

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Radiation Therapy, Selective Internal Microspheres (SIRT)	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/L025	Page: 1 of 5

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary

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.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria – requests for intra-hepatic radiation therapy (transarterial radioembolization [TARE]) with yttrium-90 microspheres - Must satisfy any of the following: I - VI

- I. Primary hepatocellular carcinoma (HCC) that is unresectable⁸; or
- II. Unresectable liver metastases from primary colorectal cancer¹²; or
- III. Primary hepatocellular carcinoma (HCC) as a bridge to liver transplantation (ie, meets transplantation guidelines but awaiting donor)⁸; or
- IV. Hepatocellular carcinoma (HCC) *downstaging* (ie, does not meet transplantation guidelines)⁸; 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 (eg, debilitating flushing, wheezing and diarrhea)⁹; or
 - B. Pancreatic endocrine tumors with liver-prominent disease¹¹.
- VI. Unresectable intrahepatic cholangiocarcinoma.¹⁰

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:

Downstaging:

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

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Radiation Therapy, Selective Internal Microspheres (SIRT)	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/L025	Page: 2 of 5

BACKGROUND:

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 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). See Attachment A.

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Radiation Therapy, Selective Internal Microspheres (SIRT)	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/L025	Page: 3 of 5

Prior Authorization: Yes, per network provider agreement

CODING:

CPT® or HCPCS

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

C2616 Brachytherapy source, nonstranded, yttrium-90, per source (microspheres)

CPT codes copyright 2024 American Medical Association. All Rights Reserved. CPT is a trademark of the AMA. The AMA assumes no liability for the data contained herein.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clinical Policy: FDA-Approved Humanitarian Use Devices (MP/H008)
4. MDS Nordion Inc. TheraSphere Yttrium-90 glass microspheres. Package Insert. Rev. 6. Kanata, ON: MDS Nordion; 1999. Retrieved from: https://www.accessdata.fda.gov/cdrh_docs/pdf/H980006C.pdf Accessed 06-18-24.
5. CDRH Humanitarian Device Exemptions. TheraSphere® MDS Nordion, Inc., Kanata, Ontario, Canada. H980006 10-Dec-1999 99M-5539 Retrieved from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H980006> Accessed 06-18-24.
6. Sirtex Medical Pty Ltd. SIRTEx SIR-Spheres Y-90 resin microspheres. Package Insert. Shop 6. St. Leonards, NSW, Australia. 2019. Retrieved from: <https://www.sirtex.com/media/55rpxv2/ssl-us-14-sir-spheres-microspheres-ifu-us.pdf>. Accessed 06-18-24.
7. Sirtex Medical Inc. SIR-Spheres (Yttrium-90 microspheres). Product Labeling. Rockville, MD: U.S. Food and Drug Administration, Center for Devices and Radiological Health; March 5, 2005. FDA PMA Database. SIR-Spheres. Sirtex Medical Pty Ltd. St. Leonards, New South Wales, Australia. P990065. 03-05-2002. Retrieved from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990065>. Accessed 06-18-24.
8. National Comprehensive Cancer Network (NCCN). Hepatocellular Carcinoma. NCCN Clinical Practice Guidelines in Oncology, Version 1.2024, 04-09-24. HCC-G, MS-17 - 19. Accessed 06-18-24.
9. National Comprehensive Cancer Network (NCCN). Neuroendocrine and Adrenal Tumors. NCCN Clinical Practice Guidelines in Oncology. Version 1.2023, 08/02/23. NE-I. Accessed 06-18-24.
10. National Comprehensive Cancer Network (NCCN). Biliary Tract Cancers: Intrahepatic Cholangiocarcinoma. NCCN Clinical Practice Guidelines in Oncology. Version 2.2024, 04/09/24. INTRA-1, INTRA-D, MS-13-14. Accessed 06-18-24.
11. National Comprehensive Cancer Network (NCCN). Neuroendocrine and Adrenal Tumors: Neuroendocrine Tumors of the Pancreas. NCCN Clinical Practice Guidelines in Oncology. Version 1.2023, 08/02/23. PanNET-13. Accessed 06-18-24.
12. National Comprehensive Cancer Network (NCCN). Colon Cancer. NCCN Clinical Practice Guidelines in Oncology. Version 3.2024, 05/24/24. COL-C 2 of 3, COL-E 1 of 2, MS-30 – 31. Accessed 06-18-24.

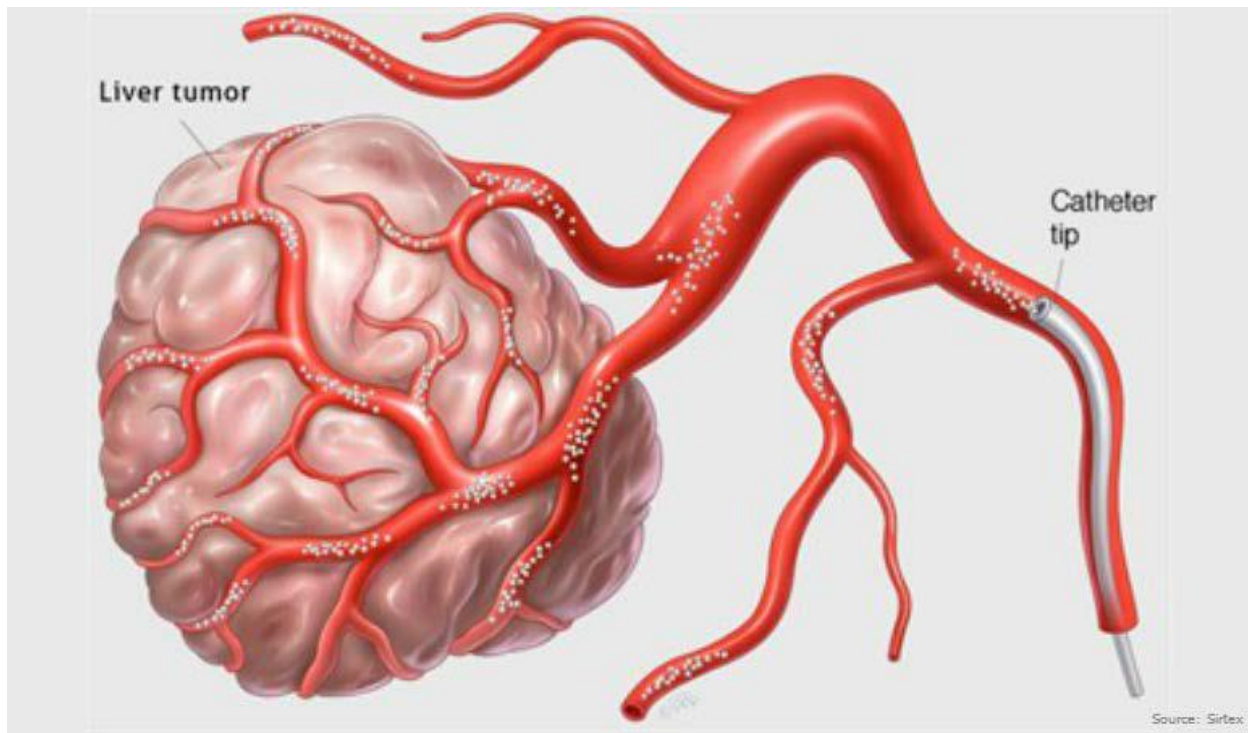
Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Radiation Therapy, Selective Internal Microspheres (SIRT)	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/L025	Page: 4 of 5

DOCUMENT HISTORY:

Created Date: 11/16/20
Reviewed Date: 07/06/21, 06/13/22, 06/12/23, 06/10/24
Revised Date: 03/12/21, 06/24/22, 01/27/23, 06/15/23

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Radiation Therapy, Selective Internal Microspheres (SIRT)	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/L025	Page: 5 of 5

Attachment A



Retrieved from Sirtex Medical Inc. SIR-Spheres (yttrium-90 microspheres).

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 أعلى رقم الهاتف 1-800-332-6501 (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 मु त म भाषा सहायता सेवाएं उपल थ 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 numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (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 Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).