Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 8/1/2024
Policy Number: ccp.1493	**Effective Date:** 8/2021 **Revision Date:** July 1, 2024
Policy Name: Intracranial hypertension stent	

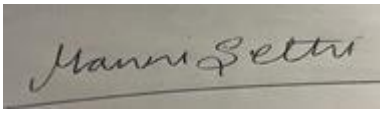
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Previously retired. Reactivated policy See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Intracranial hypertension stent

Clinical Policy ID: CCP.1493

Recent review date: 7/2024

Next review date: 11/2025

Policy contains: idiopathic intracranial hypertension, pseudotumor cerebri, venous sinus stent.

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania on a case by case basis when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.

Coverage policy

Venous sinus stents for intracranial hypertension are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Diuretic medication therapy (e.g., acetazolamide).
- Shunting (insertion of tube into brain).
- Weight loss support and consultation.

Background

Idiopathic intracranial hypertension, also known as pseudotumor cerebri, is a condition marked by persistently increased intracranial pressure, papilledema, and radiological findings with no known identifiable origin (Wang, 2022). Incidence for all ages is approximately one in 100,000 persons, and is highest in overweight women ages 20 to 44 years, estimated at 19 in 100,000 (Daggubati, 2019).

Common symptoms of intracranial hypertension are often nonspecific and may include headache, transient visual obscurations, pulse synchronous tinnitus, photopsia, retrobulbar pain, diplopia, and visual loss. While the pathophysiology of idiopathic intracranial hypertension is poorly understood, likely causative factors are cerebral spinal fluid dysregulation and dysfunction and increasing venous sinus pressure (Wang, 2022).

The criteria used to diagnose idiopathic intracranial hypertension include: signs and symptoms attributable only to elevated intracranial pressure; cerebrospinal fluid opening pressure of greater than 25 centimeters H_2O; normal cerebrospinal fluid composition; and no evidence after neuroimaging of mass lesion or other structural causes. Fundoscopy, optical coherence tomography, neuroimaging (often magnetic resonance imaging), and lumbar puncture with manometry are used in diagnosis (Friedman, 2013).

Multiple treatment options for idiopathic intracranial hypertension exist. Weight loss remains the only established therapy that modifies the disease process typically for patients with a baseline body mass index > 35 kg/m^2 as first line treatment in the absence of fulminant disease (Wang, 2022). Monitoring of psychosocial issues is important, although consensus is lacking in standardized measures. The most common medical treatment is acetazolamide — a diuretic and carbonic anhydrase inhibitor — sometimes combined with other drugs (Thurtell, 2021).

Surgical treatments in cases refractory to conservative approaches include various approaches to shunting cerebrospinal fluid, optic nerve sheath fenestration, and cerebral venous sinus stents (also known as intracranial hypertension stents). The process of stenting includes cerebral angiography with a guide catheter through femoral artery puncture, and venography/venous manometry (under conscious sedation) through femoral vein access, with a shuttle catheter at the internal jugular vein. Venous stents, placed under general anesthesia, span 10 millimeters pre-stenosis and post-stenosis (Daggubati, 2019).

Findings

Guidelines

A consensus guideline issued by four British professional medical societies on management of idiopathic intracranial hypertension does not recommend neurovascular stenting for either visual loss or headache alone, as the role of the procedure is not established. Reasons include observed complications, lack of long-term data on efficacy and safety, and methodological limits, i.e., studies are mostly case series, not randomized, and have small sample sizes (Mollan, 2018).

A guideline from the European Headache Foundation states that while some institutions employ venous sinus stenting to treat idiopathic intracranial hypertension, “utility is debated.” This guideline also does not recommend the procedure to treat headaches in persons with the disorder (Hoffmann, 2018).

A guideline from the Royal College of Physicians states that ventriculoperitoneal shunts can be used to divert cerebrospinal fluid, and that optic nerve sheath fenestration is an alternative to treating intracranial hypertension. However, the ability of endovascular stenting to improve long-term outcomes is uncertain (Wakerley, 2020).

The American Academy of Ophthalmology has not issued professional guidance for idiopathic intracranial hypertension, but a related article on the Academy’s website points out the general low quality evidence for venous sinus stenting that fails to address the true complication rates and comparative effectiveness relative to more established shunting procedures. The authors agree that a head-to-head controlled clinical trial is necessary to answer these questions. While standard criteria for venous stenting are lacking, there is general agreement that venous sinus stenting may be considered when patients have failed or are intolerant to maximum medical therapy, have a documented venous sinus pressure gradient on manometry, and have failed, refused, or are not an appropriate candidate for cerebrospinal fluid shunting or optic nerve sheath fenestration (Lee, 2024).

Evidence reviews

Patients who fail conservative measures are generally referred for cerebrospinal fluid shunting or optic nerve sheath fenestration, but venous sinus shunting is increasing in popularity in the United States. From 2016 to

2020, the number of venous sinus stenting procedures increased 80%, while the number of cerebrospinal fluid shunting procedures and optic nerve sheath fenestration procedures decreased 19% and 54%, respectively (Khunte, 2023).

The evidence base reported in the analyses below consists of non-randomized and single cohort studies of short duration. Most participants were female and obese. Weight loss, acetazolamide therapy, and surgical interventions prior to venous sinus stenting were reported inconsistently. Venous sinus stenting appears to be efficacious for improving symptoms associated with idiopathic intracranial hypertension in patients who do not respond to medical therapy or have significant neurological or visual symptoms. Major complications and adverse events are infrequent, but rates of treatment failure, recurrence of idiopathic intracranial hypertension, and restenosis are variable.

A systematic review and meta-analysis of 36 non-randomized studies included 1,066 participants with medically refractory idiopathic intracranial hypertension (Azzam, 2024). The mean age at stenting was 33 years (range 13.4 to 41.8 years), and the mean follow-up time was 17.4 months (range three to 49 months). The majority of participants were female with a mean body mass index of 34.3 kilograms/m^2 (range 24.1 to 41.5 kilograms/ m^2). The mean time to stenting since diagnosis was 22.9 months. Venous sinus stenting was performed as a first-line surgery in 78% (265/341) and as a second-line surgery in 18.9% (71/374). The overall risk of bias in the included studies was graded as moderate.

There was a significant reduction in trans-stenotic gradient pressure and lower cerebrospinal fluid opening pressure following venous sinus stenting. Symptomatic improvement in tinnitus (95% of participants), papilledema (89%), visual disturbances (88%), and headache (79%) occurred following the procedure. Treatment failure, defined as worsening symptoms and recurrence of idiopathic intracranial hypertension, occurred in 8.35%. The major complications and adverse events rate was 3.93%, including subdural hematoma, subdural hemorrhage, worsening of headache, and visual impairment. The minor complications and adverse events rate was 2.72%, including transient headache, retroorbital pain, and neck hematoma (Azzam, 2024).

A systematic review and meta-analysis of 24 studies compared the rates of restenosis and symptom recurrence in 694 participants (781 total venous sinus stenting procedures) with ophthalmological and neurological symptoms refractory to previous therapies. The mean age was 33.9 years, and the mean body mass index was 35.3 kilograms/m^2. After the procedure, 77.7% experienced symptom improvement, and 22.3% had persistent or worsened symptoms. The pooled restenosis rate was 17.7% (Lim, 2024).

A systematic review of 109 studies compared outcomes for various types of surgery for idiopathic intracranial hypertension. Venous sinus stenting improved papilledema, visual fields, and headaches in 87.1%, 72.7%, and 72.1% of patients, with failure and complication rates of 2.3% and 11.3%, respectively. Less efficacy and safety generally resulted after cerebrospinal fluid diversion (78.9%, 66.8%, 69.8%, 9.4%, and 43.4%), and optic nerve sheath fenestration (90.5%, 65.2%, 49.3%, 2.2%, and 9.4%) (Kalyvas, 2021).

A meta-analysis of 29 studies (n = 410) assessed outcomes of patients who underwent dural venous sinus stenting for refractive idiopathic intracranial hypertension. Technical success was 99.5%, the rate of major complication rate was 1.5%, and repeated procedure occurred in 10% of cases (Leishangthem, 2019).

A systematic review/meta-analysis of 20 studies (n = 474) of intracranial venous sinus stenting for idiopathic intracranial hypertension included 88% females with a mean age of 35 and a mean mass body index of 35 kg/m^2, who were followed for a median of 18 months after treatment. The review reported rates of papilloedema improvement (93.7%), headache improvement/resolution (79.6%), and pulsatile tinnitus resolution (90.3%). The rate of symptom recurrence was 9.8%, and major complications occurred in 1.9% of patients (Nicholson, 2019).

In 2023, we updated the references and added a systematic review of 27 studies with an average sample size of 27 participants that confirmed serious limitations in the evidence base, notably a lack of ophthalmological

outcomes associated with dural venous sinus stenting for treating medically-refractory idiopathic intracranial hypertension (Kabanovski, 2022). No policy changes are warranted.

In 2024, we removed older references and added two new systematic reviews/meta-analyses to the policy. No policy changes are warranted.

References

On June 4, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “intracranial hypertension (MeSH),” “stents (MeSH),” “idiopathic intracranial hypertension,” “pseudotumor cerebri,” “benign intracranial hypertension,” and “stent.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2021: initial review date and clinical policy effective date: 8/2021

7/2022: Policy references updated.

7/2023: Policy references updated.

7/2024: Policy references updated.