



Liver Diagnostic Tests and Tumor Treatment

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon
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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 results from chronic liver injury and characterized by progressive accumulation of fibrotic tissue. It is commonly associated with both alcohol-related and nonalcoholic liver disease and is significant risk factor for the development of hepatic tumors.

Hepatic tumors may be primary (e.g., hepatocellular carcinoma) or metastatic from other sites. Management depends on disease extent. Surgical resection, liver transplantation, and ablative therapies may be appropriate for limited disease, while locoregional therapies are used for unresectable tumors, palliative management, or as a bridge to transplantation to maintain transplant eligibility.

Enhanced Liver Fibrosis (ELF) Test

The Enhanced Liver Fibrosis Test is a blood-based assay that measures three (3) biomarkers (hyaluronic acid, procollagen III amino terminal peptide, and tissue inhibitor of metalloproteinase 1) to assess fibrosis severity and risk of progression.

Locoregional Treatment Options Include:

- **Chemoembolization/Embolization**

Transcatheter Arterial Chemoembolization (TACE)/Transcatheter Arterial Embolization (TAE) delivers chemotherapy and/or embolic agents to occlude tumor blood supply.

- **Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT)**

Transarterial radioembolization delivers radioactive microspheres via the hepatic artery to provide targeted radiation.

- **Percutaneous Ethanol Injection**

Percutaneous ethanol injection (PEI) injects ethanol directly into tumors to induce necrosis.

- **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.

- **Thermal Ablation (Radiofrequency and Microwave)**

Radiofrequency ablation (RFA) and Microwave ablation (MWA) uses heat to destroy tumor tissue under imaging guidance.

- **Cryoablation**

Cryoablation uses freezing to destroy tumor cells.

Criteria

Commercial

Prior authorization is required.

I. Enhanced Liver Fibrosis (ELF) Test

A. 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.

1. Performance of the Enhanced Liver Fibrosis test is not more than twice per year
2. 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)

A. PacificSource considers Transcatheter Arterial Chemoembolization or Transcatheter Arterial Embolization for hepatic malignancy medically necessary for **ONE** of the following indications:

1. Palliative treatment for hepatic malignancy when other treatments have failed to control liver tumor related symptoms

OR

2. Hepatocellular carcinoma (HCC) for **EITHER** of the following:

- a. Primary treatment of surgically unresectable disease
- b. As a bridge to liver transplantation

AND

- c. when **ALL** of the following criteria is met:

- Preserved liver function defined as Childs-Turcotte-Pugh Class A or B
 - Three (3) or fewer encapsulated nodules and each nodule is less than or equal to 5 centimeters in diameter
 - No evidence of extra-hepatic metastases
 - No evidence of severe renal function impairment
 - No evidence of portal vein occlusion
3. Neuroendocrine Cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver when **ALL** of the following criteria is met:
- a. Liver tumor related symptoms persist despite systemic therapy
 - b. Tumor(s) are not unresectable

III. Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT)

A. PacificSource considers Transarterial Radioembolization (TARE) medically necessary for **EITHER** of the following indications:

1. Unresectable Hepatic Tumors when **ONE** of the following criteria is met:
 - a. Unresectable primary-hepatocellular liver cancer
 - b. Unresectable liver metastases from primary colorectal cancer
 - c. Unresectable cholangiocarcinoma
 - d. Liver metastases from neuroendocrine tumors in individuals who are not surgical candidates when systemic therapy has failed to control symptoms
2. Bridge to liver transplant or downstaging therapy on when used to maintain or achieve transplant eligibility based on review with Medical Director approval

IV. Transarterial Chemoembolization combined with Radiofrequency Ablation

A. 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

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

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

1. Member is not currently awaiting liver transplantation, and **ONE** or more of the following criteria is met:
 - a. Unresectable primary liver tumors with **ALL** of the following criteria is met:
 - Tumor(s) is 5 cm or less in diameter
 - There are no more than 3 hepatic lesions throughout the liver
 - There is documentation that the tumor(s) is unresectable (e.g., due to comorbidities or an estimate of inadequate liver volume following resection)

2. Unresectable 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. Unresectable 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 (PCS) follows the general coverage, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200. Relevant coverage guidance, including but not limited to Guideline Notes 12, 78, and 185 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services; as well as any applicable Oregon Administrative Rules (OARs) may be used to determine coverage of Liver diagnostic testing and tumor treatment.

PCS follows the "Unlisted and Unspecified Procedure Codes" policy for requests for unlisted codes.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) coverage requirements in OAR 410-151-0000 through 410-151-0003 for EPSDT beneficiaries. Relevant coverage guidance, including but not limited to Guideline Notes 12, 78, and 185, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) policy for details.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow commercial criteria within a specific PacificSource policy, as applicable, or external criteria for determination of coverage and medical necessity coverage.

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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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

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Related Policies

Clinical Criteria Used in UM Decisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Unlisted and Unspecified Procedure Codes

Appendix

Policy Number:

Effective: 8/1/2020

Next review: 8/1/2027

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): (OARs) 410-120-1200, 410-141-3820, 410-141-3825, 410-151-0000 through 0003. ; 42 CFR § 422.101(b-c)

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