Medicare Medical Policy

Blood Brain Barrier Disruption and Bypass

MEDICARE MEDICAL POLICY NUMBER: 335

Effective Date: 1/1/2025

Last Review Date: 12/2024

Next Annual Review: 6/2025

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.

<table>
<tr><th>Service</th><th>Medicare Guidelines</th></tr>
<tr><td>Blood Brain Barrier Disruption (BBBD)</td><td>National Coverage Determination (NCD): Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (110.20)</td></tr>
<tr><td colspan="2">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 BBBD via the convection-enhanced delivery (CED) method in a coverage manual.
• National Coverage Determination (NCD): Medicare has an NCD for BBBD using osmotic disruption (see above), stating this is the most common technique used. However, Medicare does not have an NCD for BBBD via the CED method, nor does it address the use of magnetic resonance image guided low intensity focused ultrasound (MRgFUS) with BDDD and microbubble resonators.
• 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 CED BBBD.
• 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.</td></tr>
<tr><td>Convection-enhanced delivery (CED)

Magnetic Resonance Image Guided Low Intensity Focused Ultrasound (MRgFUS) with BBBD Using Microbubble Resonators (CPT 0947T)</td><td>Company medical policy for Blood Brain Barrier Disruption and Bypass

I. These procedures are considered not medically necessary for Medicare Plan members based on the Company medical policy. See Policy Guidelines below.</td></tr>
</table>

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

None

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

POLICY GUIDELINES

BACKGROUND

The blood-brain barrier (BBB) prevents uptake of most traditional chemotherapeutic agents into the brain, thereby limiting the efficacy of treatment. Standard methods of local delivery of most drugs into the brain, either by intravenous injection and passage through the BBB, or intra-ventricular injection, has relied on diffusion, which results in a non-homogenous distribution of most agents.

In contrast to techniques that rely on diffusion, CED uses a pressure gradient established at the tip of an infusion catheter to push a drug into the extra-cellular space. The intention is to distribute the drug more evenly, at higher concentrations, and over a larger area than when administered by diffusion alone.

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 **all** techniques used for blood brain barrier disruption (BBBD) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for some techniques will be applied.

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	0947T	Magnetic resonance image guided low intensity focused ultrasound (MRgFUS), stereotactic blood-brain barrier disruption using microbubble resonators to increase the concentration of blood-based biomarkers of target, intracranial, including stereotactic navigation and frame placement, when performed
	36215	Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family
	36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family
	36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family
	36218	Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)
	64999	Unlisted procedure, nervous system
	96549	Unlisted chemotherapy procedure
HCPCS	None	

***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
7/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
9/2023	Annual review; no criteria changes, but some language revision due to Company policy change from "investigational" to "not medically necessary"
7/2024	Annual review; no changes
1/2025	Q1 2025 code updates