Medical Affairs Policy

**Service:** Selective Internal Radiation Therapy (SIRT) for Liver Tumors (SIR Spheres, TheraSpheres, Radioembolization with Yttrium-90 microspheres, Transarterial Radioembolization, TARE)

**PUM 250-0012**

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<th>Medical Policy Committee Approval</th>
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<td>Effective Date</td>
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<td>Prior Authorization Needed</td>
<td>Yes</td>
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**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

**Description:**

Selective internal radiation therapy (SIRT), also known as transarterial radioembolization (TARE) or Yttrium brachytherapy involves the placement of radioactive tagged glass or resin spheres via an intraarterial catheter into the hepatic arteries that supply a malignant liver tumor or multiple liver tumors. Blood supply to normal liver tissue comes primarily from the portal vein. Blood flow to liver tumors is primarily from the hepatic artery. Treatment provided through the hepatic artery allows for internal radiation to be provided directly to the tumor/tumors while sparing normal liver tissue.

Survival rates for unresectable hepatic malignancies and recurrence rates for resected malignant lesions are poor despite treatment options that include chemotherapy, radiofrequency ablation, and cryotherapy. Because significant liver damage occurs with low doses of radiation, conventional external radiation therapy is rarely recommended. Selective internal radiation therapy may provide sufficient radiation to limit progression of the disease while minimizing liver damage.

Clinical Trials are ongoing for the use of SIRT in conjunction with conventional chemotherapy for liver metastasis in colorectal cancer or pancreatic cancer.

**Indications of Coverage:**

A. SIRT is considered medically necessary for the treatment of any one of the following when there is documentation of which standard therapies, such as surgical resection, systemic chemotherapy, TransArterial Chemoembolization
(TACE), cryoablation, percutaneous ethanol injection, radiofrequency ablation (RFA), have failed or why they are contraindicated or documented to be medically inferior alternatives to SIRT:

1. Unresectable hepatocellular carcinoma (HCC) lesions. (HCC does not include intrahepatic cholangiocarcinoma - see Limitations of Coverage)

2. Unresectable metastatic liver tumors from primary colorectal cancer

3. Unresectable metastatic liver tumors from primary neuroendocrine tumors which have failed systemic therapy

**Limitations of Coverage:**

A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

D. Selective internal radiation therapy is considered not medically necessary for individuals where a vascular abnormality has been identified that would not allow the catheter to be passed to the target vessel.

E. SIRT (Transarterial Hepatic Yttrium -90 Radioembolization) for Treatment of Unresectable Intrahepatic Cholangiocarcinoma is considered experimental, investigational, and unproven to affect health outcomes.

F. SIRT for downstaging primary hepatocellular carcinoma and/or as a bridge to liver transplantation or surgery is considered not medically necessary unless other standard therapies [such as systemic chemotherapy, TransArterial Chemoembolization (TACE), cryoablation, percutaneous ethanol injection,) radiofrequency ablation (RFA)] have failed or are contraindicated.

G. SIRT in conjunction with conventional chemotherapy for liver metastasis in colorectal cancer or pancreatic cancer considered experimental, investigational, and unproven to affect health outcomes.

**Documentation Required:**

- Office note
• Procedure report

References:


9. Wisconsin Physicians Service Medicare Local Coverage Determination (LCD): Selective Internal Radiation Therapy (SIRT) for Primary and Secondary Hepatic Malignancy (90Y-Microsphere Hepatic Brachytherapy). LCD L30137. Revised: 01/01/2014 Available at:


19. Gibbs P, Heinemann V, Sharma N. SIRFLOX: Randomized phase III trial comparing first-line mFOLFOX6 ± bevacizumab (bev) versus mFOLFOX6 + selective internal radiation therapy (SIRT) ± bev in patients (pts) with metastatic
colorectal cancer (mCRC). J Clin Oncol 33, 2015 (suppl; abstr 3502)
http://meetinglibrary.asco.org/content/145884-156

WPS / Arise Review History:

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➢ Note: For review/revision history prior to 2014 see previous Medical Policy or Coverage Policy Bulletin

Approved by the Medical Director