

EFFECTIVE DATE: 08|19|2014
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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 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 ab externo aqueous shunts approved by the U.S. Food and Drug Administration 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.

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

BlueCHiP for Medicare

Insertion of ab interno aqueous stents approved by the Food and Drug Administration as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure, is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Use of an ab externo aqueous shunt or ab interno aqueous stent for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Insertion of ab interno aqueous stents approved by the Food and Drug Administration as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure, is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Use of an ab externo aqueous shunt or ab interno aqueous stent for all other conditions, including in patients with glaucoma when intraocular pressure is adequately controlled by medications, is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

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

BACKGROUND

GLAUCOMA

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, 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 (eg, hemorrhage, scarring, hypotony, infection, leaks, bleb-related endophthalmitis and long-term failure).

Currently, minimally invasive glaucoma surgeries (MIGS) are alternative, less invasive techniques that are being developed and evaluated. Similar to trabeculectomy, the objective of MIGS is to lower IOP by improving outflow of eye fluid; however, MIGS involves less surgical manipulation of the sclera and the conjunctiva compared than a trabeculectomy. MIGS can either be performed outside the eye (ab externo) or inside the eye (ab interno).

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 (approximately 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.

Examples of ab interno devices either approved or given marketing clearance by 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; 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 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 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 into 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 1 stent 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.

For individuals who have refractory open-angle glaucoma who receive ab interno aqueous stents, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are covered only when used for a covered indication.

- 66183** Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach
- 0191T** Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; initial insertion
- 0253T** Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space
- 0376T** Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)
- 0449T** Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
- 0450T** 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)
- 0474T** Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

RELATED POLICIES

Viscocanalostomy and Canaloplasty

PUBLISHED

Provider Update, November/December 2018

Provider Update, November 2017

Provider Update, July 2016

Provider Update, December 2015

Provider Update, November 2014

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