

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

Published: 08/01/2019

Next Review: 07/2020

Last Review: 07/2019

Medicare Link(s) Revised: 08/01/2019

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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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.

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)*	<p>See References^[1]</p> <p>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.</p>
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	<p>For radioembolization of liver tumors:</p> <ul style="list-style-type: none"> ✓ Treatment with Yttrium-90 Microspheres - R1 (A52950) <p>The Federal Drug Administration (FDA) and Humanitarian Device Exemption (HDE) approval status for each agent is noted within the LCA.</p> <ol style="list-style-type: none"> 1. If all requirements of the FDA’s Premarket Approval (PMA) approved indications (full approval based on safety and efficacy), use of yttrium microspheres will be covered. 2. If the treatment indication is under study with an Investigation Device Exemption (IDE), claims and an application for (IDE) study coverage should be submitted to the local Medicare contractor. 3. If the product has FDA HDE approval (reasonable safety but efficacy not demonstrated), submit the claim, noting the HDE number. If the claim is denied, an appeal will need to be submitted for reconsideration. <p>**Scroll to the “Public Version(s)” section at the bottom of the LCA for links to prior versions if necessary.</p>
Medical Policy Manual	<p><i>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</i></p>

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,

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).

CROSS REFERENCES

[Charged-Particle \(Proton\) Radiotherapy](#), Medicine, Policy No. M-49

[Intensity Modulated Radiation Therapy \(IMRT\)](#), Medicine, 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 **not** included in any medical policy. 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	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
	Q3001	Radioelements for brachytherapy, any type, each
	S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres (<i>Not valid for Medicare purposes</i>)

***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.