Medicare Medical Policy

Liver Tumor Treatment

MEDICARE MEDICAL POLICY NUMBER: 265

Effective Date: 1/1/2023

Last Review Date: 11/2022

Next Annual Review: 11/2023

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

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 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.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Bariatric Surgery, MP37
- Cosmetic and Reconstructive Procedures, MP232

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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.

Table 1: Medicare-Approved IDE Studies

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.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

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

CODES*

CPT	0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
	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
	47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency
	47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
	47379	Unlisted laparoscopic procedures on the liver
	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
	47399	Unlisted procedure, liver
HCPCS	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
	Q2616	Brachytherapy source, non-stranded, yttrium-90, per source
	Q3001	Radioelements for brachytherapy, any type, each

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Annual review (converted to new format 2/2023)