Aqueous Shunts and Stents for Glaucoma
Corporate Medical Policy

Description/Summary

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches (e.g., trabeculectomy), a variety of shunts are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Policy

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I - Coding Table

When a service may be considered medically necessary

Aqueous shunts may be considered medically necessary when all the following criteria have been met:

- Shunt is approved by the U.S. Food and Drug Administration (FDA); AND
- Diagnosis of Glaucoma; AND
- Conservative therapy has failed.

Microstents may be considered medically necessary when all the following criteria have been met:

- Microstent is approved by the U.S. Food and Drug Administration (FDA); AND
- Microstent is being used in conjunction with cataract surgery; AND
- Diagnosis of mild-to-moderate Open-Angle Glaucoma; AND
- Undergoing active treatment with an ocular hypotensive medication.
When a service is considered investigational

Aqueous shunts are considered investigational when the above criteria has not been met.

Microstents are considered investigational when the above criteria has not been met.

Policy Guidelines

Shunts and stents are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

Background

Glucoma

Surgical procedures for glaucoma aim to reduce intraocular pressure (IOP) resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Treatment

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering “blebs” on the eye, and is associated with numerous complications (eg, leaks, bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed herein) include trabecular laser ablation, deep sclerectomy (which removes the outer wall of the Schlemm canal and excises deep sclera and peripheral cornea), and viscocanalostomy (which unroofs and dilates the Schlemm canal without penetrating the trabecular meshwork or anterior chamber).

The Trabectome, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of the Schlemm canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Canaloplasty involves dilation and tension of the Schlemm canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack illuminated microcatheter (iScience Interventional) to access and dilate the entire length of the Schlemm canal and to pass the suture loop through the canal (see evidence review 9.03.26).

Aqueous shunts may also be placed in the anterior or posterior chamber to facilitate drainage of aqueous humor. Examples of shunts cleared by the U.S. Food and Drug Administration include the Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Molteno (IOP), and EX-Press mini-shunt (Alcon), which shunt aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ by explant surface areas, shape, plate
thickness, presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts compared to trabeculectomy, but IOP outcomes are worse than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is lower with shunts than with trabeculectomy, and failure rates are similar (≈10% of devices fail annually). The primary indication for aqueous shunts is for failed medical or surgical therapy, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Aqueous stents are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into the Schlemm canal or the suprachoroidal space. They include the iStent (Glaukos), which is a 1-mm long stent inserted into the end of the Schlemm canal by an internal approach through the cornea and anterior chamber; the second-generation iStent inject; the third-generation iStent supra, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass (Transcend Medical) suprachoroidal stent.

Because aqueous humor outflow is pressure-dependent, pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used (eg, <15 mm Hg) and are not indicated for patients for whom very low IOP is desired (eg, those with advanced glaucoma). It has been proposed that stents such as the iStent, CyPass, and Hydrus Microstent may be useful in patients with early-stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than 1 shunt to achieve desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

**Reference Resources**

1. Aqueous Shunts and Stents for Glaucoma, Blue Cross & Blue Shield Association MPRM. Last reviewed May 2018.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered compete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.
Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

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<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>06/2017</td>
<td>New policy</td>
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<tr>
<td>11/2018</td>
<td>Reviewed literature, provider &amp; industry input and updated references</td>
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<tr>
<td>11/2018</td>
<td>Reviewed and archived medical policy effective 07/01/2019. Codes no longer require PA: 66179, 66180, 66183, 66184, 66185, 0191T, 0474T</td>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors       Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, FAAP
Senior Medical Director
### Attachment I

#### Coding Table

The following codes will be considered medically necessary when applicable criteria have been met.

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Brief Description</th>
<th>Policy Instructions</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>66179</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft</td>
<td>Medically Necessary</td>
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<tr>
<td>CPT®</td>
<td>66180</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft</td>
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<td>CPT®</td>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
<td>Medically Necessary</td>
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<td>CPT®</td>
<td>66184</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft</td>
<td>Medically Necessary</td>
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<tr>
<td>CPT®</td>
<td>66185</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft</td>
<td>Medically Necessary</td>
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<td>CPT®</td>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion</td>
<td>Medically Necessary</td>
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The following codes are considered investigational.

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<th>Brief Description</th>
<th>Policy Instructions</th>
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<tr>
<td>CPT®</td>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the subarachnoid space</td>
<td>Investigational</td>
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<tr>
<td>CPT®</td>
<td>0376T</td>
<td>Each additional device insertion (List separately in addition to code for primary procedure)</td>
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<td>CPT®</td>
<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device</td>
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<td>CPT®</td>
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