Protocol

Aqueous Shunts and Stents for Glaucoma

(90321)

Medical Benefit		**Effective Date**: 04/01/14	**Next Review Date**: 01/15
Preauthorization	No	**Review Dates**: 03/10, 03/11, 07/11, 01/12, 09/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but recommended if the patient does not meet the criteria of the Protocol.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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. Micro-stents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Background

Surgical procedures for glaucoma aim to reduce intraocular pressure (IOP) resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm's 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's 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's 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. Other surgical procedures (not addressed in this Protocol) include trabecular laser ablation, deep sclerectomy, which removes the outer wall of Schlemm's canal and excises deep sclera and peripheral cornea, and viscocanalostomy, which unroofs and dilates Schlemm's canal without penetrating the trabecular meshwork or anterior chamber.

More recently the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm's 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 Schlemm's 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 Schlemm's canal and to pass the suture loop through the canal.

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 in comparison with trabeculectomy, but IOP outcomes are higher 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 less than after 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.

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

Since 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., below 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 for 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 one 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.

Regulatory Status

Device	Manufacturer	Type	FDA Status	Date
AquaFlow™	Staar Surgical	Drainage device	PMA	2001
Trabectome™	NeoMedix	Electrocautery device	510(k)	2006
Ahmed™	New World Medical	Aqueous glaucoma shunt	510(k)	< 1993
Baerveldt®	Advanced Medical Optics	Aqueous glaucoma shunt	510(k)	< 1993
Krupin	Eagle Vision	Aqueous glaucoma shunt	510(k)	< 1993
Molteno®	Molteno Ophthalmic	Aqueous glaucoma shunt	510(k)	< 1993
Ex-PRESS™	Alco	Mini-glaucoma shunt	510(k)	2003
iStent®	Glaukos	Micro-stent	PMA	2012
Hydrus™	Ivantis	Micro-stent	Not Approved	
iStent inject®	Glaukos	Suprachoroidal stent	Not Approved	
iStent supra®	Glaukos	Suprachoroidal stent	Not Approved	
CyPass®	Transcend Medical	Suprachoroidal stent	Not Approved	

The first generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno (Molteno Ophthalmic) aqueous shunts received marketing clearance from the U.S. Food and Drug Administration (FDA) between 1989 and 1993; modified Ahmed and Molteno devices were most recently 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 AquaFlow™ Collagen Glaucoma Drainage

Device received premarket approval from the FDA in 2001 for the maintenance of sub-scleral space following non-penetrating deep sclerectomy. The Ex-PRESS™ Mini Glaucoma Shunt received 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb.

In 2012, the FDA approved the Glaukos Corporation's iStent® Trabecular Micro-Bypass Stent, PMA P080030, as indicated 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.

The 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 device has been demonstrated only in patients with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and 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 with prior glaucoma surgery of any type, including argon laser trabeculoplasty
    - In patients with medicated intraocular pressure greater than 24 mm Hg
    - In patients with unmedicated IOP less than 22 mm Hg nor greater than 36 mm Hg after "washout" of medications
    - For implantation of more than a single stent
    - After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy 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

Note: Use of the iStent® has subsequently been reported for many of the circumstances or conditions listed above; most of the publications are case series.

The SOLX gold shunt and Hydrus Microstent are currently in FDA-regulated trials. They have received regulatory approval in Europe, but are not FDA-approved/cleared for use in the U.S. at this time.

Related Protocol

Viscocanalostomy and Canaloplasty

Policy (Formerly Corporate Medical Guideline)

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 **investigational**.

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.

Use of a micro-stent for all other indications is considered **investigational**.

Policy Guideline

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.

Medicare Advantage

An anterior segment aqueous drainage device, without extraocular reservoir, implanted under a partial thickness scleral flap may be a **medically necessary** alternative or adjunct to standard guarded trabeculectomy, especially for patients with advanced glaucoma in need of low intraocular pressures with a high risk for hypotonus complication.

An anterior segment aqueous drainage device, without extraocular reservoir, performed with cataract surgery (internal approach) may be **medically necessary** for Medicare Advantage members with mild to moderate glaucoma on medication.

Devices must be devices approved by the FDA.

Other indications via external or internal approach are considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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