Clinical Policy Title: Aqueous shunts for glaucoma

Clinical Policy Number: 10.03.08

Effective Date: July 1, 2018
Initial Review Date: May 1, 2018
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Related policies:
CP# 10.01.04 Glaucoma testing
CP# 10.01.05 Fundus photography
CP# 10.03.03 Canaloplasty and viscocanalostomy in treatment of glaucoma

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 Select Health of South Carolina 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. Select Health of South Carolina’s 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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of aqueous shunts to be clinically proven and, therefore, medically necessary for:

- Members diagnosed with open-angle glaucoma who meet both criteria (American Academy of Ophthalmology, 2018a; Tseng, 2017; American Optometric Association, 2010):
  - 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, 2018a; American Association for Pediatric Ophthalmology and Strabismus, 2014; Chen, 2014):

Policy contains:
- Aqueous shunt.
- Tube shunt or seton glaucoma surgery.
- Intraocular pressure.
- Glaucoma.
- 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). 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 is more common in the elderly but can develop at any age (McMonnies, 2017). Other risk factors include African American ancestry, family history of glaucoma, diabetes, previous cataract surgery, and elevated intraocular pressure.

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:**

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).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
We conducted searches on March 30, 2018. Search terms were: “Glaucoma” (MeSH), “Glaucoma Drainage Implants” (MeSH), and free text terms “aqueous shunt” and “glaucoma drainage.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**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 (Tseng, 2017; HaiBo, 2015; Chen, 2014). The available evidence consists of multiple randomized controlled trials of older pediatric and adult populations and nonrandomized case series of younger children 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, 2018a and b; National Institute for Health and Care Excellence, 2017; American Optometry Association, 2010; American Optometry Association, 2001). 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 (American Association for Pediatric Ophthalmology and Strabismus, 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, 2018a).

Policy updates:
None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tseng (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Cochrane review</td>
<td>• Systematic review and meta-analysis of 27 randomized controlled trials (2,099 total participants of mixed glaucoma types) comparing aqueous shunts (Ahmed or Baerveldt) to standard surgery (four trials), another type of aqueous shunt (Ahmed, Baerveldt, or Molteno) five trials), or modification to the aqueous shunt procedure (18 trials); one trial included children with pediatric aphakic glaucoma.</td>
</tr>
<tr>
<td>Aqueous shunts for</td>
<td>• Overall quality: low with a moderate-to-high risk of bias.</td>
</tr>
<tr>
<td>glaucoma</td>
<td>• Inconclusive evidence to determine the superiority of aqueous shunts over trabeculectomy (very low-certainty evidence), one type of aqueous shunt to another (low- and moderate-certainty evidence), or any procedure modification (low-quality).</td>
</tr>
<tr>
<td>haiBo (2015)</td>
<td>• There are no well-justified or widely accepted generalizations about the superiority of one surgical procedure or device over another.</td>
</tr>
<tr>
<td>Comparison of Ahmed</td>
<td>Key points:</td>
</tr>
<tr>
<td>glaucoma valve</td>
<td>• Systematic review and meta-analysis of six controlled clinical trials (two randomized, four nonrandomized) comparing the efficacy and safety of Ahmed glaucoma valve implantation with trabeculectomy in patients older than 4 years with glaucoma of varying risk.</td>
</tr>
<tr>
<td>implantation and</td>
<td>• Overall quality: quality scores were &gt; 50%, deemed adequate by investigators.</td>
</tr>
<tr>
<td>trabeculectomy for</td>
<td>• Ahmed glaucoma valve was equivalent to trabeculectomy in reducing the intraocular pressure, the number of glaucoma medications, success rates, and rates of the most common complications, but was associated with a significantly lower frequency of overall adverse events.</td>
</tr>
<tr>
<td>glaucoma</td>
<td>• Most common complications were hypotony, hyphema, shallow anterior chamber, bleb leakage, and corneal drying/dellen.</td>
</tr>
<tr>
<td></td>
<td>• Pragmatic randomized controlled trials with long duration and a large sample size are needed.</td>
</tr>
</tbody>
</table>
Citation | Content, Methods, Recommendations
---|---
Chen (2014) for the American Academy of Ophthalmology | **Key points:**
- Systematic review of 15 nonrandomized case series of patients younger than 18 years with primary congenital glaucoma, juvenile open-angle glaucoma, and secondary glaucoma with other associated ocular abnormalities.
- Success rates, or probabilities of success, ranged from 31.3% to 97.2%.
- Tube shunt surgery may be a good option in aphakic patients who have lower success rates with trabeculectomy and who may require contact lens wear for visual rehabilitation.
- Complications more commonly found in pediatric populations include tube migration, tube erosion, and infection.
- Many children require intraocular pressure-lowering medications after tube shunt surgery, with reported rates of up to 85.8%.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

A52432 Local Coverage Article: Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (0192T).

**Local Coverage Determinations (LCDs):**
No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion</td>
<td></td>
</tr>
<tr>
<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device</td>
<td></td>
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<tr>
<td>0450T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)</td>
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<tr>
<td>66180</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft</td>
<td></td>
</tr>
<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
<td></td>
</tr>
<tr>
<td>66185</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>H40.1110 - H40.1194</td>
<td>Primary open-angle glaucoma</td>
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<thead>
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<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>C1783</td>
<td>Ocular implant, aqueous drainage assist device</td>
<td></td>
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<tr>
<td>L8612</td>
<td>Aqueous shunt</td>
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