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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE:

Hepatic cellular carcinoma (HCC) is the fifth most common cancer and the second leading cause of cancer deaths. HCC currently represents 90% of primary liver cancers. Few patients (20%-30%) are diagnosed in early stages when many treatment options are most effective. Over 70% of HCC patients are diagnosed with unresectable disease. Current treatment options include transarterial chemoembolization (TACE) and systemic therapy with sorafenib for first-line treatment.

Selective Internal Radiation Therapy (SIRT) with Yttrium-90 (Y-90), also referred to as transarterial radioembolization (TARE) or Yttrium-90 (Y-90) radioembolization, is a locoregional therapy involving intra-arterial delivery of radioactive microspheres to hepatic tumors. Examples of FDA-approved Y-90 microsphere products include SIR-Spheres® resin microspheres and TheraSphere™ glass microspheres.

SIRT is considered a locoregional treatment option for unresectable hepatocellular carcinoma and may be used as an alternative to or in place of other locoregional therapies (e.g., transarterial chemoembolization) in appropriately selected patients. SIRT may also be used for tumor downstaging and/or bridging to surgical resection or liver transplantation in appropriately selected patients. Although two phase III trials failed to show superiority of SIRT over sorafenib, SIRT remains used in selected patients based on tumor burden, liver function, performance status, treatment goals, and multidisciplinary assessment.

The intent of this policy is to provide coverage guidelines for SIRT.

This policy applies to FDA-approved Yttrium-90 microsphere products, including but not limited to glass microspheres (e.g., TheraSphere™) and resin microspheres (e.g., SIR-Spheres®). Coverage criteria may differ based on product-specific FDA labeling, contraindications, and clinical evidence.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

COVERAGE INDICATIONS:

General coverage indications

- All healthcare services must be ordered by a provider
- All healthcare services must be medically necessary
- All applicable conservative treatments must have been tried
- Patients must have adequate functional status (e.g., ECOG performance status 0–1 unless otherwise justified).
- Cases should be evaluated by a multidisciplinary team with expertise in hepatic malignancies and locoregional therapies when feasible.

SIRT procedures are considered medically necessary when either I-VI applies:

- I. Primary hepatocellular carcinoma (HCC) that is unresectable; SIRT may be used as a locoregional treatment option and as an alternative to or in place of other locoregional therapies (e.g., transarterial chemoembolization) in appropriately selected patients; or
- II. Unresectable liver metastases from primary colorectal cancer. Treatment planning should incorporate individualized dosimetry to optimize tumor absorbed dose and clinical response when feasible; or
- III. Primary hepatocellular carcinoma (HCC) as a bridge to surgical resection or liver transplantation in appropriately selected patients; or
- IV. Hepatocellular carcinoma (HCC) tumor downstaging for potential surgical resection or liver transplantation in appropriately selected patients; or
- V. For treatment of liver-dominant neuroendocrine metastases, including tumor control and symptom palliation, involving the liver – must satisfy any of the following: A – B
 - a. Carcinoid tumors – after failure of systemic therapy with somatostatin analogues (SSAs) octreotide or lanreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea); or
 - b. Pancreatic endocrine tumors with liver-prominent disease.
- VI. Unresectable, liver-confined intrahepatic cholangiocarcinoma where locoregional disease control is the treatment objective.

Pre-treatment evaluation must include hepatic arterial mapping, evaluation for extrahepatic shunting, lung shunt fraction assessment, and measures to prevent non-target embolization. These steps are required prior to SIRT administration.

Exclusions

There is inadequate safety and/or efficacy data in the following populations:

- Pregnancy

- Breast feeding women
- In whom shunting of blood to lungs could result in high doses to lungs
- In whom hepatic artery catheterization is contraindicated
- In those who have pulmonary insufficiency (arterial O₂ < 60 mm HG or O₂ saturation <90%)
- Impaired liver function (Child-Pugh score B or C)
- Portal vein thrombosis (PVT): For resin microspheres (e.g., SIR-Spheres®), PVT is considered a contraindication consistent with FDA labeling. For glass microspheres (e.g., TheraSphere™), treatment may be considered in selected patients without advanced (e.g., Type 4) PVT and with demonstrable radiotracer uptake on pre-treatment mapping. Coverage is contingent upon product-specific criteria.
- >70% tumor replacement in liver
- Poor candidate for locoregional radiation treatment

Medical Records Documentation

Benefit coverage is determined by review of member specific benefit plan information and all applicable laws. Medical records documentation may be required to assess if the member meets criteria; however, provision of records does not guarantee coverage.

DEFINITIONS

Downstaging: Decreasing the size, extent of metastases, and/or lymph node involvement of a tumor by means of therapy

Selective Internal Radiation Therapy (SIRT): Selective Internal Radiation Therapy (SIRT), also referred to as transarterial radioembolization (TARE) or Yttrium-90 (Y-90) radioembolization, is a locoregional therapy involving intra-arterial delivery of radioactive microspheres to hepatic tumors. For the purposes of this policy, the terms SIRT, TARE, radioembolization, and Y-90 microsphere therapy are used interchangeably.

APPLICABLE CODES

Note: The code list below is provided for guidance. Not all procedures will contain these codes. Code coverage will depend on coverage guidelines above. All intrauterine procedure coverage requests will require medical review.

FDA-approved indications for Y-90 microsphere products now include treatment of unresectable hepatocellular carcinoma for select devices.

Code Type	Code	Description
37243	CPT	Vascular embolization and occlusion procedures on arteries and veins
36247	CPT	Selective placement of a catheter into a third order of more selective artery branch
36248	CPT	Selective catheter placement within the arterial system
75726	CPT	Visceral angiography
77778	CPT	Interstitial radiation source complex
79445	CPT	Administration of radiopharmaceutical intra arterial
C2616	HCPSC	Yttrium-90 non-stranded
S2095	HCPSC	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

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POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
09/10/25	Initial Policy Development	Optum Medical and Pharmacy Subcommittee
09/09/26	Annual Policy Review: Updated title to align with appropriate terminology; added device specific criteria (glass vs resin); clarified HCC use and strengthened safety, dosimetry, and multidisciplinary requirements	Optum Medical and Pharmacy Subcommittee

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Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

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Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

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