



Chemoembolization and Radioembolization of Liver Tumors

State(s):

Idaho Montana Oregon Washington Other:

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

Preauthorization is required

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

a. Primary Hepatic Malignancy or Metastatic Tumors to the Liver

(TACE) or (TAE) is considered medically necessary for the following indication:

- Palliative treatment for any primary or metastatic hepatic tumors when other treatments have failed to control liver related symptoms

b. Hepatocellular Carcinoma or Bridge to Liver Transplantation

(TACE) or (TAE) is considered 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; **and**
2. Three (3) or fewer encapsulated nodules and each nodule is less than or equal to 5 centimeters in diameter; **and**
3. No evidence of extra-hepatic metastases; **and**
4. No evidence of severe renal function impairment; **and**
5. No evidence of portal vein occlusion.

II. Radioembolization

a. **Unresectable Tumors** Radioembolization with TheraSpheres or SIR-Spheres may be approved by the nurse reviewer when the clinical documentation supports ANY of the following conditions:

- Unresectable primary hepatocellular liver cancer.
- Unresectable metastatic liver (hepatocellular) tumors from primary colorectal cancer.
- Unresectable **Intrahepatic** cholangiocarcinoma.

b. **Bridge to Transplant:** Radioembolization with TheraSpheres or SIR-Spheres for bridge to transplant or downstaging therapy require Medical Director review and will be covered on a case-by-case review.

c. **Other:** Radioembolization is considered experimental, investigational or unproven to treat liver metastases from any other primary tumors or unresectable cholangiocarcinoma.

III. Transarterial Chemoembolization (TACE) combined with Radiofrequency Ablation (RFA)

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

Experimental, Investigational or Unproven

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

Medicaid

PacificSource Community Solutions follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-141-3830 to 3825 and Guideline Notes 12 & 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.

Coding Information

37242 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

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

Hoffman R, et al. Transarterial hepatic yttrium-90 radioembolization in patients with unresectable intrahepatic cholangiocarcinoma: factors associated with prolonged survival. *Cardiovasc Intervent Radiol*. 2012; 35:105-16. Accessed August 18, 2017, August 21, 2018, September 5, 2019, June 1, 2020 <http://www.ncbi.nlm.nih.gov/pubmed/21431970>

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](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: [Policy Number]

Effective: 8/1/2020

Next review: 8/1/2021

Policy type: Commercial

Author(s):

Depts: Health Services

Applicable regulation(s): [Applicable Regulation(s)]

[External Entities Affected]