Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**

Title: Percutaneous Transluminal Angioplasty (PTA) for the Treatment of Cerebral Vasospasm

Description/Background

Cerebral aneurysmal rupture leading to subarachnoid hemorrhage (SAH) is reported to occur at a rate of about 7 per 100,000 annually in North America. Subarachnoid hemorrhage is a devastating clinical event with high mortality, and high morbidity among survivors.[1]

A possible complication of SAH is delayed cerebral ischemia, which occurs in about 30% of patients, typically between day 4 and day 14 following symptom onset. The definition of delayed cerebral ischemia requires focal neurologic impairment (such as hemiparesis, aphasia, apraxia, hemianopia, or neglect) or a decrease of at least two points on the Glasgow Coma Scale that lasts for at least one hour. These conditions were not apparent immediately after the aneurysm occlusion and cannot be attributed to other causes after appropriate clinical assessment, brain imaging, and laboratory studies. The most common cause of delayed cerebral ischemia after SAH is assumed to be vasospasm. Risk factors for vasospasm include severity of bleeding and its proximity to major intracerebral vessels, patient age less than 50 years, and hyperglygemia.[2]

There has been no protocol identified that prevents vasospasm. However, to reduce the risk of poor outcomes from delayed cerebral ischemia, maintaining euvolemia and administering nimodipine are recommended. First-line therapy for the treatment of new-onset delayed cerebral ischemia includes induced hypertension with vasopressors such as phenylephrine, norepinephrine or dopamine and maintenance of euvolemia. Earlier versions of therapy included hypervolemia, hemodilution and hypertension, known as triple-H therapy; however, studies revealed that hypervolemia was not beneficial, and could be harmful. In those who do not respond to pressors alone, other agents may be added. Vasodilators, administered intraarterially, are used for diffuse vasospasm involving smaller arterial branches. Balloon angioplasty is being investigated as a treatment option for symptomatic focal vasospasm of the larger cerebral arteries that is refractory to hemodynamic augmentation, although this is despite an absence of clinical trial data.[2]

Regulatory Status

The U.S. Food and Drug Administration (FDA) in its approvals of devices appropriate for percutaneous transluminal angioplasty does not list the specific indication “treatment of cerebral vasospasm.” A percutaneous catheter approved by the FDA to treat cerebral aneurysm (product code DQY) would be used for this intervention.

Medical Policy Statement

The effectiveness of percutaneous transluminal angioplasty for the treatment of cerebral vasospasm following subarachnoid hemorrhage has not been established, therefore, it is considered **experimental/investigational.**

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

61640 61641 61642

Rationale

Choi et al (2011) evaluated the safety and efficacy of transluminal balloon angioplasty (TBA) for subarachnoid hemorrhage induced vasospasm.[3] The study included 11 patients with confirmed significant vasospasm, defined as >50% vessel narrowing with clinical deterioration. Fifty-four vessel segments were treated by TBA using Hyper-Glide or Hyper-Form balloons (MicroTherapeutics, Irvine, CA). Transluminal balloon angioplasty was successful in 48 of 54 vasospastic segments without complications. In 3 patients, TBA was not possible due to unfavorable angles in the artery that prevented navigation of the balloon microwire. This study reported success rates of 100% for the distal internal carotid arteries, middle cerebral arteries and vertebrobasilar artery and 70% success for the anterior cerebral arteries. The authors concluded that endovascular treatment should be considered when symptomatic cerebral vasospasm is refractory to medical management.

Khatri et al (2011) retrospectively studied 146 patients who were admitted for treatment of symptomatic cerebral vasospasm in patients with subarachnoid hemorrhage.[4] Treatment options included endovascular embolization, surgical treatment, non-selective intra-arterial

treatment, external ventricular drainage, percutaneous transluminal angioplasty (PTA) alone or with superselective intra-arterial vasodilator treatment. Eighteen (32%) patients underwent PTA with or without intra-arterial vasodilator treatment. A nonsignificant trend was observed with reduced rate of severe disability and mortality at discharge and 1 year mortality after PTA. The authors recommended further research with larger study populations.

Chalouhi et al (2014) conducted a retrospective study to assess the safety and efficacy of endovascular treatment for cerebral vasospasm in 116 patients.[5] Balloon angioplasty was performed in 52.6% of the study population, 19.8% were treated with intra-arterial nicardipine infusion, and 27.6% were treated with both angioplasty and intra-arterial infusion. Balloon angioplasty and nicardipine were found to be equally effective.

Veldeman et al (2016) performed a systematic review of literature related to current prevention and treatment strategies for delayed cerebral ischemia (DCI).[6] Forty-nine studies met inclusion criteria. The reviewers found that clazosentan, magnesium, and simvastatin have been tested in large high-quality trials but failed to show a beneficial effect. Cilostazol, eicosapentaenoic acid, erythropoietin, heparin, and methylprednisolone yielded promising results in smaller, nonrandomized or retrospective studies and warrant further investigation. Topical application of nicardipine via implants after clipping has been shown to reduce clinical and angiographic vasospasm. Methods to improve subarachnoid blood clearance have been established, but their effect on outcome remains unclear. Hemodynamic management of DCI is evolving towards euvolemic hypertension. Endovascular rescue therapies, such as percutaneous transluminal balloon angioplasty and intra-arterial spasmolysis, are able to resolve angiographic vasospasm, but their effect on outcome needs to be proved. The reviewers concluded that many of the current strategies need to be tested in larger RCTs.

The effectiveness of balloon angioplasty in the treatment of cerebral vasospasm following subarachnoid hemorrhage has not been established. Although preliminary evidence has been promising, studies to date have been small and retrospective.

Supporting Information

American Heart Association/American Stroke Association

2023 Guideline for the Management of Patients With Aneurysmal Subarachnoid Hemorrhage: A Guideline From the American Heart Association/ American Stroke Association, 2023[7]

This guideline addresses the diagnosis and treatment of aSAH in adults and is intended to update and replace the AHA/ASA 2012 aSAH guideline. This 2023 guideline is limited explicitly to aSAH and does not address other types of SAH such as those caused by trauma, vascular malformation, or hemorrhage-prone neoplasm. Furthermore, this guideline does not overlap with AHA/ASA guidelines or scientific statements on the treatment of intracerebral hemorrhage (ICH),13 arteriovenous malformations, and unruptured intracranial aneurysms.15 This guideline aims to cover the full course of aSAH (Figure 1), from initial diagnosis (Section 4), systems of care (Section 5), and acute interventions (Sections 6, 7, and 7.1) to further inpatient care of post-aSAH complications (Sections 8–8.5). New sections in this 2023 aSAH guideline include nursing care (Section 8.1) and recovery (Section 9). Risk factors for recurrent aSAH are also addressed (Section 10); however, risk factors for aneurysm development and rupture

and management of unruptured aneurysms are not included in this guideline because these topics are addressed in a separate guideline for management of unruptured intracranial aneurysms. The new, important emphases in this guideline are shared decision making, health equity, and systems of care. Some aspects of inpatient aSAH medical care and post-aSAH rehabilitation and recovery are likely to be similar between patients with aSAH and patients with other types of stroke. Readers are therefore referred to relevant AHA/ASA guidelines and scientific statements in these overlapping areas.

Government Regulations

National:

NCD - Percutaneous Transluminal ANGIOPLASTY (PTA) (20.7)
Effective Date: 10/11/2023

Indications and Limitations of Coverage

B. Nationally Covered Indications
The PTA is covered when used under the following conditions:

1. Treatment of Atherosclerotic Obstructive Lesions
[NOTE: see the NCD for specific criteria]
2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials
[NOTE: see the NCD for specific criteria]
3. Concurrent with Carotid Stent Placement in FDA-Approved Post Approval Studies
[NOTE: see the NCD for specific criteria]
4. ***Concurrent with Carotid Stent Placement***
[NOTE: see the NCD for specific criteria]
5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials
[NOTE: see the NCD for specific criteria]

C. Nationally Non-Covered Indications
All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.
All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain noncovered.

D. Other
In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at the discretion of the MACs..

Local:

There is no local coverage policy on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
- Extracranial Carotid Artery Stenting

References

1. Singer RJ, Ogilvy CS, Rordorf G. Aneurysmal subarachnoid hemorrhage: epidemiology, risk factors, and pathogenesis. UpToDate. 12/10/24. https://www.uptodate.com/contents/aneurysmal-subarachnoid-hemorrhage-epidemiology-risk-factors-and-pathogenesis?search=aneurysmal%20subarachnoid%20hemorrhage&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3 Accessed 12/10/24.
2. Singer RJ, Ogilvy CS, Rordorf G. Aneurysmal subarachnoid hemorrhage: treatment and prognosis. UpToDate. Oct 2024. https://www.uptodate.com/contents/aneurysmal-subarachnoid-hemorrhage-treatment-and-prognosis?search=cerebral%20vasospasm%20following%20subarachnoid%20hemorrhage&topicRef=1130&source=see_link Accessed 12/10/24.
3. Choi BJ, Lee, TH, Lee J, et al. Safety and efficacy of transluminal balloon angioplasty using a compliant balloon for severe cerebral vasospasm after an aneurysmal subarachnoid hemorrhage. J Korean Neurosur Soc. 2011 March; 49(3): 157-62. PMID 21556235
4. Khatri R, Memon MZ, Zacharatos H, et al. Impact of percutaneous transluminal angioplasty for treatment of cerebral vasospasm on subarachnoid hemorrhage patient outcomes. Neurocrit Care. 2011 August;15(1): 28-33. PMID 21360234
5. Chalouhi H, Tjoumakaris S, Thakkar V, et al. Endovascular management of cerebral vasospasm following aneurysm rupture: outcomes and predictors in 116 patients. Clin Neurol Neurosurg. 2014 Marcc;118:26-31. PMID 24529225
6. Veldeman M, Hollig A, Clusmann H, et al. Delayed cerebral ischaemia prevention and treatment after aneurysmal subarachnoid haemorrhage: A systematic review. Br J Anaesth. 2016;117(1):17-40.
7. Hoh, Ko, Amin-Hanjani et al. 2023 Guideline for the Management of Patients With Aneurysmal Subarachnoid Hemorrhage: A Guideline From the American Heart Association/ American Stroke Association, 2023 2023 Guideline for the Management of Patients With Aneurysmal Subarachnoid Hemorrhage: A Guideline From the American Heart Association/American Stroke Association | Stroke accessed 12/10/24
8. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database, National Coverage Determination. Percutaneous Transluminal Angioplasty (PTA) (20.7), Effective date 10/11/2023.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/10/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/12	2/21/12	2/21/12	Joint policy established
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance
5/1/18	2/20/18	2/20/18	Routine maintenance
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance Added ref 1, 13
5/1/22	2/15/22		Routine maintenance Reference 6 added
5/1/23	2/21/23		Routine maintenance (jf) Vendor Review: NA
5/1/24	2/20/24		Routine maintenance (jf) Vendor Review: NA Added Ref 7
5/1/25	2/18/25		Routine maintenance (jf) Vendor Review: NA

Next Review Date: 1st Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) FOR THE TREATMENT OF CEREBRAL VASOSPASM

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.