Radioembolization with Yttrium-90 Microshpheres (TheraSphere and SIR-Spheres)

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Policy

The Medical Management Department reviews referral requests for authorization of Radioembolization with Yttrium-90 Microspheres (TheraSphere and SIR-Spheres).

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

To facilitate the authorization process referral requests must include the following:

1. The diagnosis and current symptoms of the illness that supports the request for treatment with TheraSphere or Sir-Spheres.

2. Outline of an expected number of treatments which will be necessary as part of the treatment plan.

B. Criteria for Medical Necessity:

Radioembolization with Yttrium-90 microspheres (TheraSphere manufactured by MDS Nordion and SIR-Spheres manufactured by Sirtex) is considered medically necessary if **ONE** of the following indications are met:

1. Hepatocellular carcinoma that is **ONE** of the following:
    a. Unresectable and patient is not a transplant candidate **OR**
    b. Local disease only or local disease with minimal extrahepatic disease and patient is inoperable by performance status or comorbidity; **OR**
    c. Unresectable and the patient is a candidate for transplantation, to be used as a bridge to liver transplantation if other standard treatments such as systemic chemotherapy, transarterial chemoembolization, cryoablation, or radiofrequency ablation have failed or are contraindicated.

2. Intrahepatic cholangiocarcinoma that is unresectable and no concurrent chemotherapy with radiation is planned, **OR**

3. Unresectable liver metastases from colorectal carcinoma in patients with predominant hepatic metastases that are refractory/resistant to other therapies or who are not candidates for chemotherapy, **OR**

4. Neuroendocrine tumors involving the liver (i.e., carcinoid and pancreatic endocrine tumors) with hepatic-prominent (liver only or liver dominant) progressive disease or poorly controlled carcinoid syndrome who have failed systemic therapy for symptom control, e.g., octreotide.

C. Indications Considered Experimental, Investigational or not Medically Necessary (*Not an all-inclusive list*)

1. All other hepatic metastasis not FDA approved for use of radioembolization.
2. Patient has Child Pugh Class C liver disease.
3. Patient has main portal vein thrombosis (Partial or branch portal vein thrombosis is acceptable for use).
4. Patient has a serum bilirubin of >3mg/dL.
5. The presence of significant extrahepatic cancer that represents an imminent life-threatening outcome.

CPT/HCPCS CODES:

77790	Supervision, handling, loading of radiation source
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic or lower extremity artery branch, with a vascular family
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram) radiological supervision and interpretation
77778	Interstitial radiation source application, complex includes supervision, handling, loading of radiation source, when performed
79445	Radiopharmaceutical therapy, by intra-articular administration
C2616	Brachytherapy source, yttrium-90, per source
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres
Q3001	Radioelements for brachytherapy, any type, each

References

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