

Chemoembolization and Radioembolization of Liver Tumors

State(s): ⊠ Idaho	LOB(s): ⊠ Commercial ⊠ Medicare ⊠ Medicaid

Enterprise Policy

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 determination 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

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 (RE) also called Selective Internal Radiation Therapy (SIRT) is a form of radiation therapy done in an outpatient setting by interventional radiologists to treat liver cancer. Radioactive particles (microspheres) are delivered through the bloodstream to the liver tumor via the hepatic artery. Glass microspheres tagged with radioactive Yttrium-90 (Y-90) are known as TheraSpheres (MDS Nordion); resin microspheres tagged with Y-90 are known as SIR-Spheres (Sirtex Medical). Radiation in the microspheres decreases gradually over a two week period. Response to treatment is assessed at 30 days and re-treatment may be required.

Criteria

Commercial

Prior authorization is required.

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

- **A.** PacificSource considers (TACE) or (TAE) for Primary Hepatic Malignancy or Metastatic Tumors to the Liver medically necessary for the following indication:
 - 1. Palliative treatment for any primary or metastatic hepatic tumors when other treatments have failed to control liver related symptoms.
- **B.** PacificSource considers (TACE) or (TAE) for Hepatocellular Carcinoma or Bridge to Liver Transplantation medically necessary as a primary treatment for either surgically unresectable primary hepatocellular carcinoma or as a bridge to liver transplantation. **ALL** of the following criteria must be met for either indication:
 - 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; and
 - 5. No evidence of portal vein occlusion.
- C. PacificSource considers (TACE) or (TAE) for Neuroendocrine Cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver medically necessary for ALL of the following indications:
 - 1. Symptoms persist despite systemic therapy; and
 - 2. Tumor(s) are not eligable of surgical resection.

II. Radioembolization

- A. PacificSource considers Radioembolization with TheraSpheres or SIR-Spheres for Unresectable Tumors medically necessary when the clinical documentation supports ONE or more of the following conditions:
 - 1. Unresectable primary hepatocellular liver cancer;
 - 2. Unresectable metastatic liver (hepatocellular) tumors from primary colorectal cancer;
 - 3. Unresectable Intrahepatic cholangiocarcinoma.
- **B.** PacificSource requires Medical Director review when Radioembolization with TheraSpheres or SIR-Spheres for bridge to transplant or downstaging therapy is requested. The procedure will be covered on a case-by-case review.
- III. Transarterial Chemoembolization (TACE) combined with Radiofrequency Ablation (RFA)

PacificSource considers Transarterial Chemoembolization (TACE) combined with Radiofrequency Ablation (RFA) as a medically necessary treatment for hepatocellular carcinoma (HCC) in members with small to intermediate-size 3-5cm tumors who are not candidates for surgery.

Medicaid

PacificSource Community Solutions follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-141-3825 to 3830 and Statement of Intent 1 and Guideline Notes 12, 78, & 185 of the OHP Prioritized List of Health Services for coverage of Chemoembolization and Radioembolization of Liver Tumors.

Medicare

PacificSource Medicare follows National Coverage Determination 20.28 for Therapeutic Embolization and Local Coverage Article A52950: Billing and Coding: Treatment with Yttrium-90 microspheres.

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

Experimental, Investigational or Unproven

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

PacificSource considers Radioembolization to be experimental, investigational or unproven to treat liver metastases from any other primary tumors or unresectable cholangiocarcinoma.

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.

- Arterial, other than hemorrhage or tumor (eg, 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
- 75894 Transcatheter therapy, embolization, any method, radiological supervision and interpretation
- 79445 Radiopharmaceutical therapy, by intra-arterial particulate administration
- C2616 Brachytherapy source, Yttrium-90, per source
- S2095 Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using Yttrium-90 microspheres

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

References

Al-Adra DP, et al. Treatment of unresectable intrahepatic cholangiocarcinoma with yttrium-90 radioembolization: A systematic review and pooled analysis. European Journal of Surgical Oncology. 2015; 41:120-7. Accessed August 18, 2017, August 21, 2018, August 30, 2019, June 1, 2020 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4316196/

Hayes Medical Technology Directory. Radioactive Yttrium-90 Microspheres for Treatment of Secondary Liver Cancer. Winifred S. Hayes Inc., March 31, 2015. Archived April 29, 2020

Hayes Medical Technology Directory. Radioactive Yttrium-90 Microspheres for Treatment of Primary Unresectable Liver Cancer as a Bridge to Transplantation or Surgery. Winifred S. Hayes Inc., October 22, 2014. Annual review Sep 11, 2019

Ibrahim S, et al. Treatment of unresectable cholangiocarcinoma using yttrium-90 microspheres. Cancer. 2008; 113:119-28. Accessed August 18, 2017, August 21, 2018, September 4, 2019, June 1, 2020. http://onlinelibrary.wiley.com/doi/10.1002/cncr.23818/pdf

Mouli S, et al. Yttrium-90 radioembolization for intrahepatic cholangiocarcinoma: safety, response, and survival analysis. J Vasc Interv Radiol. 2013; 24:1227-34. Accessed August 18, 2017, August 21, 2018, September 4, 2019, June 1, 2020. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3800023/

National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers. NCCN Clinical Practice Guidelines in Oncology v.4.2020. Fort Washington, PA; Available at: http://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf

Rafi S, et al. Yttrium-90 radioembolization for unresectable standard-chemorefractory intrahepatic cholangiocarcinoma: survival, efficacy, and safety study. Cardiovasc Intervent Radiol. 2013 Apr; 36(2):440-8. Accessed August 18, 2017, August 21, 2018, September 4, 2019, June 1, 2020 http://www.ncbi.nlm.nih.gov/pubmed/22956045

Salem, R. et al. Radioembolization for Hepatocellular Carcinoma Using Yttrium-90 Microspheres: A Comprehensive Report of Long-Term Outcomes. Gastroenterology 2010; 138-52-64. Accessed August 18, 2017, August 21, 2018, September 4, 2019, June 1, 2020 http://www.gastrojournal.org/article/S0016-5085(09)01574-1/pdf

Saxena A, et al. Yttrium-90 radiotherapy for unresectable intrahepatic cholangiocarcinoma: a preliminary assessment of this novel treatment option. Ann Surg Oncology. 2010; 17:484-91. Accessed August 18, 2017, August 21, 2018, September 4, 2019, June 1, 2020 http://www.ncbi.nlm.nih.gov/pubmed/19876691

Appendix

Policy Number:

Effective: 8/1/2020 Next review: 7/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s):

Commercial Ops: 10/2021

Government Ops: 10/2021