MEDICAL POLICY	Liver Tumor Treatment (Medicare Only)
Effective Date: 1/1/2023  1/1/2023 Medical Officer Date	Medical Policy Number: 265 Medical Policy Committee Approved Date: 10/2020; 11/2021; 11/2022

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
Treatment with Yttrium-90 (Y-90) Microspheres	Local Coverage Article (LCA): Billing and Coding: Treatment with Yttrium-90 Microspheres (A52950)
Histotripsy (e.g., HistoSonics)	Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, 10 - Coverage of Medical Devices **NOTES:** • While FDA approval does not guarantee coverage under Medicare, in order to be considered for coverage by Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received the appropriate and necessary regulatory approval would not be considered medically reasonable or necessary. As of the most recent review, this technology/procedure has **not** received FDA approval. This device not appear to be available in the US and is considered to be investigational. Investigational items or

	procedures are considered **not medically necessary** for Medicare Plan members. • The trial #HOPE4LIVER (NCT04573881; G200253) is a Medicare-approved Category **A** IDE study as of 3/4/2021. Coverage may be provided for members enrolled and services performed in the context of this Medicare-approved study. If not, coverage is **not** available for this procedure/service. *(To confirm participation in a Medicare-approved IDE study, the NCT number must be provided and be verified as a Medicare-approved study on the CMS website for IDEs.)*
Liver Tumor Treatments Not Otherwise Specified *Examples:* • *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** Y-90 for the treatment of hepatocellular carcinoma and hepatic metastases from colorectal tumors* • *Radioembolization (Y-90) for indications not addressed by the LCA, including but not limited to, Y-90 for hepatic metastases from neuroendocrine tumors and intrahepatic cholangiocarcinoma, Y-90 for hepatic mestatases from melanoma or breast cancer, etc.* • *High-intensity focused ultrasound (HIFU) or magnetic resonance guided focused ultrasound (MRgFUS) for treatment of liver tumors*	Company medical policy for Liver Tumor Treatment (All Lines of Business Except Medicare) I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "investigational" by the Company policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members.* See *Policy Guidelines below.*

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 (aka, "A Traditional Feasibility Study of Gemcitabine, Cisplatin, and 90Y TARE for 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
The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER)	NCT04573881	G200253	03/04/2021

Medicare and Medical Necessity

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national

coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

For Y-90 used for clinical scenarios not addressed by the Noridian LCA above, the Company medical policy criteria will be applied. By utilizing Company policy criteria for certain indications, the Plan is being less restrictive than Medicare and the related LCA.

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:

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

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 Note: 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
Not Covered	
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
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
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.