


MEDICAL POLICY	Liver Tumor Treatment (Medicare Only)
Effective Date: 1/1/2022	Medical Policy Number: 265
 01/1/2022	Medical Policy Committee Approved Date: 10/2020; 11/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
<i>Treatment with Yttrium-90 Microspheres</i>	Local Coverage Article (LCA): Billing and Coding: Treatment with Yttrium-90 Microspheres (A52950)

*In the absence of a Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.), Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare Managed Care Manual, Ch. 4, §90.5) Therefore, the commercial medical policy, **Liver Tumor Treatment (All Lines of Business Except Medicare)**, applies to the following services:*

- Ablative therapies (radiofrequency, cryoablation, percutaneous ethanol injection [PEI], microwave) for treatment of liver tumors
- Transarterial chemoembolization (TACE) for treatment of liver tumors
- Radioembolization **other than** Yttrium-90 microspheres for the treatment of hepatocellular carcinoma and hepatic metastases from colorectal tumors
- Yttium-90 microspheres for the treatment of hepatic metastases from neuroendocrine tumors and intrahepatic cholangiocarcinoma

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- Transarterial chemoembolization or radioembolization for the treatment of hepatic metastases from breast cancer
- High-intensity focused ultrasound (HIFU) or magnetic resonance guided focused ultrasound (MRgFUS) for treatment of liver tumors

POLICY GUIDELINES

According to the above LCA, “Noridian receives requests for coverage of the treatment of various conditions with yttrium-90 microspheres. If all requirements of the Federal Drug Administration’s (FDA) Premarket Approval (PMA) approved indications (full approval based on safety and efficacy), use of yttrium microspheres will be covered. If the treatment indication is under study with an Investigation Device Exemption (IDE), submit an application for (IDE) study coverage.”

Thus, Medicare coverage of yttrium-90 microspheres is based on FDA-approved indications and Noridian or Medicare-approved IDE studies. While the LCA does include some approved IDE studies, additional Medicare-approved IDE studies are as follows:

Study Title	NCT Number	IDE Number	Medicare Approved
90Y Transarterial Radioembolization (TARE) Plus Gemcitabine and Cisplatin in Unresectable Intrahepatic Cholangiocarcinoma	NCT02512692	G150096	01/10/2017
SIRT Followed by CIS-GEM Chemotherapy Versus CIS-GEM Chemotherapy Alone as 1st Line Treatment of Patients With Unresectable Intrahepatic Cholangiocarcinoma (SIRCCA)	NCT02807181	G160128	10/26/2017
Immunotherapy Combined With Yttrium-90 RadioEmbolization in the Treatment of Colorectal Cancer With Liver Metastases [iRE-C - Clinical Trial]	NCT04108481	G200069	11/19/2020
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 duration of response (DoR) & overall response rate (ORR) in Unresectable Hepatocellular Carcinoma Patients	NCT04736121	G200352	05/05/2021

By utilizing our Commercial policy criteria for certain indications, the Company is being less restrictive than Medicare.

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BILLING GUIDELINES

- A code from the range 36245-36248 for catheter placement would be billed in conjunction with 37243. Code 75726 may also be billed if diagnostic angiography is performed prior to 37243 and the decision to perform embolization was based on this angiography.

Vascular embolization or occlusion (37243) only requires prior authorization when paired with any of the following diagnosis codes for liver malignancy:

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|---------|---------|----------|
| ○ C22.0 | ○ C22.4 | ○ C78.7 |
| ○ C22.1 | ○ C22.7 | ○ C7B.02 |
| ○ C22.2 | ○ C22.8 | ○ D01.5 |
| ○ C22.3 | ○ C22.9 | |

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
Q2616	Brachytherapy source, non-stranded, yttrium-90, per source
C2698	Brachytherapy source, stranded, not otherwise specified, per source
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance
Q3001	Radioelements for brachytherapy, any type, each
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
47380	Ablation, open, of 1 or more liver tumor(s); radiofrequency
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical
47382	Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation
Prior Authorization Required	
<u>Note:</u> The following code requires prior authorization only when billed with a diagnosis code for liver malignancy.	
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
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
47399	Unlisted procedure, liver

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47379	Unlisted laparoscopic procedures on the liver
77799	Unlisted procedure, clinical brachytherapy

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.