

## Medical Coverage Policy | Radioembolization for Primary and Metastatic Tumors of the Liver



**EFFECTIVE DATE:** 10|06|2009

**POLICY LAST UPDATED:** 11|19|2013

### OVERVIEW

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.

### PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products.

### POLICY STATEMENT

#### BlueCHiP for Medicare and Commercial:

Radioembolization is considered medically necessary when the below criteria has been met.

### MEDICAL CRITERIA

Radioembolization may be considered **medically necessary** as a treatment for the following:

- Primary hepatocellular carcinoma that is unresectable and limited to the liver.
- In primary hepatocellular carcinoma as a bridge to liver transplantation.
- Hepatic metastases from neuroendocrine tumors (carcinoid and noncarcinoid) with diffuse and symptomatic disease when systemic therapy has failed to control symptoms.
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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.

### BACKGROUND

Hepatic tumors can arise either as primary liver cancer or by metastasis to the liver from other organs. Local therapy by surgical resection with tumor-free margins or liver transplantation is the only potentially curative treatment. Unfortunately, most hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, concurrent nonmalignant liver disease, or insufficient hepatic reserve.

Radioembolization involves the infusion of radioactive microspheres (e.g., <sup>131</sup>I-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, 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-fluorouridine (5-FU) 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.

**Hepatocellular carcinoma (HCC):** Studies have demonstrated that radioembolization is comparable to TACE (which is considered to be therapy of choice) for patients with unresectable HCC in terms of tumor response and OS. Disadvantages of TACE include the necessity of multiple treatment sessions and hospitalization, its contraindication in patients with portal vein thrombosis, and its poorer tolerance by patients.

**Intrahepatic cholangiocarcinoma (ICC):** To date, studies on use of radioembolization in patients with intrahepatic cholangiocarcinoma consist of small case series. No studies have been published comparing radioembolization to other treatments such as chemotherapy or chemoradiation. Available studies varied with respect to patient characteristics, particularly presence of extrahepatic disease, previous therapy and performance status.

**Metastatic colorectal cancer:** A major cause of morbidity and mortality in patients with colorectal disease metastatic to the liver is liver failure, as this disease tends to progress to diffuse, liver-dominant involvement. Therefore, the use of radioembolization to decrease tumor bulk and/or halt the time to tumor progression and liver failure, may lead to prolonged progression free and overall survival in patients with no other treatment options (i.e., those with chemotherapy refractory liver-dominant disease). Other uses include palliation of symptoms from tumor bulk. Two Phase III trials are currently underway that compare first-line chemotherapy with and without radioembolization in patients with metastatic colorectal cancer.

**Metastatic neuroendocrine tumors:** Studies have included heterogeneous patient populations, and interpretation of survival data using radioembolization is difficult. Few studies report relief of symptoms from carcinoid syndrome in a proportion of patients. Surgical debulking of liver metastases has shown palliation of hormonal symptoms; debulking by radioembolization may lead to symptom relief in some patients.

**Miscellaneous:** A few studies on the use of radioembolization in metastatic breast cancer and melanoma to the liver have shown promising initial results; however, the data are limited and the studies have been small and composed of heterogeneous patients. The use of radioembolization in other tumors metastatic to the liver is too limited to draw meaningful conclusions; this use is considered not medically necessary as there is no proven efficacy.

## **COVERAGE**

### **BlueCHiP for Medicare and Commercial:**

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

## CODING

### BlueCHIP for Medicare and Commercial

There are no specific CPT codes describing radioembolization therapy. Providers should file using the unlisted code:

**77399**

## RELATED POLICIES

None

## PUBLISHED

Provider Update	Jan 2014
Provider Update	Dec 2012
Provider Update	Mar 2011

## REFERENCES

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