Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT) for the Treatment of Malignant Cancers of the Liver (for Kentucky Only)

Policy Number: CS060KY.10
Effective Date: May 1, 2026

Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Note: This policy applies to individuals 19 years of age and older. Transarterial radioembolization/selective internal radiation therapy is covered without further review for individuals younger than 19 years of age.

Transarterial radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 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.

Click here to view the InterQual® criteria.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

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 federal, state, or contractual requirements 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
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
79445	Radiopharmaceutical therapy, by intra-arterial particulate administration

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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 April 17, 2025)

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 April 17, 2025)

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 April 17, 2025)

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. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200029. (Accessed April 17, 2025)

Policy History/Revision Information

Date	Summary of Changes
05/01/2026	**Coverage Rationale** • Added language to indicate this policy applies to individuals 19 years of age and older; transarterial radioembolization/selective internal radiation therapy is covered without further review for individuals younger than 19 years of age ***Members 18 Years of Age and Older*** • Replaced instruction to "refer to the InterQual® CP: Procedures, Ablative or Transarterial Therapy, Liver *for age ≥ 18* for medical necessity clinical coverage criteria" with "refer to the InterQual® CP: Procedures, Ablative or Transarterial Therapy, Liver for medical necessity clinical coverage criteria" ***Members Under 18 Years of Age*** • Removed language indicating:

Date	Summary of Changes
	○ Transarterial Radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 microspheres is proven and medically necessary for the following indications in individuals with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2: ▪ Primary hepatocellular carcinoma (HCC) that is unresectable and limited to the liver ▪ Primary hepatocellular carcinoma as a bridge to liver transplantation ▪ Unresectable liver metastases from neuroendocrine tumors when systemic therapy has failed to control symptoms ▪ Unresectable liver metastases from colorectal carcinoma in individuals with limited extra-hepatic disease who are refractory to or relapsed following systemic chemotherapy ▪ Unresectable intrahepatic cholangiocarcinoma ○ Transarterial radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 microspheres is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy **Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request **Definitions** • Removed definition of: ○ Eastern Cooperative Oncology Group (ECOG) Scale of Performance Status ○ Limited Extra-Hepatic Disease ○ Refractory ○ Transarterial Radioembolization (TARE) **Supporting Information** • Removed *Clinical Evidence* and *References* sections • Archived previous policy version CS060KY.09

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, 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.