



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

Policy Number: CS060OH.B Effective Date: October 1, 2024

Instructions for Use

Page
1
1
1
2
2
2

Related Policies	
None	

## **Application**

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

## **Coverage Rationale**

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<sup>®</sup> CP: Procedures, Ablative or Transarterial Therapy, Liver for age ≥ 18.

Click here to view the InterQual® criteria.

Transarterial radioembolization (TARE) using yttrium-90 (90Y) microspheres is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.

## **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 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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Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT) for the Treatment of Malignant Cancers of the Liver (for Ohio Only)
UnitedHealthcare Community Plan Medical Policy

Page 1 of 3

Effective 10/01/2024

HCPCS Code	Description
S2095	Trans catheter 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 <sup>90</sup>Y microspheres: TheraSphere® and SIR-Spheres®. SIR-Spheres (Sirtex Medical) are resin <sup>90</sup>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 January 29, 2024)

TheraSphere (BTG) are glass <sup>90</sup>Y microspheres and are indicated for radiation treatment or as a neoadjuvant to surgery or transplantation in for individuals with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters. Glass <sup>90</sup>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 January 29, 2024)

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 January 29, 2024)

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 January 29, 2024)

#### References

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01. Accessed April 30, 2024.

# **Policy History/Revision Information**

Date	Summary of Changes
10/01/2024	Title Change
	Previously titled Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors (for Ohio Only)
	Related Policies
	<ul> <li>Removed reference link to the Medical Policy titled Abnormal Uterine Bleeding and Uterine Fibroids (for Ohio Only)</li> </ul>
	Coverage Rationale
	<ul> <li>Added language to indicate selective internal radiation therapy (SIRT) using yttrium-90 microspheres is proven and medically necessary in certain circumstances</li> </ul>
	Applicable Codes
	Added CPT code 75894
	Supporting Information
	Added References section
	Updated FDA section to reflect the most current information
	Archived previous policy version CS060OH.A

#### **Instructions for Use**

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state [Ohio Administrative Code (OAC)] or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) 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 Ohio 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.