Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Radioembolization for hepatic tumors is COVERED for the treatment of:

a. unresectable primary hepatocellular carcinoma
b. unresectable metastatic liver tumors from primary colorectal cancer
c. unresectable metastatic liver tumors from neuroendocrine tumors
d. unresectable primary intrahepatic cholangiocarcinoma
e. unresectable primary hepatocellular carcinoma as a bridge to transplantation.

Radioembolization for hepatic tumors is investigative and unproven and therefore NOT COVERED for the treatment of all other indications. Reliable evidence does not permit conclusions concerning its effectiveness.

Note: This determination does not apply to devices that have an FDA-approved humanitarian device exemption (HDE), e.g., TheraSphere (MDS Nordion Inc.; currently manufactured by BTG International Inc.). Medica considers an FDA-approved HDE device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

Note: See related Medica coverage policies: Chemoembolization for Hepatic Tumors and Pelvic Vein Embolization.

Description

Radioembolization is a treatment for unresectable hepatic (liver) tumors that is used as an alternative means to deliver radiation. Radioembolization is also known as: transarterial radioembolization (TARE), Yttrium-90 microsphere radioembolization (SIR-Spheres or TheraSphere), selective internal radiation therapy (SIRT) or intrahepatic microsphere radiation (IMR). A physician inserts a catheter at the femoral artery into the hepatic artery and injects microscopic beads (glass or resin) that contain a radioactive element. The microscopic beads become lodged in the blood vessels surrounding the tumor thereby delivering high doses of radiation directly to the tumor(s). This is less toxic to the adjacent, healthy tissue than radiation delivered by other means. After approximately two weeks, the radiation dissipates, but the beads remain in the liver permanently. The goal of the procedure is to irradiate and destroy the tumor(s) while sparing normal liver tissue.
FDA Approval
The use of microspheres for the treatment of unresectable liver cancer is a procedure and therefore not subject to FDA regulation. However, devices, drugs, biologics or tests used as a part of this procedure may be subject to FDA regulation. Examples include, but are not limited to:

1. **SIR-Spheres (Sirtex Medical Ltd.):** FDA issued Premarket Approval (PMA) on March 5, 2002 for treatment of unresectable metastatic liver tumors from primary colorectal cancer with flouxuridine adjuvant intrahepatic artery chemotherapy.

2. **TheraSphere (MDS Nordion Inc.; currently manufactured by BTG International Inc.):** FDA issued a Humanitarian Device Exemption (HDE) on December 10, 1999, for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes
- 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
- S2095 - Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

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