

| Department of Origin: | Effective Date: |
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| Integrated Healthcare Services | 09/28/23 |
| Approved by: | Date Approved: |
| Medical Policy Quality Management Subcommittee | 09/22/23 |
| Clinical Policy Document: | Replaces Effective Clinical Policy Dated: |
| Radiation Therapy, Selective Internal Microspheres | 03/01/23 |
| (SIRT) | |
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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 [TACE]) 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) *; 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); 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



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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.



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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)

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REFERENCES:

- 1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
- 2. Clinical Policy: MP/C009 Coverage Determination Guidelines
- 3. Clinical Policy: MP/H008 FDA-Approved Humanitarian Use Devices
- 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 06-12-23.
- 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 06-12-23.
- 6. Sirtix Medical Pry Ltd. SIRTeX SIR-Spheres Y-90 resin microspheres. Package Insert. Shop 6. St. Leonards, NSW, Australia. 2019. Retrieved from: https://www.sirtex.com/media/55rprxv2/ssl-us-14-sir-spheres-microspheres-ifu-us.pdf. Accessed 06-12-23.
- 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 06-12-23.
- 8. National Comprehensive Cancer Network (NCCN). Hepatocellular Carcinoma. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023, 03/10/23. HCC-E 1 of 2, MS-17 19. Accessed 06-12-23.
- 9. National Comprehensive Cancer Network (NCCN). Neuroendocrine and Adrenal Tumors. NCCN Clinical Practice Guidelines in Oncology. Version 2.2022, 12/21/22. NE-H. Accessed 06-12-23.
- 10. National Comprehensive Cancer Network (NCCN). Biliary Tract Cancers: Intrahepatic Cholangiocarcinoma. NCCN Clinical Practice Guidelines in Oncology. Version 2.2023, 05/10/23. INTRA-1, MS-13-14. Accessed 06-12-23.
- 11. National Comprehensive Cancer Network (NCCN). Neuroendocrine and Adrenal Tumors: Neuroendocrine Tumors of the Pancreas. NCCN Clinical Practice Guidelines in Oncology. Version 2.2022, 12/21/22. PanNET-7. Accessed 06-15-23.
- 12. National Comprehensive Cancer Network (NCCN). Colon Cancer. NCCN Clinical Practice Guidelines in Oncology. Version 2.2023, 04/25/23. COL-E 1 of 2. Accessed 06-15-23

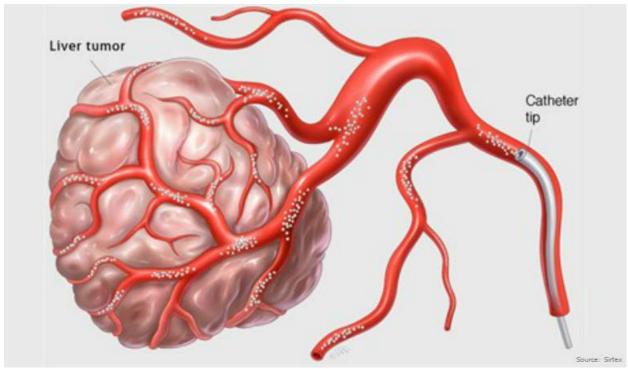
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Attachment A



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



Nondiscrimination & Language Access Policy

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, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

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

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator

Aspirus Health Plan, Inc.

PO Box 1062

Minneapolis, MN 55440

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.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic تنبيع: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً . اتصل بن اعلى رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_: य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນນີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY:711).