Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors (for Kentucky Only)

Policy Number: CS060KY.07
Effective Date: September 1, 2023

Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Transarterial radioembolization (TARE) using yttrium-90 (^{90}Y) microspheres is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ablative or Transarterial Therapy, Liver for age ≥ 18.

Click here to view the InterQual® criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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
79445	Radiopharmaceutical therapy, by intra-arterial particulate administration

HCPCS Code	Description
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved two commercial forms of ^{90}Y microspheres; TheraSphere® and SIR-Spheres®. SIR-Spheres (Sirtex Medical) are resin ^{90}Y microspheres and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of floxuridine (FUDR). SIR-Spheres received FDA premarket approval (P990065) on March 5, 2002. Supplemental approvals have been identified for the PMA Product Code NAW. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p990065a.pdf. (Accessed May 2, 2023)

TheraSphere (BTG) are glass ^{90}Y microspheres and are indicated for radiation treatment or as a neoadjuvant to surgery or transplantation for individuals with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters. Glass ^{90}Y microspheres are approved by the FDA under the provisions of a Humanitarian Device Exemption (H980006). Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/H980006b.pdf. (Accessed May 2, 2023)

The use of TheraSphere and SIR-Spheres is also regulated by the United States Nuclear Regulatory Commission (U.S. NRC), which grants a license for the use of these products. Refer to the following guidance for further information: https://www.nrc.gov/docs/ML1535/ML15350A099.pdf. (Accessed May 2, 2023)

On March 17, 2021, the FDA approved TheraSphere (Boston Scientific Corporation) pre-market approval (PMA) for use as SIRT for local tumor control of solitary tumors (1-8 cm in diameter) for individuals with unresectable hepatocellular carcinoma, Child-Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status (PMA Number: P200029). In addition, 2 additional approvals were recognized (PMA Numbers: P200029 S001, P200029 S002). Additional information is available at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200029. (Accessed May 2, 2023)
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200029S001. (Accessed May 2, 2023)
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200029S002. (Accessed May 2, 2023)

Policy History/Revision Information

Date	Summary of Changes
09/01/2023	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures, Uterine Artery Embolization (UAE) for age ≥ 18 **Supporting Information** • Updated *FDA* section to reflect the most current information • Archived previous policy version CS060KY.06

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.