Medical Coverage Policy | Aqueous Shunts and Stents for Glaucoma

EFFECTIVE DATE: 08|19|2014
POLICY LAST UPDATED: 05|17|2016

OVERVIEW
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 such as trabeculectomy, a variety of devices, including aqueous 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Insertion of aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure.

Use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Implantation of a single FDA-approved microstent in conjunction with cataract surgery may be considered **medically necessary** in patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Use of a microstent for all other conditions is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery coverage/benefits and limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
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 Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

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 (e.g., leaks or bleb-related endophthalmitis) and long-term failure.

Aqueous shunts may also be placed in the anterior or posterior chamber to facilitate drainage of aqueous humor. Established shunts include the Ahmed™ (New World Medical), Baerveldt® (Advanced Medical Optics), Molteno® (IOP), ExPress® mini-shunt (Alco), and the SOLX® DeepLight® Gold Micro-Shunt (SOLX), which shunts aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ depending on explant surface areas, shape, plate thickness, the 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, with about 10% of devices failing each year. The primary indication for aqueous shunts is when prior medical or surgical therapy has failed, 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. These 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, the pressure in the reservoir and venous system are critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used (e.g., <15 mm Hg) and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). It has been proposed that stents such as the iStent, CyPass, and Hydrus Microstent may be useful to lower IOP 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 the desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy, complications, and durability of the device.

CODING

BlueCHiP for Medicare and Commercial Products

When the following codes are filed for the medically necessary conditions listed in the Policy Statement, they are covered. When the codes are filed for other conditions, they are considered not medically necessary.

0253T
0376T
0474T (code effective date 7/1/2017)
66183

The following code is covered for BlueCHiP for Medicare. For Commercial products, it is covered for the medically necessary conditions listed in the Policy Statement and is considered not medically necessary when filed for other conditions.

0191T

The following codes are not medically necessary:
0449T (New code effective 1/1/2017)
0450T (New code effective 1/1/2017)

RELATED POLICIES
Viscocanalostomy and Canaloplasty

PUBLISHED
Provider Update, July 2016
Provider Update, December 2015
Provider Update, November 2014
Provider Update, July 2013
Provider Update, July 2011
Provider Update, July 2010
Provider Update, June 2009

REFERENCES

1. Minckler DS, Vedula SS, Li TJ, et al. Aqueous shunts for glaucoma. Cochrane Database Syst Rev. 2006(2):CD004918. PMID 16625616
2. Minckler DS, Francis BA, Hodapp EA, et al. Aqueous shunts in glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology. Jun 2008;115(6):1089-1098. PMID 18519069
3. Boland MV, Ervin AM, Friedman D, et al. Treatment for Glaucoma: Comparative Effectiveness. Comparative Effectiveness Review No. 60. (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. HHSA 290-2007-10061-I.) AHRQ Publication No. 12-EHC038-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2012.
4. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. Am J Ophthalmol. May 2012;153(5):789-803 e782. PMID 22245458
5. Netland PA, Sarkisian SR, Jr., Moster MR, et al. Randomized, prospective, comparative trial of EX-PRESS glaucoma filtration device versus trabeculectomy (XVT study). Am J Ophthalmol. Feb 2014;157(2):433-440 e433. PMID 24210765
6. de Jong LA. The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: a prospective randomized study. Adv Ther. Mar 2009;26(3):336-345. PMID 19337705
7. de Jong L, Lafuma A, Aguade AS, et al. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. Clin Ophthalmol. 2011;5:527-533. PMID 21607021
8. U.S. Food and Drug Administration. FDA Executive Summary, Glaucos, Inc. iStent Trabecular Micro-Bypass Stent. 2010; http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/UCM220398.pdf. Accessed July 7, 2015.

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