Aqueous shunts for glaucoma

Clinical Policy ID: CCP.1381

Recent review date: 6/2021

Next review date: 10/2022

Policy contains: Aqueous shunt; glaucoma; glaucoma drainage device; intraocular pressure; tube shunt; seton.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's 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 Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Aqueous shunts are clinically proven and, therefore, medically necessary for:

- Members diagnosed with open-angle glaucoma who meet both criteria (American Academy of Ophthalmology, 2018; American Optometric Association, 2010; Tseng, 2017):
    - Progressive visual field loss on maximal medical therapy, intolerance to glaucoma medications, or poor adherence to current treatment plan.
    - Failure or likely failure of angle surgery (e.g., laser trabeculoplasty or trabeculectomy) to adequately control intraocular pressure (e.g., neovascular glaucoma, uveitic glaucoma, conjunctival scarring from previous ocular surgery, or cicatrizing diseases of the conjunctiva).
- Members with congenital or pediatric glaucoma who meet either criterion (American Academy of Ophthalmology, 2018; American Association for Pediatric Ophthalmology and Strabismus, 2018; Chen, 2014):
    - Failure or likely failure of primary goniotomy or trabeculotomy to adequately reduce intraocular pressure to an acceptable level (e.g., less than 21 mmHg).
    - Presence of aphakia that may require contact lens wear for visual rehabilitation.

Limitations

All other uses of aqueous shunts are not medically necessary, including members with glaucoma when intraocular pressure is adequately controlled by medications.

Relative contraindications to aqueous shunts include, but are not limited, to:

- Anterior chamber placement in eyes with endothelial dysfunction or shallow anterior chamber.
- Intraocular tumors.
- Poor adherence to postoperative and follow-up care.

Alternative covered services

- Pharmacologic management (prostaglandin analogs, alpha2-adrenergic agonists, beta-blocking agents, carbonic anhydrase inhibitors, cholinergic agonists-miotics, and combination agents).
- Laser trabeculoplasty.
- Filtration surgical procedures (e.g., thermal sclerostomy, posterior or anterior lip sclerectomy, trephination, and trabeculectomy).

Background

Glaucoma describes a group of ocular disorders with characteristic progressive optic neuropathy and structural and functional features of visual field loss, and is a leading cause of irreversible blindness (McMonnies, 2017). Risk factors include advanced age, African American ancestry, family history of glaucoma, diabetes, previous cataract surgery, and elevated intraocular pressure. A major limitation of current diagnostic approaches is the inability to positively diagnose glaucoma before considerable damage to the retina has already occurred (Davis, 2016).

Glaucoma subtypes are classified based on the presence of elevated intraocular pressure, glaucomatous optic neuropathy, an open- or closed-angle, and a distinguishable pathological cause (Casson, 2012). Open- or closed-angle refers to the junction between the cornea and iris where aqueous humor (fluid) leaves the eye through a spongy trabecular meshwork. The open-angle subtype is a chronic condition in which the drainage angle remains open but fluid passes through too slowly and may or may not result in elevated intraocular pressure in the absence of a cause. An angle-closure is an acute presentation in which the peripheral iris blocks the trabecular meshwork resulting in elevated intraocular pressure. “Primary” refers to the detected optic neuropathy in the presence of normal or elevated intraocular pressure with no distinguishable pathological cause, whereas “secondary” refers to elevated intraocular pressure with an identifiable cause.

The most common subtypes in adults and children are primary open-angle glaucoma and primary closed-angle glaucoma. Other subtypes include (Casson, 2012):

- Ocular hypertension — Elevated intraocular pressure without detectable glaucomatous optic neuropathy.
- Glaucoma suspect — Individual or ocular features suggestive of glaucoma (e.g., consistently elevated intraocular pressure, suspicious looking optic nerve, or abnormal visual field), but insufficient for a conclusive diagnosis.

The goals of treatment are to lower intraocular pressure and slow visual field loss (Gupta, 2016; Tan, 2016). Treatment options are topical and oral medications and surgery. Surgical options include laser iridotomy, laser trabeculoplasty, and incisional surgery (e.g., trabeculectomy, goniotomy, and aqueous shunting) depending on the glaucoma subtype and patient needs. Incisional surgery bypasses the normal outflow of aqueous humor via the trabecular meshwork by shunting it to the subconjunctival space where it is absorbed into nearby blood vessels. Newer nonpenetrating techniques, such as viscocanalostomy and deep sclerectomy, are emerging that attempt to improve upon the outcomes and complication rates associated with incisional procedures (Francis, 2011).

Aqueous shunt surgery (also called tube-shunt or seton glaucoma surgery) involves placing a flexible plastic tube with an attached silicone drainage pouch in the eye to help drain fluid. The U.S. Food and Drug Administration regulates aqueous shunts as implantable devices intended to reduce intraocular pressure in the

anterior chamber of the eye in patients with neovascular glaucoma or with glaucoma when medical and conventional surgical treatments have failed (21CFR 886.3920). They differ in their design with respect to the size, shape, material composition of the end plate, and presence of a valve mechanism to limit flow through the shunt if the intraocular pressure becomes too low (American Academy of Ophthalmology, 2018).

The U.S. Food and Drug Administration (2018) has approved several devices for marketing in the United States. Examples of nonvalved implants are the Baerveldt® glaucoma implant (Abbott Medical Optics, Santa Ana, California) and the Molteno® implant (Molteno Ophthalmic Ltd., Dunedin, New Zealand). An example of a valved implant is the Ahmed® glaucoma valve (New World Medical Inc., Rancho Cucamonga, California).

Findings

We included three systematic reviews and six evidence-based guidelines for this policy. The systematic reviews assessed the safety and efficacy of aqueous shunt surgery for treatment of mixed glaucoma subtypes (majority with primary open-angle subtype) in pediatric and adult populations (Chen, 2014; HaiBo, 2015; Tseng, 2017). The available evidence consists of multiple randomized and nonrandomized controlled trials of older pediatric and adult populations (HaiBo, 2015; Tseng, 2017) and nonrandomized case series of younger children (Chen, 2014) comparing aqueous shunts to trabeculectomy, to each other, or to modifications of the procedure. The three most commonly studied aqueous shunts represented in these reviews were the Baerveldt implant, the Molteno implant, and the Ahmed glaucoma valve. Overall, the evidence is limited in quality, even among higher level study designs, due to a high risk of bias and poor reporting of study designs and findings.

The evidence suggests aqueous shunts are effective in reducing intraocular pressure, the number of glaucoma medications, and overall adverse events. Contraindications are related to existing eye morphology and pathology, and patient adherence to postprocedure requirements. The principal long-term complication of anterior chamber aqueous shunts is corneal endothelial decompensation. Complications more commonly found in pediatric populations include tube migration, tube erosion, and infection. The evidence for determining the superiority of aqueous shunts over trabeculectomy or other procedures, one type of aqueous shunt to another, or any procedure modification is inconclusive (Tseng, 2017).

Guidelines agree that aqueous shunts are an effective surgical option for glaucoma, but controversy persists regarding when they should be used in the sequence of glaucoma surgeries (American Academy of Ophthalmology, 2018; American Optometry Association, 2010; National Institute for Health and Care Excellence, 2017). Surgery is generally reserved for patients who continue to show progressive visual field loss on maximal medical therapy, are intolerant of glaucoma medications, or are poorly adherent to treatment plans. Most cases of primary pediatric glaucoma are treated with surgery such as trabeculotomy and goniotomy, but aqueous shunts can be beneficial (Chen, 2014). The importance of aqueous shunts has grown substantially in the last few decades, as lifespans increase and more people with advanced glaucoma require vision-sustaining therapies beyond traditional medical and surgical treatments (American Academy of Ophthalmology, 2018).

In 2019, we added four systematic reviews and meta-analyses to the policy (King, 2018; Pimentel, 2018; Ramdas, 2019; Wang, 2018). The new results are consistent with the current policy and warrant no changes. The policy ID was changed from CP# 10.03.08 to CCP.1381.

In 2020, we added findings from a Cochrane review (Foo, 2019) and a randomized prospective study comparing the safety and efficacy of the Ahmed (n = 266 patients) and Baerveldt (n = 286 patients) devices (Moschos, 2019). Foo (2019) examined the safety and effectiveness of intraoperative mitomycin C compared to no mitomycin C in aqueous shunt surgery for primary and secondary glaucoma. Mitomycin C is an antifibrotic agent applied during aqueous shunt surgery to prevent scar tissue formation around the implanted shunt. A meta-analysis of five randomized controlled trials (n = 333 total eyes) found no clear effect of mitomycin C on mean

intraocular pressure at 12 months (mean difference -0.12 mmHg, 95% confidence interval -2.16 to 2.41; low-certainty evidence).

In the comparative study (Moschos, 2019), both the Ahmed and Baerveldt devices achieved significant reductions in intraocular pressure, but recipients of the Ahmed valve had a significantly greater intraocular pressure reduction and a significantly lower number of medications required from baseline to 1, 3 and 5 years postoperatively than recipients of the Baerveldt device. The incidence of treatment failure and the rate of glaucoma reoperation were significantly higher in the Baerveldt group (40%) compared to the Ahmed group (17%). The new findings warranted no changes to the policy.

In 2021, we added no new findings to the policy. No policy changes are warranted.

References

On March 10, 2021, 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 “Glaucoma” (MeSH), “Glaucoma Drainage Implants” (MeSH), “aqueous shunt,” and “glaucoma drainage.” 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

5/2018: initial review date and clinical policy effective date: 7/2018

6/2019: Policy references updated. Policy ID changed.

6/2020: Policy references updated.

6/2021: Policy references updated.