Medical Coverage Policy

Radioembolization for Primary and Metastatic Tumors of the Liver-PREAUTH

☐ Device/Equipment ☐ Drug ☐ Medical ☒ Surgery ☐ Test ☐ Other

Effective Date:	10/6/2009	Policy Last Updated:	12/20/2011

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description:
Radioembolization (RE), referred to as selective internal radiation therapy or "SIRT" in older literature has been developed for the treatment of unresectable primary and secondary liver cancer. The technique involves the infusion of radioactive microspheres (e.g., 131-labeled-lipiodol or yttrium-90 [Y90]-either glass or resin microspheres) that are delivered selectively to the tumor through the hepatic artery. The microspheres become preferentially lodged in the arteriolar vasculature surrounding metastatic tumor deposits, delivering high doses of radiation to the area. Maximum tissue penetration for the pure beta-emitter Y90 is 1.1 cm, so most normal liver parenchyma is spared.

Currently there are two commercial forms of 90Y microspheres. SIR-Spheres®, a product consisting of 90Y-labeled biocompatible resin microspheres (20 to 40 micrometers in diameter), is available in North America and approved in the United States (concurrent with HIA injection of FUDR) for the treatment of unresectable liver metastases from primary CRC. Approval was based upon results from a single controlled trial, in which 74 patients with liver-isolated CRC metastases were randomly assigned to HIA chemotherapy with FUDR alone or in conjunction with a single intrahepatic artery administration of SIR-Spheres [106]. Combined therapy was associated with a significantly better objective complete response rate (44 versus 18 percent), and median time to progression (16 versus 10 months), and similar grade 3 and 4 toxicity. Although the one, two, three, and five-year survival rates for patients receiving SIR-Spheres (72, 39, 17, and 4 percent, respectively) did not differ significantly from those of patients in the control arm (68, 29, 7, and 0 percent, respectively), Cox regression analysis suggested a survival benefit for patients who lived longer than 15 months.

Currently, two commercial forms of yttrium-90 microspheres are available: a glass sphere, TheraSphere® and a resin sphere, SIR-Spheres®. While the commercial products use the same radioisotope (yttrium-90) and have the same target dose (100 Gy), they differ in microsphere size profile, base material (i.e., resin vs. glass), and size of commercially available doses. These physical characteristics of the active and inactive ingredients affect the flow of microspheres during injection, their retention at the tumor site, spread outside the therapeutic target region, and dosimetry calculations. Note also that the U.S. Food and Drug Administration (FDA) granted premarket approval of SIR-Spheres® for use in combination with 5-floxuridine (5-FUDR) chemotherapy by hepatic arterial infusion (HAI) to treat unresectable hepatic metastases

from colorectal cancer. In contrast, TheraSphere® was approved by humanitarian device exemption (HDE) for use as monotherapy to treat unresectable hepatocellular carcinoma (HCC). In January 2007, this HDE was expanded to include patients with hepatocellular carcinoma who have partial or branch portal vein thrombosis. For these reasons, results obtained with one product do not necessarily apply to other commercial (or noncommercial) products.

There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of 90Y microsphere radioembolization for liver metastases from any site other than colorectal or neuroendocrine including but not limited to breast cancer, cholangiocarcinoma, and pancreatic cancer.

Medical Criteria:
Radioembolization may be considered **medically necessary** for the following:

- to treat primary hepatocellular carcinoma that is unresectable and limited to the liver.
- in primary hepatocellular carcinoma as a bridge to liver transplantation.
- to treat hepatic metastases from neuroendocrine tumors (carcinoid and noncarcinoid) with diffuse and symptomatic disease when systemic therapy has failed to control symptoms.
- to treat unresectable hepatic metastases from colorectal carcinoma that are both progressive and diffuse, in patients with liver-dominant disease who are refractory to chemotherapy or are not candidates for chemotherapy.

Radioembolization is considered not medically necessary for all other hepatic metastases except for metastatic neuroendocrine tumors and metastases from colorectal cancer as noted above because there is lack of data with which to draw meaningful conclusions.

Policy:
Radioembolization may be considered medically necessary when the criteria above are met.

Radioembolization is not medically necessary for all other hepatic metastases except for metastatic neuroendocrine tumors or metastases from colorectal cancer.

Preauthorization is required for Blue CHiP for Medicare and recommended for all other BCBSRI products.

Coverage:
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber agreement or Benefit Booklet for the applicable radiology benefits.

Coding:
The coding for radioembolization may depend on the medical specialty that is actually providing the therapy. The following CPT codes might possibly be used:

Since this therapy involves radiation therapy, a variety of radiation therapy planning codes may be a component of the overall procedure. For example, CPT code 77399 (unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services) may be used.

There are no specific CPT codes describing radioembolization therapy. The following nonspecific CPT codes might possibly be used for radioembolization therapy for liver tumors:

37204
75894
79445
77778

The following code is **not separately reimbursed**:
C2616 Brachytherapy source, yttrium-90, per source.

The following code is **not covered** and an appropriate CPT code should be used:
S2095 Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

Also Known As:
Radioembolization
Selective Internal Radiation Therapy
SIRT
Microspheres
SIR-Spheres®
TheraSphere®

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References:

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