaging therapy on a case-by-case review with Medical Director approval

III. Transarterial Chemoembolization combined with Radiofrequency Ablation

PacificSource considers Transarterial Chemoembolization combined with Radiofrequency Ablation medically necessary for hepatocellular carcinoma with small to intermediate-size (3-5 cm) tumors who are not candidates for surgery.

IV. Percutaneous Ethanol Injection, Cryoablation, Radiofrequency and Microwave Ablation

PacificSource considers percutaneous ethanol injection, cryoablation, radiofrequency and microwave local ablative techniques medically necessary for liver tumors when **ONE** of the following is met:

A. Member is not currently awaiting liver transplantation, and **ONE** or more of the following criteria is met:

1. Unresectable primary liver tumors with **ALL** of the following criteria is met:

a. Tumor(s) is 5 cm or less in diameter

b. There are no more than 3 hepatic lesions throughout the liver

c. There is documentation that the tumor(s) is unresectable (e.g., due to comorbidities or an estimate of inadequate liver volume following resection)

2. Hepatic metastases from colorectal tumor(s) when **ALL** of the following criteria is met:

a. The metastatic tumor(s) is 5 cm or less in diameter

b. There are no more than 5 hepatic lesions throughout the liver

c. There is documentation that the tumor(s) is unresectable (e.g., due to comorbidities, or an estimate of inadequate liver volume following resection)

d. No extrahepatic metastatic disease is present

3. Hepatic metastases from neuroendocrine tumors when **ALL** of the following criteria are met:

a. Systemic therapy has failed to control disease symptoms

b. There is documentation that the tumor(s) is unresectable (e.g., due to comorbidities or an estimate of inadequate liver volume following resection)

B. As a bridge to liver transplantation when the intent is to prevent tumor progression or decrease tumor size to achieve or maintain a member's candidacy for liver transplant

Medicaid

PacificSource Community Solutions follows Oregon Administrative Rules (OARs) 410-141-3820 through 3830 and the Oregon Health Plan (OHP) Prioritized List of Health Services, including Guideline Note 12 and Statement of Intent 1 for coverage of treatments for liver tumors.

For treatment coverage of hepatic metastases (C78.7), PacificSource Community Solutions follows Guideline Note 78 of the OHP Prioritized List of Health Services in addition to the criteria above.

For treatment with Yttrium-90 radioembolization, PacificSource Community Solutions follows the coverage criteria in Guideline Note 185 of the OHP Prioritized List of Health Services. Pre-treatment embolization is not covered due to insufficient evidence of effectiveness.

PacificSource Community Solutions considers HCPCS code 47383 to have no evidence of effectiveness for both hepatocellular carcinoma and metastatic disease per Guideline Note 173 of the OHP Prioritized List of Health Services.

PacificSource Community Solutions (PCS) additionally follows OARs 410-151-0000 through 0003 for coverage of members under the age of 21.

Medicare

PacificSource Medicare follows National Coverage Determination 20.28 for Therapeutic Embolization

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

Experimental, Investigational, or Unproven

PacificSource considers Transcatheter Arterial Chemoembolization (TACE) to be experimental, investigational, or unproven to treat liver metastases for any other tumor types not noted above.

PacificSource considers percutaneous ethanol injection, cryoablation, radiofrequency and microwave ablation to experimental, investigational, or unproven as treatment for all other benign or malignant liver tumors that do not meet the medical necessity criteria above.

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

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	Arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysm)
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
47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
47379	Unlisted laparoscopic procedure, liver

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

47383 Ablation, 1 or more liver tumor(s), percutaneous, cryoablation

47399 Unlisted procedure, liver

75894 Transcatheter therapy, embolization, any method, radiological supervision, and interpretation

79445 Radiopharmaceutical therapy, by intra-arterial particulate administration

81517 Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years

C2616 Brachytherapy source, Yttrium-90, per source

S2095 Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using Yttrium-90 microspheres

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Appendix

Policy Number:

Effective: 8/1/2020 **Next review:** 8/1/2025

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): (OARs) 410-141- 3820 through 3830, Statement of Intent 1, Guideline Notes 12, 78, 173 and 185 of the OHP Prioritized List of Health Services; NCD 20.28; Article A52950

Commercial Ops: 2/2025

Government Ops: 1/2025