Intracranial hypertension stent

Clinical Policy ID: CCP.1493

Recent review date: 7/2023

Next review date: 11/2024

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

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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, 2021). Incidence for all ages is approximately 1 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, 2021).

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, 2021). 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

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).

An article in an American Academy of Ophthalmology magazine, in which two prominent experts are interviewed, cites fenestration and shunting as potential surgical options for idiopathic intracranial hypertension, but does not mention stents (Weiner, 2015). Another article published on the American Academy of Ophthalmology’s website suggests venous sinus stenting as a treatment for fulminant idiopathic intracranial hypertension in the presence of venous sinus stenosis. They based their recommendation on the results of one prospective trial of 13 participants who experienced a reduction of intracranial pressure and improvement in ocular parameters and symptoms associated with intracranial hypertension (Al-Zubidi, 2023).

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%). Authors regard sinus stenting as first-line treatment (Kalyvas, 2021).

A systematic review/meta-analysis of 24 studies (n = 473) of patients with idiopathic intracranial hypertension followed patients for an average of 18.9 months after venous sinus stenting. Authors documented rates of stent survival (84%) and stent-adjacent stenosis (14%). Authors encouraged more study to identify causes of both stenosis and stent failure (Saber, 2018).

A meta-analysis of 29 studies (n = 410) assessed outcomes of patients who underwent dural venous sinus stenting for refractive idiopathic intracranial hypertension, noting stenting is an accepted treatment, but "there are no randomized controlled studies" on outcomes and complications. 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).

A meta-analysis compared outcomes for optic nerve sheath fenestration (n = 712), diversion of cerebrospinal fluid (n = 435), and dural venous sinus stenting (n = 136) for treating refractory idiopathic intracranial hypertension. Stenting, compared with fenestration and fluid diversion, had superior outcomes for improving vision (78% versus 59% and 54%); headache (83% versus 44% and 80%); and papilledema (97% versus 80% and 70%). Stenting also had lower rates of major complications (2.9% versus 1.5% and 7.6%) and minor complications (4.4% versus 16.4% and 32.9%). Authors note the paradigm of using cerebrospinal fluid diversion as first-line surgery "may need to be re-examined" (Satti, 2015).

A review of 41 studies (n = 728), including 36 case series and five case reports, compared efficacy of surgical treatments for idiopathic intracranial hypertension, including venous sinus stenting (n = 155). Stenting had satisfactory results in vision and headache improvement, the best complication profile, and a low relapse rate, but with longer follow-up required. No surgical modality was clearly superior. Authors state that stenting as a first-line treatment "may need to be re-examined," a conclusion opposite that reached by Satti et al. two years earlier (Kalyvas, 2017).

A 2015 Cochrane review reviewed all randomized trials of treatment for idiopathic intracranial hypertension. No such randomized trials existed for stenting; the only two trials in the review addressed treatment with the drug acetazolamide (Piper, 2015).

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.

References

On April 24, 2023, 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.