Medicare Medical Policy

Liver Tumor Treatment

MEDICARE MEDICAL POLICY NUMBER: 265

Effective Date: 5/6/2025

Last Review Date: 5/2025

Next Annual Review: 11/2025

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, and Providence Plan Partners 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
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 **B** IDE study (previously a Category **A** IDE study) as of 3/4/2021. • The trial #HOPE4KIDNEY (NCT05820087; G230008) is a Medicare-approved Category **B** IDE study as of 6/15/2023. • Coverage may be provided for members enrolled and services performed in the context of one of these Medicare-approved studies. If not, coverage is **not** available for this procedure/service.

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Medicare does not have criteria for liver tumor treatments in a coverage manual.
- **National Coverage Determination (NCD):** Medicare does not have an NCD for liver tumor treatments.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for liver tumor treatments (the LCA Noridian had previously was retired in 2023).
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available.
- ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

Liver Tumor Treatments Not Otherwise Specified *Examples:* • *Ablative therapies (radiofrequency, cryoablation, percutaneous ethanol injection [PEI], microwave) for treatment of liver tumors* • *High-intensity focused ultrasound (HIFU) or magnetic resonance guided focused ultrasound (MRgFUS) for treatment of liver tumors* • *TheraBionic® P1 (HCPCS E0767)* • *Three-dimensional (3D) contour **simulation** of liver lesion(s) for image-guided microwave ablation (CPT 0944T) and radioembolization (C8004)*	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 "not medically necessary" by the Company policy. 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

Prior to November 1, 2023, the Noridian Local Coverage Article (LCA) for *Billing and Coding: Treatment with Yttrium-90 Microspheres* (A52950) stated, "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 was based on FDA-approved indications and Noridian or Medicare-approved IDE studies. While the LCA did include some approved IDE studies, additional Medicare-approved Category B IDE studies were also listed on the CMS webpage for IDE studies.

While the Noridian LCA A52950 was retired effective November 1, 2023, Medicare coverage requirements for Category B IDE studies remains. For services rendered outside of a Medicare Category A or B IDE study, due to the retirement of the Noridian LCA A52950, the Company medical policy criteria will be applied (see below for more information).

MEDICARE AND MEDICAL NECESSITY

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)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or

meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

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.

Since there are not fully established coverage criteria for liver tumor treatments available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

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

CODES*		
CPT	0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
	0944T	3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation
	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	C2616	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
	C8004	Simulation angiogram 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 angiogram, for subsequent therapeutic radioembolization of tumors

	C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance
	E0767	Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories
	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)
12/2023	Interim update due to retirement of LCA for yttrium 90 microspheres
2/2024	Annual review, no change to criteria but language revision due to Company policy change from "investigational" to "not medically necessary"
4/2024	Q2 2024 code updates
10/2024	Q4 2024 code updates
12/2024	Annual review, no change to criteria
1/2025	Q1 2025 code updates (3/24/2025: Corrected Q2616 to C2616)
4/2025	Q2 2025 code updates
5/6/2025	Interim update; remove vascular embolization procedures from scope, transfer to Carelon