


MEDICAL POLICY	Blood Brain Barrier Disruption and Bypass (Medicare Only)
Effective Date: 7/1/2022  <div style="text-align: right;">7/1/2022</div>	Medical Policy Number: 335 Medical Policy Committee Approved Date: 6/2022
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>Blood Brain Barrier Disruption (BBBD)</i>	National Coverage Determination (NCD): Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (110.20)
<i>Convection-enhanced delivery (CED)</i>	Company medical policy for Blood Brain Barrier Disruption and Bypass (All Lines of Business Except Medicare) I. These procedures are considered not medically necessary for Medicare Plan members based on the Company medical policy. <i>“Investigational” services are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</i>

POLICY GUIDELINES

Medicare and Medical Necessity

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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.), 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).

For Medicare, 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*)

General

The blood-brain barrier (BBB) prevents uptake of most traditional chemotherapeutic agents into the brain, thereby limiting the efficacy of treatment. However, new treatments have been developed in an effort improve drug delivery to brain tumors and lead to prolonged survival. Such techniques include:

- **Blood-brain barrier disruption (BBBD):** A technique also referred to as “barrier modification” therapy that typically utilizes a hyperosmotic solution such as mannitol to increase the permeability of the blood-brain barrier (BBB). The osmotic agent is purported to temporarily shrink the brain’s protective barrier of tightly knit cells, to allow for transport of drugs to the brain.
- **Convection-enhanced delivery (CED):** CED is a delivery technique to bypass the blood brain barrier (BBB) and administer therapeutic agents directly into targeted brain parenchyma or tissue through surgically implanted catheters. CED has the potential to optimize the delivery of drugs to the affected area through positive-pressure via a micro-infusion pump to control drug distribution.

CPT/HCPCS CODES

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Prior Authorization Required	
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)
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 it will be denied as not covered .	
64999	Unlisted procedure, nervous system
96549	Unlisted chemotherapy procedure

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.