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Clinical Policy Document: Selective Internal Microspheres	Date Approved: 09/10/25
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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), also known as radioembolization, is a procedure in which tiny radiation filled beads, called microspheres, are delivered directly to the HCC tumor. The microspheres are delivered through a catheter placed in the femoral artery and threaded through the hepatic artery to the tumor site. The microspheres contain yttrium-90. Examples of this type of treatment include SIR-Spheres, and Theraspheres, which are spheres made of glass. May also be known as transhepatic arterial radiation therapy (TARE).

Although two phase III trials failed to show superiority of SIRT over sorafenib due to its lower toxicity profile, SIRT remains recommended for early and intermediate stage HCC, which is unsuitable for other therapies and for advanced stage HCC without extrahepatic metastasis. SIRT has been gaining acceptance for treatment with metastasis.

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

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

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

- I. Primary hepatocellular carcinoma (HCC) that is unresectable; or
- II. Unresectable liver metastases from primary colorectal cancer; or
- III. Primary hepatocellular carcinoma (HCC) as a bridge to liver transplantation (i.e., meets transplantation guidelines but awaiting donor); or
- IV. Hepatocellular carcinoma (HCC) downstaging (i.e., does not meet transplantation quidelines); or
- V. For treatment of neuroendocrine cancers 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 intrahepatic cholangiocarcinoma.

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
- >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

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

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.

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	HCPCS	Yttrium-90 non-stranded
S2095	HCPCS	Transcatheter occlusion or embolization for tumor destruction,
		percutaneous, any method, using yttrium-90 microspheres

^{*}CPT® is a registered trademark of the American Medical Association

POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
09/10/25	Initial Policy Development	Optum Medical and Pharmacy Subcommittee

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Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Nondiscrimination Grievance Coordinator

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.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه : إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً اتصل بن اعلى رقم الهاتف6501-332-800-1(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द _: य _द आप िहंदी बोलते ह _तो आपके िलए मृ _त म _ भाषा सहायता सेवाएं उपल _ध ह _ । 1-800-332-6501 (TTY: 711) पर कॉल कर _ ।

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 numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп:

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).