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Medicare Advantage Policy Manual **Policy ID:** M-MED140

Radioembolization, Transarterial Embolization (TAE), and Transarterial Chemoembolization (TACE)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Radioembolization is the intra-arterial delivery of small beads (microspheres) impregnated with yttrium-90 via the hepatic artery. The microspheres, which become permanently embedded, are delivered to the tumor. Yttrium-90 is a pure beta-emitter with a relatively limited effective range and short half-life that helps focus the radiation and minimize its spread. This procedure was formerly referred to as selective internal radiation therapy or "SIRT."

Transcatheter arterial chemoembolization (TACE) is a minimally invasive procedure which involves the injection of highly concentrated doses of chemotherapeutic agents. The embolic agent(s) causes ischemia and necrosis of the tumor and slows anticancer drug washout. TACE is a proposed alternative to conventional systemic or intra-arterial chemotherapy for

unresectable hepatocellular carcinoma (HCC) and for liver transplant. Transarterial embolization (TAE) with non-radioactive agents is also a technique used to treat some types of liver cancer, kidney cancer, and neuroendocrine tumors. It may also be used to treat uterine fibroids, aneurysms, and other conditions. TAE blocks the artery and stops the flow of blood to the tumor or abnormal area of tissue.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	See Therapeutic Embolization (20.28)[1] According to the NCD, therapeutic embolization is covered for "conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient." However, it does not provide clinical criteria to be considered when determining what indications may be considered reasonable and necessary for embolization treatment for a member.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	For ***radioembolization of liver tumors***: ✓ Billing and Coding: Treatment with Yttrium-90 Microspheres (A52950) SIR-Spheres® and TheraSphere® are available microsphere products and the LCA allows coverage when requirements are met. See "Policy Guidelines" below for specific details regarding Food and Drug Administration (FDA) premarket approvals, Investigational Device Exemption (IDE) studies, and FDA Humanitarian Device Exemption (HDE) approvals for these products.
Medical Policy Manual	*Medicare coverage guidance is not available in the health plan's service area for radioembolization for indications other than liver tumors, transarterial embolization (TAE) or transarterial chemoembolization (TACE). Therefore, the health plan's medical policy is applicable.* For ***radioembolization for indications* other than *tumors the liver, including the use of TAE with non-radioactive agents and TACE***: ✓ Radioembolization, Transarterial Embolization (TAE), and Transarterial Chemoembolization (TACE), Medicine, Policy No. 140 *(see "NOTE" below)*

NOTE: According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16,*

Ch. 4, §90.5). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of the planned therapy, including the embolization agent to be used (if applicable);
- Specific description of the disease, including the following:
    - Tumor type (primary vs. metastatic)
    - Extent and location of disease
- Rationale for determination that tumor is unresectable; or,
- If applicable, indication of participation in the SIRFLOX clinical trial for SIR-Spheres® or TheraSphere®
- For hepatocellular cancer (HCC) specify if whether treatment is proposed as radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable HCC or, for partial or branch portal vein thrombosis/occlusion, when clinical evaluation warrants the treatment,

MEDICARE COVERAGE UNDER NORIDIAN

According to the Noridian LCA, coverage of various conditions using yttrium-90 microspheres may be allowed under specific conditions, including FDA approved indications, IDE studies, and FDA HDE approval.

- If all requirements of the Federal Drug Administration's (FDA) Premarket Approval (PMA) approved indications (full approval based on safety and efficacy). See "Regulatory Status" below for FDA approved indications for each product available.
- If the treatment indication is under study with a Medicare-approved IDE, coverage may be considered.
    - As of January 1, 2015, IDE studies are no longer approved by local contractors, but they are approved by Medicare directly. Medicare-approved IDE studies approved ***on or after*** January 1, 2015, include the following:
        - *A Prospective, Multicenter, Open-label Single Arm Study Evaluating the Safety & Efficacy of Selective Internal Radiation Therapy Using SIR-Spheres® Y-90 Resin Microspheres on DoR & ORR in Unresectable Hepatocellular Carcinoma Patients* (NCT04736121; Approved 05/2021; IDE Number G200352)

        - *SIRT Followed by CIS-GEM Chemotherapy Versus CIS-GEM Chemotherapy Alone as 1st Line Treatment of Patients With Unresectable Intrahepatic Cholangiocarcinoma (SIRCCA)* (NCT02807181; Approved 11/2020; IDE Number G200069). This IDE evaluates SIR-Spheres®.
        - *SIRT Followed by CIS-GEM Chemotherapy Versus CIS-GEM Chemotherapy Alone as 1st Line Treatment of Patients With Unresectable Intrahepatic Cholangiocarcinoma (SIRCCA)* (NCT02807181; Approved 10/2017; IDE Number G160128) This IDE evaluates TheraSphere® Y-90 resin microspheres.
    - Treatment indications under study with an IDE ***prior to*** January 1, 2015 had to be approved by the local Medicare contractor. Such studies are called out within the LCA and include:
        - An IDE study called SIRFLOX, involving SIR-Spheres® in combination with FOLFOX6 +/- Avastin as a first line treatment for patients with metastatic colorectal cancer (mCRC) (NCT00724503).
        - Other IDE studies involve TheraSpheres® in the treatment of unresectable advanced HCC if the patient is not eligible for any curative procedures and for whom standard-of-care therapy with sorafenib is planned (NCT01556490).
- If the product has FDA Humanitarian Device Exemption (HDE) approval (reasonable safety but efficacy not demonstrated), coverage may be considered as well. See “Regulatory Status” below for FDA HDE approvals for their respective products.

REGULATORY STATUS

Currently, two commercial forms of yttrium-90 microspheres are available:

- TheraSphere®, a glass sphere (MDS Nordion, Inc.); and
- SIR-Spheres®, a resin sphere (Sirtex Medical Limited).

While the aforementioned products use the same radioisotope (yttrium-90) and have the same target dose (100 Gy), they differ in microsphere size profile, base material (i.e., resin vs. glass), and size of commercially available doses. These physical characteristics of the active and inactive ingredients affect the flow of microspheres during injection, their retention at the tumor site, spread outside the therapeutic target region, and dosimetry calculations. Note, results obtained with one product do not necessarily apply to other products.

The U.S. FDA granted premarket approval of SIR-Spheres® for use in combination with 5-floxuridine (5-FUDR) chemotherapy by HAI to treat unresectable hepatic metastases from colorectal cancer.

TheraSphere® was approved by humanitarian device exemption (HDE) for use as monotherapy to treat unresectable hepatocellular carcinoma (HCC). In January 2007, this HDE was expanded to include patients with hepatocellular carcinoma who have partial or branch portal vein thrombosis.

CROSS REFERENCES

Charged-Particle (Proton) Radiotherapy, Medicine, Policy No. M-49

Intensity Modulated Radiation Therapy (IMRT), Medicine, Policy No. M-136

Radiofrequency Ablation (RFA) of Tumors Other Than the Liver, Surgery, Policy No. M-92

REFERENCES

1. NCD for Therapeutic Embolization (20.28)

CODING

NOTE: CPT code 37243 can be used for both *radioactive* and *non-radioactive* embolization procedures performed for numerous conditions/locations. Embolization codes requiring prior authorization are listed on the "Pre-authorization List" web page. There may be codes related to embolization, such as CPT 37242 which may be used for prostate artery embolization, that do not require approval. Embolization codes not listed on the pre-authorization website do not require prior approval.

HCPCS code S2095 is a Medicare Status "I" code, and therefore, is not valid for Medicare or Medicare Advantage use.

Codes	Number	Description
CPT	37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
	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
	77399	Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services
	77778	Interstitial radiation source application; complex
	79445	Radiopharmaceutical therapy, by intra-arterial particulate administration
HCPCS	C2616	Brachytherapy source, nonstranded, yttrium-90, per source
	C9797	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
	Q3001	Radioelements for brachytherapy, any type, each
	S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres *(Not valid for Medicare purposes)*

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*