

Corporate Medical Policy

Aqueous Shunts and Devices for Glaucoma

File Name:	aqueous_shunts_and_devices_for_glaucoma
Origination:	3/2010
Last CAP Review:	6/2019
Next CAP Review:	6/2020
Last Review:	6/2019

Description of Procedure or Service

Glaucoma is characterized by elevated intraocular pressure (IOP), which results in visual field loss and irreversible blindness if left untreated. 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

Ocular Medication

First-line treatment typically involves pharmacologic therapy. Topical medications either increase aqueous outflow (prostaglandins, alpha-adrenergic agonists, cholinergic agonists, Rho kinase inhibitors) or decrease aqueous production (alpha-adrenergic agonists, beta blockers, carbonic anhydrase inhibitors). Pharmacologic therapy may involve multiple medications, have potential side effects, and may be inconvenient for older adults or incapacitated patients.

Surgery

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Surgical procedures for glaucoma aim to reduce IOP from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm canal. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, which involves dissecting the conjunctiva, creating a scleral flap and scleral ostomy then suturing down the flap and closing the conjunctiva, 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., hemorrhage, scarring, hypotony, infection, leaks or bleb-related endophthalmitis) and long-term failure.

Insertion of shunts from outside the eye (ab externo) is another surgical option to lower IOP. Examples of ab externo devices cleared by the U.S. Food and Drug Administration (FDA) include the Ahmed, Baerveldt, Molteno, and EX-PRESS mini-shunt, 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 with 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

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intervention, particularly for selected conditions such as congenital glaucoma, uveitic, glaucoma, and neovascular glaucoma.

Minimally Invasive Glaucoma Surgeries

MIGS are alternative, less invasive techniques which use microscopic-sized equipment and smaller incisions, and involve less surgical manipulation of the sclera and the conjunctiva compared with other surgical techniques. There are several categories of MIGS: miniaturized trabeculectomy, trabecular bypass, milder laser photocoagulation, and totally internal or suprachoroidal stents (ab interno). This policy evaluates the placement of ab interno stents.

Examples of ab interno devices either approved or given marketing clearance by the FDA include the iStent, which is a 1-mm long stent inserted into the end of the Schlemm canal through the cornea and anterior chamber; the CyPass suprachoroidal stent; the Hydrus stent; and XEN gelatin stent. Because aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below episcleral venous pressure (eg, <10 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, 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 stents is that they may be inserted through the same incision and at the same time as cataract surgery. Also, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one stent 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.

Regulatory Status

Ab externo

The first generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision) and Molteno (Molteno Ophthalmic) ab externo aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were cleared in 2006. Their indication for use is “in patients with intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.” The EXPRESS™ Mini Glaucoma Shunt received 510(k) marketing clearance in 2003.

Ab interno

In 2016, the Xen® Glaucoma Treatment System (Allergan), which consists of the XEN45 Gel Stent preloaded into the XEN injector, was cleared for marketing by the FDA through the 510(k) process as an ab interno aqueous shunt for management of refractory glaucoma. The approval was for patients with refractory glaucoma who failed previous surgical treatment or for patients with primary open-angle glaucoma unresponsive to maximum tolerated medical therapy. FDA determined that this device was substantially equivalent to existing devices, specifically the Ahmed Glaucoma Valve and the EXPRESS Glaucoma Filtration Device.

In 2018, the iStent inject® was approved by the FDA through the 515(d) process for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication.

The iStent inject represents the next generation after the iStent Trabecular Micro-Bypass Stent. The iStent Trabecular Micro-Bypass Stent labeling describes the following precautions:

1. The safety and effectiveness of the iStent Trabecular Micro-Bypass Stent has not been established as an alternative to the primary treatment of glaucoma with medications. The effectiveness of this

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device has been demonstrated only in patients with mild to moderate open-angle glaucoma who are undergoing concurrent cataract surgery for visually significant cataract.

2. The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established in patients with the following circumstances or conditions which were not studied in the pivotal trial:
- In children
 - In eyes with significant prior trauma
 - In eyes with abnormal anterior segment
 - In eyes with chronic inflammation
 - In glaucoma associated with vascular disorders
 - In pseudophakic patients with glaucoma
 - In uveitic glaucoma
 - In patients' eyes with prior incisional glaucoma surgery or cilioablative procedures
 - In eyes with prior trabeculectomy with selective LT within 90 days prior to screening or prior to argon laser trabeculectomy at any time
 - In patients with medicated intraocular pressure greater than 24 mmHg
 - In patients with unmedicated IOP less than 21 mmHg nor greater than 36 mmHg after "washout" of medications
 - For implantation of more or less than two stents
 - After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitreotomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL (intraocular lens)
 - When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract
 - In patients with pseudoexfoliative glaucoma or pigmentary glaucoma, or in patients with other secondary open-angle glaucoma.

In August 2018, Alcon announced an immediate voluntary recall of the CyPass microstent, which had been approved by the FDA in 2016 for use in conjunction with cataract surgery in adults with mild-to-moderate open-angle glaucoma. The recall was based on five-year post surgery data from the COMPASS-ZXT long term safety study. Results showed a statistically significant increase in endothelial cell loss among patients receiving the CyPass microstent compared with patients receiving cataract surgery alone.

Related Policies:

Glaucoma Evaluation by Ophthalmologic Techniques
Viscocanaloplasty and Canaloplasty

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will cover aqueous shunts and devices for glaucoma when determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Aqueous Shunts and Devices for Glaucoma are covered

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Insertion of ab externo 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 or in patients intolerant to medical therapy.

Insertion of ab interno aqueous stents approved by the Food and Drug Administration as a stand-alone procedure as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure, or in patients intolerant to medical therapy, is considered medically necessary. (see Policy Guidelines)

Implantation of 1 or 2 FDA-approved ab interno stents in conjunction with cataract surgery may be considered medically necessary in patients with mild to moderate open-angle glaucoma treated with ocular hypotensive medication. (see Policy Guidelines)

When Aqueous Shunts and Devices for Glaucoma are not covered

Use of an ab externo aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered investigational.

Use of ab interno stents for all other conditions is considered investigational.

Policy Guidelines

At this time, the XEN gel stent and injector is the only ab interno stent system FDA-approved as a stand-alone procedure for the treatment of refractory open angle glaucoma.

The iStent inject, ab interno stent FDA approved for use in conjunction with cataract surgery, is pre-loaded with 2 stents.

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.

For individuals who have refractory open-angle glaucoma who receive ab externo aqueous shunts, the evidence includes randomized controlled trials (RCTs), retrospective studies, and systematic reviews. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. RCTs assessing U.S. Food and Drug Administration (FDA)- approved shunts have shown that the use of large externally placed shunts reduces IOP to slightly less than standard filtering surgery (trabeculectomy). However, reported shunt success rates show that these devices are noninferior to trabeculectomy in the long term. FDA-approved shunts have a different adverse event profile and avoid some of the most problematic complications of trabeculectomy. Two trials have compared the Ahmed and Baerveldt shunts. Both found that eyes treated with the Baerveldt shunt had slightly lower average IOP at 5 years than eyes treated with the Ahmed but the Baerveldt also had a higher rate of serious hypotony-related complications. The evidence is sufficient to determine quantitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have refractory open-angle glaucoma who receive ab interno aqueous stents as a stand-alone procedure, the evidence includes a nonrandomized retrospective comparative study and several single-arm studies. The relevant outcomes are a change in disease status, functional outcomes, medication use, and treatment-related morbidity. The comparative study reported that patients receiving the stent experienced similar reductions in IOP and medication use as patients undergoing trabeculectomy. The single-arm studies, with 12-month follow-up results, consistently showed that patients receiving the stents experienced reductions in IOP and medication use. Reductions in IOP ranged from 4 mm Hg to over 15 mm Hg. In addition, the FDA has given clearance to a gel stent based on equivalent IOP and medication use reductions as seen with ab externo shunts. Clearance for the stent

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was based on a review in which the FDA concluded that while there were technical differences between the stent and predicate devices (shunts), the differences did not affect safety and effectiveness in lowering IOP and medication use. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have mild to moderate open-angle glaucoma who receive aqueous microstents during cataract surgery, the evidence includes RCTs and safety data from case-series. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Implantation of one or two microstents have received FDA approval for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild-to-moderate open-angle glaucoma currently treated with ocular hypotensive medication. RCTs have been conducted in patients with cataracts and less advanced glaucoma, where IOP is at least partially controlled with medication through the first 2 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications other than cataract surgery or refractory open-angle glaucoma who are treated with aqueous shunts or microstents, the evidence includes an RCT and an observational study.. Relevant outcomes are change in disease status, functional outcomes, medication use, and treatment-related morbidity. Several RCTs have evaluated the use of multiple microstents, but comparators differed. One RCT compared a single microstent with multiple microstents. This trial reported no difference in the primary outcome (percentage of patients with 20% or greater reduction in IOP); secondary outcomes favored the multiple microstent groups. An observational study described implantation of two or three stents, at the discretion of the operating surgeon. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0191T, 0253T, 0376T, 0444T, 0445T, 0449T, 0450T, 0474T, 66179, 66180, 66183, 66184, C1783, L8612

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 12/10/2009

Senior Medical Director –3/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 5/12/2011

Specialty Matched Consultant Advisory Panel review- 6/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 5/10/12

Specialty Matched Consultant Advisory Panel review- 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 10/11/2012

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Specialty Matched Consultant Advisory Panel review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 9/12/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 3/13/2014

Specialty Matched Consultant Advisory Panel review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 9/11/2014

Specialty Matched Consultant Advisory Panel review- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 9/10/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 3/10/2016

Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 3/9/2017

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 5/4/2018

Specialty Matched Consultant Advisory Panel review- 6/2018

Medical Director review 6/2018

Medical Director review 8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 12/13/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.21, 3/14/2019

Medical Director review 4/2019

Specialty Matched Consultant Advisory Panel review- 6/2019

Policy Implementation/Update Information

- 3/30/10 New policy implemented. Reviewed by Senior Medical Director 3/4/2010. "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 patients with glaucoma when intraocular pressure is controlled by medications, is considered investigational. "Canaloplasty is considered investigational as a method to reduce intraocular pressure in patients with glaucoma." (btw)
- 6/22/10 Policy Number(s) removed. (amw)
- 1/4/11 Added new CPT codes 66174, 66175, 0253T to Billing/Coding section. Removed deleted CPT code 0177T. (lpr)

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- 7/19/11 Under Description section: added “Stents and tensioning devices 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.” Under “When Covered” section added: “Canaloplasty may be considered **medically necessary** as a method to reduce intraocular pressure in patients with glaucoma under the following conditions: medical therapy has failed to adequately control intraocular pressure, AND the patient is not a candidate for any other intraocular pressure lowering procedure (e.g. trabeculectomy or glaucoma drainage implant).” Under “When Not Covered” section: added “under all other conditions, including angle closure glaucoma as a method to reduce intraocular pressure” to investigational statement. Specialty Matched Consultant Advisory Panel review meeting 6/29/2011. Reference added. (lpr)
- 7/10/12 Specialty Matched Consultant Advisory Panel review meeting 6/20/12. Removed CPT codes 66174 and 66175 from Billing/Coding section. Removed canaloplasty references under When Covered section since new Canaloplasty policy addresses. Revised description section and policy guidelines. No changes to policy statement.(lpr)
- 12/11/12 Revised the description and policy guidelines sections. Under “When Not Covered” section added investigational statement: “Use of a micro-stent is considered investigational.” Notification given 12/11/12 for effective date 3/12/13. (lpr)
- 7/16/13 Specialty Matched consultant advisory panel review 6/19/2013. No changes to policy statement. (lpr)
- 10/29/13 Revised Description and Policy Guidelines sections. Under “When Covered” section added the statement “Implantation of a single FDA-approved micro-stent 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.” Reference added. (lpr)
- 12/31/13 Added CPT code 66183 and deleted 0192T from the Billing/Coding section for 2014 code update. (lpr)
- 7/15/14 Specialty matched consultant advisory panel meeting 6/24/2014. No change to policy statement. (lpr)
- 10/28/14 Minor revisions to Description and Policy Guidelines sections. Reference added. No change to policy statement. (lpr)
- 12/30/14 Added CPT codes 0376T, 66179, 66184 to the Billing/coding section for effective date 1/1/2015. (lpr)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 10/30/15 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/29/16 Updated Policy Guidelines. Reference added. No change to policy statement. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. Added CPT codes 0444T and 0445T to the Billing/Coding section for effective date 7/1/2016. No change to policy statement. (lpr)
- 12/30/16 Added CPT codes 0449T and 0450T to Billing/Coding section for effective date 1/1/2017.(lpr)

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- 3/31/17 Added HCPCS codes C1783 and L8612 to the Billing/Coding section. Updated Description and Policy Guidelines sections. Removed the word “currently” from covered statement #2 beginning with “Implantation of a single FDA approved microstent...” under “When Covered” section. Reference added. (lpr)
- 7/28/17 Added CPT code 0474T to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 9/28/18 Specialty Matched Consultant Advisory Panel review 6/27/2018. Added intolerance to medical therapy to policy statement in “When Covered” section. Updated Description section. Medical Director review 8/2018. Reference added. (lpr)
- 4/16/19 Extensive revisions to Policy Guidelines, Description sections. Updated Regulatory Status. Under “When Covered” section: added medical necessity language for ab externo and ab interno stents as well as implantation of 1 or more ab interno stents. References added. Medical Director review 4/2019. (lpr)
- 7/16/19 Specialty Matched Consultant Advisory Panel review 6/17/2019. Updated description section. No change to policy statement. Medical director review 6/2019. (lpr)

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