



# Medical Coverage Policy

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## Glaucoma Surgical Procedures

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## Overview

This Coverage Policy addresses established and emerging surgical procedures for the treatment of glaucoma including aqueous shunts and various proposed surgical interventions.

## Coverage Policy

### Aqueous Shunts/Aqueous Drainage Devices

**Any of the following aqueous shunts/aqueous drainage devices (CPT®/HCPCS Codes 66179, 66183) is considered medically necessary for refractory glaucoma when there is failure, intolerance or contraindication to conventional medical (i.e., topical or oral medication) and surgical (i.e., laser therapy, trabeculectomy) treatment:**

- Ahmed™ glaucoma valve
- Baerveldt® glaucoma implant
- ExPRESS™ mini glaucoma shunt
- Krupin eye valve
- Molteno® implant

**Insertion of a single XEN®45 Gel Stent (CPT Codes® 0449T, 66183) is considered medically necessary for the management of refractory glaucoma, including ANY of the following:**

- primary open angle glaucoma
- failure of previous surgical treatment
- pseudoexfoliative or pigmentary glaucoma with open angles that is unresponsive to maximum tolerated medical therapy

**Insertion of iStent Infinite (CPT 0671T) in an individual age 18 years or older with open-angle glaucoma is considered medically necessary when there is failure, intolerance or contraindication to conventional medical and surgical treatment for reduction of intraocular pressure.**

**Each of the aqueous shunt/aqueous drainage devices listed above is considered not medically necessary for ANY other indication.**

### Procedures

**Canaloplasty (CPT Code® 66174, 66175), whether performed ab externo or ab interno, is considered medically necessary in an individual age 18 years or older for the treatment of open-angle glaucoma when there is failure, intolerance or contraindication to conventional medical management (i.e., topical or oral medication).**

**EACH of the following procedures is considered experimental, investigational or unproven for ANY indication:**

- transciliary fistulization (transciliary filtration, Singh filtration) (CPT Code® 66999)

- viscocanalostomy (including phacoviscocanalostomy) (CPT Code® 66999)

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

According to the Centers for Disease Control and Prevention (CDC), glaucoma is one of the leading causes of irreversible blindness in the United States (CDC, 2023). More than three million Americans have glaucoma. By 2050, that number is expected to rise to 6.3 million. According to the National Eye Institute (2023), a branch of the National Institute of Health (NIH), and the American Academy of Ophthalmology (AAO) (2020) those at risk for developing glaucoma include:

- Black/African American people at a younger age (age 40 years)
- People over the age of 60 years especially those of Hispanic/Latino descent
- People with diabetes
- People with a family history of glaucoma

## General Background

Glaucoma is a group of eye diseases that are depicted by chronic, progressive optic neuropathy. It is characterized by optic nerve damage that results in the progressive loss of retinal ganglion cell axons and is usually associated with increased intraocular pressure (IOP) (Jacobs, 2024). There are several forms of glaucoma with primary open angle glaucoma (POAG) being the most common. If left untreated, glaucoma can result in partial or complete visual impairment or blindness. Currently, intraocular pressure (IOP) is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision. Early diagnosis and treatment are essential to prevent visual disability.

In most cases, topical or oral medication is the first treatment of choice. For patients who are unwilling or unable to use medications or are unresponsive to medications, laser therapy or trabeculectomy, may be an option. Although laser therapy reduces IOP initially, its effects diminish over the course of a few years, and repetition of the procedure may not be beneficial. Trabeculectomy, an invasive procedure, is the current standard surgical technique for reduction of IOP, but it can result in extremely low IOP, causing ocular damage. Over time, the surgery may fail due to scar formation at the drainage site. Aqueous shunts have been developed as an alternative surgical treatment for patients with inadequately controlled glaucoma. Microstents have also been evaluated in the treatment of mild to moderate glaucoma in patients who are receiving treatment with ocular hypotensive medication.

Minimally invasive or microincisional glaucoma surgery (MIGS) has been proposed to provide a medication-sparing, conjunctival-sparing approach to lower intraocular pressure for patients with mild-to-moderate glaucoma. MIGS is proposed to be safer than traditional incisional glaucoma surgery. The terms goniotomy, trabeculotomy, and trabeculotomy ab interno all describe the same anatomical procedure which is opening of the trabecular meshwork to allow aqueous access to Schlemm's canal to reduce outflow resistance and consequently lower intraocular pressure. The

current approaches include: trabecular meshwork bypass by stent placement (e.g., iStent, iStent inject, Hydrus stent); trabecular meshwork bypass by tissue excision (e.g., Kahook Dual Blade Goniotomy, Trabectome, Goniocopy Assisted Transluminal Trabeculotomy [GATT], TRAB 360/OMNI); enhancing aqueous outflow through Schlemm's canal (e.g., Visco 360/OMNI, Ab Interno Canaloplasty [ABiC]); enhancing aqueous outflow through the suprachoroidal space (e.g., CyPass micro-stent); and shunting aqueous outflow into the subconjunctival space (e.g., XEN gel stent) (American Academy of Ophthalmology [AAO], 2023; Richter, et al., 2016). Alcon has voluntarily withdrawn the CyPass Micro-Stent from the global market based on five-year post-surgery data from the COMPASS-XT long-term safety study. The study demonstrated a clinically and statistically significant increase in corneal endothelial cell loss reported in the CyPass Micro-Stent group compared to the cataract surgery-only control group (FDA, 2018).

Additional surgical procedures including excimer laser trabeculostomy, transiliary fistulization and viscocanalostomy have been proposed for the treatment of glaucoma. However, there is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of these procedures.

### **Aqueous Shunts/Aqueous Drainage Devices**

Aqueous shunts, also known as aqueous drainage devices, glaucoma drainage devices, setons, tube implants and tube shunts, are drainage devices used to control intraocular pressure (IOP) in the management of glaucoma. First generation shunts in widespread use (e.g., Ahmed [New World Medical, Inc., Rancho Cucamonga CA], Baerveldt [Advanced Medical Optics, Inc. Santa Ana, CA], Krupin [Eagle Vision, Inc., Memphis TN], Molteno [Nova Eye Medical Limited, Fremont CA]) follow the same principles. They include an explant plate that, when encapsulated, creates a potential space into which aqueous humor can drain via a connecting tube. The explant plates are constructed of polypropylene or silicone rubber to which fibroblast cannot tightly adhere. Typically, the tube of a shunt is placed into the anterior chamber of the eye and drains into one or more plates. Shunts differ based on the type of materials used (e.g., silicone, gold, stainless steel); presence or absence of a valve or flow restrictor in the tube; explant surface area; and shape, size, thickness and number of plates. Aqueous shunts are associated with intraoperative and postoperative complications similar to trabeculectomy plus an additional risk related to implantation of a foreign body and erosion of the tube. Diplopia has also been reported. However, the risk of postoperative infection appears less with shunts compared to trabeculectomy. When a single quadrant device is in place and not providing adequate IOP control (i.e., clinical failure), an option is to add a second device in another quadrant (Minckler, et al., 2008; Schwartz, et al., 2006).

The EXPRESS™ Mini Glaucoma Shunt (Optonol, Israel) is a stainless steel non-valved device designed to have more reproducible results with less dependency on surgical skills than other aqueous shunts. The device is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber to the sub-conjunctival space, forming a bleb similar to trabeculectomy. Unlike a standard trabeculectomy, the procedure is noninvasive and does not require a traditional sclerectomy or iridectomy.

**U.S. Food and Drug Administration (FDA):** Examples of first-generation aqueous drainage devices that received FDA 510(k) clearance between 1988 and 1995 include the following:

- Ahmed™ Glaucoma Valve (New World Medical, Inc., Rancho Cucamonga, CA): management of intractable glaucoma, particularly in cases where previous filtering procedures have failed or are known to have unsatisfactory results
- Baerveldt® Pars Plana Glaucoma Implant (Pharmacia Lovision, Inc., Peapack, NJ): medically uncontrollable glaucoma with poor surgical prognosis

- Krupin eye valve with disk (Hood Laboratories, Pembroke, MA)
- Molteno Valve (Staar Surgical Co., Monrovia, CA)

Modified versions of the Ahmed and Molteno devices received subsequent 510(k) clearance in 2006. The most recent version of the Molten Valve, the Molteno 3, is intended to reduce intraocular pressure in neovascular glaucoma or glaucoma where medical and conventional surgical treatments have not been successful in controlling the progression of disease. The Ahmed™ Glaucoma Valve (AGV™) Model M4 is intended for use in patients with intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.

The EXPRESS™ Mini Glaucoma Shunt (Optonol, Ltd, Israel), originally received 510(k) clearance in 2002. It was considered to be substantially equivalent to several predicate devices, including the Ahmed and Baerveldt devices, described above. A revised version, the Blunt Tip EXPRESS mini glaucoma shunt, was cleared in 2003, and is indicated for use in reduction of intraocular pressure in patients with glaucoma where medical and conventional surgical treatments have failed.

**Literature Review Ahmed, Baerveldt, Krupin, and Molteno:** The Ahmed, Baerveldt, Krupin, and Molteno are first generation devices and have become an established treatment option for selected patients with glaucoma. Systematic reviews, meta-analysis, randomized controlled trials and case series with up to ten-year follow-ups have reported that these devices are effective in lowering intraocular pressure (IOP) and improving the visual field. Overall high success rates and/or lower reoperation rates have also been reported. Complications have been transient and self-limiting (Haibo, et al., 2015; Gedde, et al., 2012a; Gedde, et al., 2012b; Budenz, et al., 2011; Christakis, et al., 2011; Molteno, et al., 2011; Wishart, et al., 2010; Gedde, et al., 2009; Woodcock, et al., 2008; Wilson, et al., 2003; Broadway, et al., 2001).

**Literature Review Express:** Meta-analysis and randomized controlled trials (Chen, et al., 2014; Netland, et al., 2014; Wang, et al., 2013; de Jong, et al., 2011; de Jong, et al., 2009) have evaluated the safety and efficacy of insertion of the EXPRESS™ Mini Glaucoma Shunt to trabeculectomy in the treatment of patients with open-angle glaucoma and uncontrolled glaucoma. Postoperatively, Ex-PRESS patients showed stable IOP or improved IOP and were more likely to achieve complete success. The responder rate was higher, time to failure was longer, EXPRESS was better tolerated and/or surgical interventions for complications were less in the EXPRESS group.

**XEN Glaucoma Treatment System:** A second device which is an aqueous gel stent also been approved for use in the United States. The XEN Glaucoma Treatment System (Allergan, Inc. Aliso Viejo, CA) consists of the crosslinked XEN Gel Stent preloaded into the XEN Injector. The Stent is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde. The Gel Stent is proposed to create a permanent channel through the sclera allowing an outflow of aqueous humor from the anterior chamber to the subconjunctival space resulting in a conjunctival bleb. The XEN Gel Stent is preloaded into the injector which is designed to place the Gel Stent in the intended position through an ab interno approach. The goal of the XEN is to lower IOP without relying on physiologic outflow pathways. Proposed advantages of the Gel Stent include: 1) the hydrophilic device swells to secure itself into the scleral tissue which is proposed to limit movement without requiring additional surgical fixation; 2) the implant material is proposed to be highly malleable compared to the silicone tubing used in tube shunt surgery which allows the XEN to bend easily and convey less force against the tissue once implanted; 3) since, the XEN is injected, no conjunctival incision is necessary. Chaudhary et al. (2018) noted that a potentially greater degree of postoperative management is needed with the XEN due to formation of a subconjunctival bleb requiring close follow-up. It is not yet been established if this additional workload is made worthwhile by its efficacy and whether the greater simplicity and

safety profile outbalance the established efficacy of traditional filtering surgery. The XEN Gel Stent comes in three models that vary in internal lumen diameter (45µm, 63 µm and 140 µm) (FDA, 2016; Sheybani, 2015; Lewis, 2014). According to the manufacturer's website, the safety and effectiveness of implanting more than one XEN gel stent in an eye has not been studied (Allergan, 2023).

**U.S. Food and Drug Administration (FDA):** In 2016, the XEN Glaucoma Treatment System (Allergan, Inc. Aliso Viejo, CA) was FDA 510(k) (K161457) approved as a Class II aqueous shunt indicated "for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy". The XEN Glaucoma Treatment System consists of the XEN45 Gel Stent preloaded into the XEN Injector. The XEN45 Gel Stent is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde. Xen-EX describes the ab externo approach and involves inserting the device externally through the conjunctiva first, then through the sclera and then through the angle into the anterior chamber.

**Literature Review:** Clinical trials evaluating the safety and effectiveness of the XEN45 system are primarily in the form of retrospective reviews and case series with small patient populations (n=30–65) and short-term follow-ups (12 months) (De Gregorio, et al., 2018; Widder, et al., 2018; Grover et al., Nov 2017; Schlenker, et al., 2017; Hengerer, et al., 2017; Pérez-Torregrosa, et al., 2016;). Case series (n=12–111) reported the six- to 12-month outcomes of Xen implant with (XenPhaco) and without cataract surgery (Hohberger, et al., 2018; Fea, et al., 2017). Studies have also been conducted investigating XEN used with mitomycin C (Galal, et al., 2017). Sng et al. (2018) investigated the use of XEN45 for the treatment of uveitic glaucoma (n=24). Some studies used the XEN140 and/or XEN63 which are no longer recommended by the manufacturer (Colby, et al., 2017; Sheybani, et al., 2016; Sheybani, et al., 2015). According to Chaudhary et al. (2018) these XEN devices are not directly comparable to the currently commercialized devices and techniques. The XEN45 system is inserted via an ab interno or an ab externo approach. The safety and effectiveness of both approaches are supported by the studies (Do, et al., 2021; Tan, et al., 2021; Panarelli, et al., 2020; Vera, et al., 2020).

Tan et al. (2021) conducted a retrospective review to compare the safety and efficacy of two different techniques for implantation of the XEN Gel Stent, ab interno (n=50 eyes) or ab externo (n=30 eyes). All patients had a diagnosis of open-angle glaucoma and had uncontrolled IOP, progressing glaucoma, and/or an intolerance to topical hypotensive drops. In the ab interno group, average age was 71.0±13.4 years, 48% female, 48% Hispanic, 30% white, 16% African American and 6% Asian. For the ab externo group, average age was 67.6±9.3 years, 70% female, 63.3% Hispanic, 13.3% white, 23.3% African American and no Asians. Patients were excluded if they received a glaucoma drainage device concomitant with XEN Gel Stent insertion and those that were lost to follow-up before six months. Mean intraocular pressure (IOP) was 8.4±1.7 mmHg (28.6% decrease) in the ab interno group and 12.8±3.0 mmHg (40.1% decrease) in the ab externo group (p=0.208) at 12 months. The ab interno cohort demonstrated a mean reduction in medication use of 1.81±0.29 medications at 12 months, compared to a mean reduction of 1.86±0.37 in the ab externo group (p=0.913). By 12 months, 5-fluorouracil injection was required in 58% of ab interno eyes versus 36.7% of ab externos (p=0.105). Bleb needling was applied to 42% and 26.7% of the eyes, respectively (p=0.231) and a second glaucoma surgery was necessary for 20% of the ab interno cohort and 10% of the ab externo cohort (p=0.351). Adverse events included numerical hypotony (ab interno 2/50 [4.0%], ab externo 1/30 [3.3%]), choroidal effusion (ab interno 2/50 [4.0%], ab externo 0/30 [0%]), two Snellen lines or more loss of visual acuity (ab interno 5/50 [10%], ab externo 3/50 [10%]). The vision loss was accounted to cataract formation in two cases in the ab interno group and one case in the ab externo group. An advantage of this study is the racial diversity of the patient population. Author noted study

limitations included the retrospective study design, small patient populations, short term follow up and the potential impact of the surgeon's increase in technique proficiency over time. Patient outcomes were very similar between ab interno and ab externo placement of the XEN Gel Stent. Both approaches are safe and effective for lowering IOP.

Reitsamer et al. (2019) conducted a case series (n=218 eyes; 200 patients) to evaluate the safety and efficacy of XEN45 implant in the treatment of medically uncontrolled moderate primary open angle glaucoma (POAG). Inclusion criteria were:  $\geq 18$  years of age, diagnosis of moderate POAG (defined by a mean deviation score between  $-3$  and  $-12$  dB); uncontrolled on topical therapy; medicated IOP  $\geq 18$  and  $\leq 33$  mmHg; use of one to four topical IOP-lowering medications; area of healthy, free, and mobile conjunctiva in the target quadrant; Shaffer angle grade  $\geq 3$  in the target quadrant. Postoperative change in mean IOP and medication usage were the primary outcome measures. Clinical success was defined as achieving  $\geq 20\%$  IOP reduction on the same or fewer IOP-lowering medications at month 12 or 24 compared with baseline, without glaucoma-related secondary surgical intervention (SSI) (which did not include needling) or intention to be converted to another procedure during the study. Follow-up occurred intermittently for up to 24 months. Overall, 197/218 (90.4%) eyes completed the 12-month visit; 174/218 (79.8%) completed the 24-month visit, while 44/218 (20.2%) discontinued the study due to conversion to surgical procedure, lost to follow-up, implant malposition, explanations, and other miscellaneous issues. Average age was 71.8 years, 51.4% female, 48.6% male, 96.2% white, 1.6% Black and 2.2% Asian. There was a significant improvement at the 24-month follow-up in mean IOP ( $p < 0.001$ ) and medication usage ( $p < 0.001$ ) in the Xen alone and Xen plus cataract subjects. The clinical success was 65.8% and 72/161 eyes were medication free. The overall needling rate was 41.1% (n=83/202) with no significant difference between the groups. Ten intraoperative complications included six anterior chamber bleeds. Six eyes/patients had serious ocular adverse events. All cases of hypotony (defined as IOP  $< 6$  mm Hg) were self-limited and self-resolved within one month of surgery. An author noted limitation of the study was the variability in perioperative treatment regimen which was at the investigator's discretion. Additional limitations include the number of patients lost to the study (44/218; 20.2%), lack of an established medical or surgical comparator, and the fact that less than 5% of the study population was of Asian or Black ethnicity.

King et al. (2018) conducted a Cochrane review of randomized controlled trials (RCTs) that compared the Xen gelatin implant or InnFocus MicroShunt to other minimally-invasive glaucoma device techniques, trabeculectomy, laser treatment or medical treatment. The objective of the review was to evaluate the efficacy and safety of subconjunctival draining minimally-invasive glaucoma devices in patients with open angle glaucoma and ocular hypertension that were inadequately controlled with drops. The primary outcome was mean change in IOP. Secondary outcomes included subjects who were drop-free following the intervention; achieved an IOP of 21 mmHg or less, 17 mmHg or less or 14 mmHg or less; and the occurrence of intraoperative and postoperative complications. No RCTs were found that met the inclusion criteria.

Mansouri et al. (2018) conducted a prospective case series to evaluate the safety and efficacy of the XEN45 gel implant in the treatment of glaucoma patients (n=149 eyes; 113 patients) with uncontrolled IOP in combination with a cataract extraction procedure or as a standalone procedure. Based on visual field results, glaucoma severity ranged from mild to moderate disease with the majority of patients being in the mild stage. Subjects were age  $\geq 18$  years and diagnosed with primary or secondary OAG. Inclusion criteria for XEN surgery were uncontrolled IOP, progressing glaucoma, and/or intolerance to IOP-lowering drops. A total of 109 (73.2%) eyes underwent XEN plus cataract surgery and 40 (26.8%) underwent XEN alone. Data on 87 eyes (58%) were available one year following surgery. A significant reduction (31%) was seen in IOP ( $p < 0.01$ ) and mean medication usage ( $p < 0.001$ ). In total, 62.1% of patients achieved a  $\geq 20\%$  IOP reduction which was higher in the XEN alone group. The median IOP reduction was 40% in

the XEN alone group and 22.9% in the XEN plus cataract group. Complete success was achieved in 57.5% of the XEN alone group and 64.2% of the XEN plus cataract group using the <18mmHg threshold and in 57.5% and 57.8%, respectively, using the <16mmHg threshold. At one year, 28.7% of eyes required some antiglaucoma medications for IOP reduction. A total of 55 eyes (37%) required needling – 18 eyes (45%) in the XEN alone eyes versus 37 eyes (34%) in the XEN plus cataract eyes. Adverse effects included bleb revision (n=5 eyes), choroidal detachment (n=2 eyes), and a second glaucoma surgery due to uncontrolled IOP (n=9 eyes). Visual acuity loss was permanent in two eyes. In one eye, a second XEN device was implanted next to the first XEN due to presumed device obstruction. In the XEN plus cataract surgery group, there were two cases of intraoperative posterior capsule rupture. Limitations of the study include the small patient population, short-term follow-up, lack of a comparator, and the number of patients lost to follow-up. Additional author-noted limitations were the lack of washout at baseline which made the unmedicated IOP unknown, two surgeons performed the procedures and the decision to reinstate medications and to perform needling procedure were not standardized, and the homogenous white study population limiting generalizability to other ethnicities.

**iStent Infinite® Trabecular Micro-Bypass System, Model iS3:** The iStent infinite Trabecular Micro-Bypass System, Model iS3 (Glaukos Corp., Laguna Hills, CA) consists of three micro stents on a single preloaded injector. The stents are implanted via an ab interno approach in three separate areas of the trabecular meshwork. The three stents create a patent bypass through the trabecular meshwork into Schlemm canal to increase physiological aqueous outflow and reduce IOP.

**U.S. Food and Drug Administration (FDA):** The iStent infinite Trabecular Micro-Bypass System, Model iS3 was 510(k) (K220032) approved on August 2, 2022 “for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed”. It was approved as a standalone procedure.

**Literature Review:** Sarkisian et al. (2022) conducted a prospective, multicenter, single-arm study to evaluate the efficacy and safety of the iStent Infinite Trabecular Micro-Bypass System in the treatment of open angle glaucoma (OAG) in patients (n=72) uncontrolled by prior surgical or medical therapy. Primary outcomes included the proportion of eyes achieving  $\geq 20\%$  mean diurnal intraocular pressure (MDIOP) reduction from baseline on the same or fewer intraocular pressure (IOP)-lowering medication classes and mean change in MDIOP from baseline at 12 months. The mean medicated MDIOP was  $23.4 \pm 2.8$  preoperatively and patients were on a mean of  $3.1 \pm 0.9$  IOP-lowering medication classes. A total of 76.1% of patient met the responder endpoint with a mean reduction in MDIOP of 5.6 mmHg at 12 months. At 12 months, medication was reduced to  $2.70 \pm 1.03$ . There were no explants, infection, or device-related interventions or hypotony. The study limitations included a small patient population and short-term follow-up. iStent infinite stand-alone surgery achieved clinically significant IOP reduction and favorable safety in patients with OAG uncontrolled by prior therapy.

### **Additional devices**

Several additional devices are under development/investigation but have not yet received FDA approval. Some of these devices include: EyePass™ Glaucoma Implant (GMP Companies, Inc., Ft. Lauderdale, FL), the SOLX® Gold Shunt (SOLX, Inc., Waltham, MA), iStent Supra® (Glaukos, Laguna Hills, CA), STARflo (iSTAR Medical, Isnes, Belgium), Aquashunt (OPKO Health Inc., Miami, FL) and PRESERFLO MicroShunt (Santen Pharmaceutical Co., Ltd., Osaka, Japan [previously InnFocus MicroShunt® Innfocus Inc., Miami, FL]).

### **Technology Assessments**

**American Academy of Ophthalmology (AAO):** The American Academy of Ophthalmology (AAO) (Chopra, et al., 2024) conducted a technology assessment on aqueous shunts with



extraocular reservoir for the treatment of open-angle glaucoma (OAG) in adults. Following a systematic review of the literature, AAO made the following conclusion: "Implantation of aqueous shunts with extraocular reservoir, including valved or nonvalved devices, has been shown to be an effective strategy to lower IOP. Strong level I evidence supports the use of aqueous shunts with extraocular reservoir by clinicians for the management of adult OAG."

## **Procedures**

### **Canaloplasty**

Canaloplasty is a nonpenetrating procedure (ab externo or ab interno), similar to viscocanalostomy, aimed at lowering the IOP by permanently stretching the trabecular meshwork and restoring the natural drainage of fluid out of the eye. Conceptually, canaloplasty is an extension of viscocanalostomy with the addition of a flexible microcatheter-aided dilation using the iTRack device, the placement of a permanent suture under tension in Schlemm's canal, and the creation of an intrascleral reservoir (Kim, 2023). Proposed advantages of canaloplasty over trabeculectomy include: no subconjunctival bleb, lack of need for antimetabolites, fewer postoperative complications and simplified follow-up. The surgery is technically challenging with an initial learning curve and is contraindicated in eyes with angle recession, neovascular glaucoma, chronic angle closure, and narrow-angle glaucoma and in patients with previous ocular surgery that would prevent 360° catheterization of the Schlemm's canal. Canaloplasty also has the disadvantage of causing conjunctival scarring, which can make subsequent glaucoma surgery technically more difficult. Studies have shown a significant improvement in IOP and need for antiglaucoma hypotensive medications following canaloplasty.

**Literature Review:** Systematic reviews, randomized controlled trials and case series support the safety and efficacy of canaloplasty for the treatment of glaucoma. Canaloplasty has also evolved into an accepted treatment option for patients with open-angle glaucoma who have failed established medical management.

Zhang et al. (2017) conducted a systematic review and meta-analysis of canaloplasty (CP) compared to trabeculectomy (TE). Two randomized controlled trials, 11 prospective reviews, and 18 retrospective reviews (n=1498) were included. Twenty-eight studies were included in the quantitative analysis. Selection criteria included studies with the following: diagnosis of glaucoma, canaloplasty with or without phacoemulsification; IOP outcomes; and follow-up of at least six months. The primary outcomes were the changes in IOP and the number of antiglaucoma medications (AGMs). The secondary outcomes were the complete and qualified success rates and the incidence of adverse events. A complete success was defined as an IOP that was less than a given level without any AGMs. A qualified success rate was defined as a confirmed IOP that was less than a given level with or without AGMs. The reduction of IOP in all subgroups at six months was 10.69. Results of the meta-analysis showed that there was an IOP decrease by 9.94 mmHg with an average antiglaucoma medications reduction of 2.11 at 12 months following canaloplasty. The IOP reduction was significantly higher after trabeculectomy with an average difference of 3.61 mmHg at 12 months. TE was more efficient in IOP control than CP. There was no significant difference in the reduction of AGMs or in the complete or qualified success rates between the two groups (n=3 studies). Regarding adverse events, hyphema was more prevalent in CP. Descemet membrane detachment was only observed in CP with a reported incidence of 3%. Suprachoroidal hemorrhage and bleb needling were only reported in TE with incidences of 2.3% and 10.9%, respectively. TE had significantly higher incidences in hypotony and choroidal effusion/detachment. No significant difference was found in the incidence of conjunctiva leakage. Limitations of the study include the lack of randomized controlled trials and the high number of retrospective reviews, CP was less effective in IOP reduction, was able to achieve similar postoperative success rates and reduce the number of the AGMs. CP was also associated with

lower incidence of complications and was reported with higher patient satisfaction. The author noted that more high-quality studies, especially RCTs, are needed to verify these findings.

Liu et al. (2017) conducted a systematic review of the literature to assess the safety and efficacy of canaloplasty and trabeculectomy for the treatment of glaucoma. Four prospective case studies and four retrospective reviews met inclusion criteria. Pooled intraocular pressure (IOP) of canaloplasty (n=129) and trabeculectomy (n=179) at six and 12 months showed no significant difference in outcome of the two groups, but the postoperative IOP was higher in the canaloplasty group. The success rate of the canaloplasty group was significantly lower than that of the trabeculectomy group (p=0.010). Compared to trabeculectomy, the canaloplasty group had a higher risk of hyphema and a lower risk of hypotony and choroidal detachment. Limitations of the studies include the retrospective study designs, small patient populations, short-term follow-ups, inconsistent outcomes and lack of a comparator group.

Matlach et al. (2015) conducted a randomized controlled trial to compare the safety and efficacy of canaloplasty (CP) (n=30) and trabeculectomy (TE) (n=32) in the treatment of open angle glaucoma. Patients were included who were aged 18 years or older with medically uncontrolled primary or secondary (pseudoexfoliative and pigmentary) open-angle glaucoma. Primary outcomes was success rate which was defined as IOP  $\leq$  18 mmHg or IOP decreased by  $\geq$  20% and to  $\leq$  21 mmHg without medication (complete success) or with medication (qualified success). Secondary endpoints included the absolute reduction of IOP at the two-year follow-up, visual acuity, use of IOP-lowering medication, postoperative complications, further interventions, and early bleb management. Following surgery both groups had a significant reduction in IOP (p<0.001, each) but was not significantly different between the groups (p<0.56). At the two-year follow-up complete success was achieved in 23 TE patients and nine CP patients (p=0.001) and 21 TE patients vs. nine CE patients met success without medications (p=0.04). Complete success was significantly higher in the TE group for both success criteria (p<0.05). Qualified success was not different between the two groups for an IOP  $\leq$  21 mmHg and  $\geq$ 20% IOP reduction but was statistically significant for IOP  $\leq$  18 mm HG in the TE group (p=0.01). Twelve CP patients and eight TE patients needed additional IOP-lowering medication postoperatively. The mean number of required medications was significantly lower in the trabeculectomy group following surgery (p=0.01). Visual acuity was not significantly different between the groups during follow-up (p=0.08). Intraoperative complications in the canaloplasty group included microperforation of Descemet membrane in two eyes. There were no intraoperative complications in the TE eyes. The number of postoperative complications and second interventions was higher in the trabeculectomy group including: transient hypotony (37.5%), hypotony-related choroidal detachment (12.5%) and elevated IOP (25.0%). CP complications included elevated IOP (30%) and hyphema (23.3%). None of the trabeculectomy patients and two CP patient underwent further glaucoma surgery. Limitations of the study include the small patient populations and short-term follow-up.

Brusini et al. (2014) reported on the prospective outcomes of 214 eyes of 185 patients who underwent canaloplasty for the treatment of OAG under maximum tolerated medical therapy. Diagnosis included primary open-angle glaucoma (n=189), pseudoexfoliation glaucoma (n=53), juvenile glaucomas (n=10), and pigmentary glaucoma (n=4). Follow-ups occurred for up to five years with mean follow-up ranging from 9.7 months to 30.9 months. All patients underwent postoperative local medical treatment with levofloxacin and dexamethasone drops. The percentages of eyes that obtained postoperative IOP  $\leq$ 21mmHg,  $\leq$ 18mmHg, and  $\leq$ 16mmHg with or without medical therapy after two years were 88.7%, 73.7%, 46.2% and after three years 86.2%, 58.6%, and 37.9%, respectively. Seventeen eyes underwent trabeculectomy. The most frequent reported complications included: hyphema; descemet membrane detachment; IOP spikes; and hypotony. Limitations of the study include: the lack of a comparator; small patient population; and short-term follow-up. Also, the full procedure could not be performed in 42 eyes (16.4%) (39 patients out of the original cohort of 256 eyes). The authors concluded that

canaloplasty is a demanding and difficult surgical technique with promising outcomes but is a relatively new procedure. Future studies are needed to establish patient selection criteria; establish instruments and tools to assess whether or not collector channels are functioning; and development of simplification and standardization of the procedure.

**Viscocanaloplasty:** Viscocanaloplasty is similar to viscocanalostomy differing with injection of a viscous medication to open Schlemm's canal. The American Academy of Ophthalmology (AAO) (Kim et al., 2024) describes viscocanaloplasty or ab interno canaloplasty (ABiC) as a type of non-implant micro invasive glaucoma surgery (MIGS). The procedure, performed through a single self-sealing clear corneal incision, involves 360-degree viscodilation of the canal using either the iTrack microcatheter (Ellex) or the VISCO360® (Sight Sciences) handpiece and an ophthalmic visco-elastic device inserter. (Baker-Schena, 2018). According to the manufacturer's website, the Visco360 Viscosurgical System (Sight Sciences, Inc., Menlo Park, CA) is a non-implantable micro-invasive glaucoma surgery device indicated for ab interno microcatheterization and viscodilation of Schlemm's canal to reduce intraocular pressure (IOP) in adult patients with primary open-angle glaucoma. The procedure can be completed in conjunction with cataract surgery using the same corneal incision or as a stand-alone procedure. The Visco360 is introduced by way of a single, self-sealing, clear corneal incision (similar to clear corneal cataract surgery). Under gonioscopic visualization, the system's cannula is used to pierce the trabecular meshwork and enter Schlemm's canal. The system's microcatheter is then deployed around the entire 360° circumference of Schlemm's canal. Upon retraction of the microcatheter a small volume of viscoelastic is automatically dispensed, yielding a controlled and reproducible transluminal canal viscodilation (Sight Sciences, 2020). As of April 30, 2019, the VISCO360 is no longer available for commercial distribution (Access Gudid, 2023).

**U.S. Food and Drug Administration (FDA):** The Visco360 Viscosurgical System received FDA-approval via the 510(k) process on July 27, 2017 (K171905) The Sight Sciences Visco360 Viscosurgical System is a manually operated device for delivery of small amounts of viscoelastic fluid (e.g., Healon, Amvisc or PROVISC) during ophthalmic surgery. The device consists of the following components and accessories: Cannula; Microcatheter; Internal reservoir; Plunger tube; and Finger wheels (FDA, 2017).

**Literature Review – Viscocanaloplasty:** Although the evidence is not robust, professional societies (American Academy of Ophthalmology [AAO], American Glaucoma Society [AGS], American Society of Cataract and Refractive Surgery [ASCRS]) support the use of the procedures viscocanaloplasty and ab interno canaloplasty (ABiC) for the treatment of glaucoma (AAO, 2023; Fellman, et al., 2020). Studies are primarily in the form of retrospective reviews (Gillman, et al., 2021; Kazerounian, et al., 2021; Davids, et al., 2019; Gallardo, et al., 2018).

**Canaloplasty and trabeculotomy ab interno (OMNI® Surgical System):** The OMNI® Surgical System (Sight Sciences, Inc., Menlo Park, CA) is predicated by the iTrack Catheter (Ellex) and the VISCO360 Viscosurgical System (Sight Sciences). It is an ophthalmic surgical tool for the delivery of controlled amounts of viscoelastic fluid into the anterior segment and the cutting of the trabecular meshwork when a trabeculotomy is indicated. A catheter is advanced into Schlemm's canal, where viscoelastic is inserted in order to dilate the canal. The iTrack Microcatheter is an FDA-approved device for the delivery of viscoelastic in 360° procedures but is not a cutting device. The Omni Surgical System is an FDA-approved device that combines the functions of cutting the trabecular meshwork and delivering viscoelastic for 180° (viscocanalostomy) or 360° (canaloplasty) procedures.

**U.S. Food and Drug Administration (FDA):** The OMNI surgical system received FDA approval via 510(k) process on December 21, 2017 (K173332). The predicate devices were the iTrack Catheter (Ellex) and the VISCO360 Viscosurgical System (Sight Sciences). The OMNI™ Surgical

System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® or Healon GV® from Abbott Medical Optics (AMO), Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures. Sight Sciences received additional 510(k) approvals on July 14, 2020 (K201953) for the OMNI PLUS Surgical System and on January 21, 2021 (K202678) for the OMNI® Surgical System. The OMNI PLUS Surgical System's indications for use were the same as the predicate device the OMNI surgical system. The OMNI® Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.

**Literature Review:** Although the evidence is not robust, professional societies (American Academy of Ophthalmology [AAO], American Glaucoma Society [AGS], American Society of Cataract and Refractive Surgery [ASCRS]) support the use of the procedures canaloplasty and trabeculotomy ab interno for the treatment of glaucoma (AAO, 2023; Fellman, et al., 2020). Studies are primarily in the form of an observational study, retrospective reviews and a case series (Gallardo et al., 2021; Grabska-Liberek, et al., 2021; Hirsch, et al., 2021; Vold, et al., 2021).

### **Additional Procedures**

In an effort to forego the complications of trabeculectomy, the established surgical treatment for glaucoma, new surgical techniques are being investigated. These proposed procedures include transcliliary fistulization, and viscocanalostomy including phacoviscocanalostomy. However, there is insufficient evidence to support the safety and efficacy of these evolving surgical interventions for the treatment of glaucoma.

### **Transcliliary Fistulization**

Transcliliary fistulization, transcliliary filtration or Singh filtration uses the Fugo Blade™ (MediSURG Ltd., Norristown, PA), also called the Plasma Blade, for tissue ablation and noncauterizing hemostatic mechanisms to create a nonbleeding micropore which drains aqueous from behind the iris and into subconjunctival lymphatics. The proposed advantages of this procedure are the posterior route of aqueous filtration, lack of use of antifibrotic agents, low relative cost and shorter surgery time relative to trabeculectomy. The disadvantages are that it is an external filtration procedure with bleb formation with a risk of overfiltration and hypotony (Francis, et al., 2011, Singh and Singh, 2002).

**U.S. Food and Drug Administration (FDA):** The Fugo Blade for glaucoma (MediSURG Ltd., Norristown, PA) is 510(k) approved by the FDA for "sclerostomy for the treatment of primary open-angle glaucoma when maximum tolerated medical therapy and trabeculoplasty have failed" (FDA, 2004).

**Literature Review:** There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of transcliliary fistulization using the Fugo blade. The limited number of studies are primarily in the form of case series and retrospective reviews with small patient populations (n=16-147) and six to 12 months follow-up. Studies lacked specific inclusion and exclusion criteria and paucity of data (Francis, et al., 2011).

### **Viscocanalostomy and Phacoviscocanalostomy**

Viscocanalostomy involves the injection of ophthalmic viscoelastic device (OVD) into the Schlemm's canal (SC) on either side of an external scleral dissection site with a metal cannula. Because the cannula was not flexible, it could only be extended in the SC a limited distance. Therefore, it could only dilate a limited portion of the canal on either side of the dissection site.

This opening allows passage of fluid from the anterior chamber into the canal which lowers the IOP. Unlike trabeculectomy, viscocanalostomy avoids full-thickness penetration into the anterior chamber of the eye (Goldberg, 2006; Koerber, 2007).

Viscocanalostomy is also proposed for use in conjunction with phacoemulsification (i.e., the removal of lens nucleus within the lens capsule by breaking up the lens into tiny pieces for extraction) during cataract surgery. The combination of cataract surgery and viscocanalostomy is called phacoviscocanalostomy and is proposed for use in the place of phacotrabeculectomy. The combined surgery is used for patients who require surgical intervention for the treatment of cataract and glaucoma. Compared to cataract surgery alone, phacoviscocanalostomy is proposed to provide better long-term control of IOP, protection from postoperative IOP spikes and prevention of late-failure trabeculectomy (Kobayashi and Kobayashi, 2007; Shoji, et al., 2007; Park, et al., 2006; Wishart, et al., 2006). The evidence in the published peer-reviewed literature does not support viscocanalostomy or phacoviscocanalostomy for the treatment of glaucoma.

**Literature Review-Viscocanalostomy:** Randomized controlled trials have reported that viscocanalostomy is not clinically comparable to trabeculectomy, the standard surgical procedure for the treatment of glaucoma, in reducing and maintaining lower IOP values. Overall, significantly better reductions in IOP were seen following trabeculectomy and in some cases, with less repeat treatments needed. Eldaly et al. conducted a 2014 Cochrane review of randomized and quasi-randomized controlled trials comparing standard trabeculectomy to viscocanalostomy (n=50) for the treatment of open-angle glaucoma and concluded that limited evidence showed better control of IOP with trabeculectomy.

Chai and Loon (2010) conducted a meta-analysis of ten randomized controlled trials (n=458 eyes/397 patients) to compare the outcomes of viscocanalostomy to trabeculectomy mainly for the treatment of primary (n=371) or secondary (n=75) open-angle glaucoma. The authors compared the postoperative mean intraocular pressure (IOP), mean number of antiglaucomatous medications, as well as adverse events. Follow-ups ranged from six months to four years. At six, 12, and 24 months, a significantly lower mean IOP was reported following trabeculectomy ( $p < 0.00001$ ,  $p < 0.00001$ ,  $p < 0.0001$ , respectively). Trabeculectomy patients required a significantly less number of postoperative antiglaucomatous medications compared to viscocanalostomy ( $P < 0.00001$ ). Six studies reported that viscocanalostomy had a significantly higher relative risk of perforation of Descemet membrane ( $p = 0.007$ ). The relative risk of hypotony, hyphema, shallow anterior chamber, and cataract formation were significantly less in the viscocanalostomy group ( $p = 0.0005$ ,  $p = 0.008$ ,  $p = 0.0002$ ,  $p = 0.002$ , respectively). Author-noted limitations of the study included: the studies may not be completely comparable due to various surgical techniques and surgeon experience; two studies lacked data on IOP; and the follow-ups were short-term.

Hondur et al. (2008) performed a meta-analysis of randomized controlled trials and case series that evaluated nonpenetrating glaucoma surgery (NPGS), including deep sclerectomy (n=22) and viscocanalostomy (n=14) for the treatment of OAG. Success was defined as IOP of  $\leq 21$  millimeters of mercury (mmHg) without the use of antiglaucoma medicine. Because they affect the results of NPGS, data related to postoperative goniopuncture and needling with antimetabolite application were noted. In general, the mean follow-up of the viscocanalostomy studies was 25.6 months. The percentage of cases achieving  $\leq 21$  mmHg was 51.1% following primary viscocanalostomy (n=9) and 36.8% after viscocanalostomy with antimetabolite or implant (n=3). With lower set IOP targets, the rates of success ranged from 10%–67% following viscocanalostomy. Several factors were identified that may account for the wide variation in the success rates of NPGS including the variations in surgical techniques (i.e., use of implants and antimetabolite application) and post-operative manipulation (e.g., goniopuncture, subconjunctival 5-FU injection), variations in success criteria and targeted IOPs, and differences in follow-up

lengths. There was an absence of data regarding the severity of glaucoma in the pre-operative patient populations and a lack of data regarding visual acuity following viscocanalostomy. The authors noted that data regarding the success of NPGS beyond three years was limited. According to the authors, the analysis implied that NPGS can achieve IOP reduction. However, these procedures “may not be suitable surgical options for patients in whom vigorous IOP reduction is required.” Long-term studies with data related to glaucoma severity and proper target IOPs are needed.

Earlier published reports from randomized controlled trials also compared the results of viscocanalostomy to trabeculectomy for the treatment of glaucoma (Gilmour, et al., 2009; Cheng, et al., 2004; O’Brart, et al., 2004; Yalvac, et al., 2004; Yarangümeli, et al., 2004; Carassa, et al., 2003; Kobayashi, et al., 2003; O’Brart, et al., 2002; Lüke, et al., 2002; Jonescu-Cuypers, et al., 2001). Overall, trabeculectomy provided a statistically significant decrease in IOP and an increase in IOP control compared to viscocanalostomy. Reported complications were varied and conflicting. Some studies reported no significant differences in complications while others reported a lower incidence of post-operative cataract formation and hypotony following viscocanalostomy.

**Systematic Review of Multiple Procedures:** Rulli et al. (2013) conducted a systematic review and meta-analysis of randomized and nonrandomized trials to determine the safety and hypotensive effect of trabeculectomy (TE) vs. nonpenetrating surgeries (NPS) which included canaloplasty vs trabeculectomy (n=79 eyes) and viscocanalostomy (n=315 eyes) for the treatment of open-angle glaucoma. Analysis of the data at six-month follow-ups showed that the pooled estimate of the mean difference between the groups was -2.15 mm in favor of TE with no difference between the NPS groups. TE was more effective in reducing IOP than NPS following surgery. The absolute risk of hypotony, choroidal effusion, cataract, and flat or shallow anterior chamber was higher in the TE group than viscocanalostomy. Evidence was insufficient to assess the safety of TE vs. canaloplasty.

**Literature Review-Phacoviscocanalostomy:** The evidence in the published peer-reviewed literature does not support the safety and efficacy of phacoviscocanalostomy for the treatment of glaucoma. Published studies include a limited number of case series and retrospective reviews with small patient populations and short-term follow-ups (Awadalla and Hassan, 2011; Kobayashi and Kobayashi, 2007; Wishart, et al., 2006). The effects on postoperative medication usage, as well as the long-term effects of phacoviscocanalostomy are unknown. Studies comparing phacoviscocanalostomy to established treatment modalities are lacking.

### **Professional Societies/Organizations**

**American Academy of Ophthalmology (AAO):** The AAO published an ophthalmic technology assessment on novel glaucoma procedures (Francis, et al., 2011). The assessment included Fugo blade transcliliary filtration, iStent, Ex-PRESS glaucoma shunt, SOLX Gold Shunt, canaloplasty, and trabectome. AAO concluded that these devices and techniques “are still in the initial stage ( $\leq 5$  years) of clinical experience and lacking widespread use.” Clinical trials were limited to “nonrandomized, retrospective or prospective, interventional, clinical case series, generally classified as providing only level III evidence in support of the procedures”. Randomized clinical trials are needed to compare these procedures to trabeculectomy and phacoemulsification. AAO concluded “it is possible to state that these novel procedures show potential for the treatment of glaucoma and that they warrant continued support and future studies. It is not possible to conclude if they are superior, equal to, or inferior to surgery such as trabeculectomy or to one another”.

The AAO (2018, updated 2023) glaucoma summary benchmarks for the management of primary open-angle glaucoma (OAG) stated that medical therapy is the most common intervention initial intervention to lower intraocular pressure (IOP). Laser trabeculoplasty can be considered as initial

therapy in selected patients or an alternative for patients at high risk for nonadherence to medical therapy who cannot or will not use medications reliably.

**American Glaucoma Society (AGS):** The objective of the American Glaucoma Society Position Paper on Microinvasive Glaucoma Surgery (MIGS) (Fellman, et al., 2020) was to provide an overview of the procedures while dispelling misconceptions. MIGS were designed to lower intraocular pressure (IOP) by improving the physiologic aqueous outflow pathways with minimal disruption to the sclera or conjunctiva with or without an implanted device, or by reducing aqueous production selectively. The Society states that the advantages of MIGS over traditional glaucoma procedures include being performed with smaller incisions, an enhanced safety profile, limited discomfort, faster recovery, less impact on leisure activities (such as swimming), and reduced risk of damaging other structures in the eye that can necessitate additional ocular surgeries.

## Medicare Coverage Determinations

	<b>Contractor</b>	<b>Determination Name/Number</b>	<b>Revision Effective Date</b>
NCD	National	No National Coverage Determinations found.	
LCD	NGS	Microinvasive Glaucoma Surgery (MIGS) (L37244)	12/01/2019
LCD	Palmetto	Microinvasive Glaucoma Surgery (MIGS) (L37531)	6/23/2022
LCD	CGS	Microinvasive Glaucoma Surgery (MIGS) (L37578)	3/23/2023
LCD	Novitas Solutions	Microinvasive Glaucoma Surgery (MIGS) (L38223)	12/30/2019
LCD	First Coast	Microinvasive Glaucoma Surgery (MIGS) (L38233)	12/30/2019
LCD	Wisconsin Physicians	Category III Codes (L35490)	6/12/2022

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Aqueous Shunts/Aqueous Drainage Devices**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

<b>CPT®* Codes</b>	<b>Description</b>
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft

<b>CPT®* Codes</b>	<b>Description</b>
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

### **Procedures**

**Considered Medically Necessary when used to report canaloplasty performed either ab externo or ab interno when criteria in the applicable policy statement listed above are met:**

<b>CPT®* Codes</b>	<b>Description</b>
66174	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent

**Considered Experimental/Investigational/Unproven:**

<b>CPT®* Codes</b>	<b>Description</b>
66999 <sup>†</sup>	Unlisted procedure, anterior segment of eye

**<sup>†</sup>Note: Considered Experimental/Investigational/Unproven when used to report transciliary fistulization or viscocanalostomy (including phacoviscocanalostomy)**

**\*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

## **References**

1. Access Gudid. VISCO(TM)360 Viscosurgical System (00858027006013). National Institute of Health. Aug 22, 2023. Accessed on Mar 6, 2024. Available at URL address: <https://accessgudid.nlm.nih.gov/devices/00858027006013>
2. Allergan. Xen Gel Stent. 2023. Accessed Mar 7, 2024. Available at URL address: <https://hcp.xengelstent.com/>
3. Ahmed IIK, Fea A, Au L, Ang RE, Harasymowycz P, Jampel H, Samuelson TW, Chang DF, Rhee DJ; COMPARE Investigators. A prospective randomized trial comparing Hydrus and iStent micro-invasive glaucoma glaucoma surgery implants for standalone treatment of open-angle glaucoma: The COMPARE Study. Ophthalmology. 2019 Apr 26. pii: S0161-6420(18)31710-X.
4. American Academy of Ophthalmology (AAO). Glaucoma summary benchmarks – 2018. Accessed Mar 6, 2024. Available at URL address: <https://www.aao.org/assets/7153479a->



48ec-4ec1-ab94-8b170f2756e2/636808252879900000/bc-3105-pppsummarybenchmarks-18-glaucoma-pdf

5. American Academy of Ophthalmology (AAO). Glaucoma summary benchmarks – 2023. Accessed Mar 6, 2024. Available at URL address: <https://www.aaopt.org/education/summary-benchmark-detail/glaucoma-summary-benchmarks-2020>
6. American Academy of Ophthalmology (AAO). Microinvasive Glaucoma Surgery (MIGS). May 12, 2023. Accessed on Mar 6, 2024. Available at URL address: [https://eyewiki.aaopt.org/Microinvasive\\_Glaucoma\\_Surgery\\_\(MIGS\)#MIGS\\_Approaches](https://eyewiki.aaopt.org/Microinvasive_Glaucoma_Surgery_(MIGS)#MIGS_Approaches)
7. American Academy of Ophthalmology (AAO). Preferred practice pattern® guidelines. Primary open-angle glaucoma. 2020. Accessed Mar 6, 2024. Available at URL address: <https://www.aaopt.org/about-preferred-practice-patterns>
8. Ansari E. An Update on Implants for Minimally Invasive Glaucoma Surgery (MIGS). *Ophthalmol Ther.* 2017 Dec;6(2):233-241.
9. Awadalla MA, Hassan KM. Phacoviscocanalostomy in pseudoexfoliation glaucoma versus primary open-angle glaucoma. *Can J Ophthalmol.* 2011 Feb;46(1):77-82.
10. Barton K, Gedde SJ, Budenz DL, Feuer WJ, Schiffman J; Ahmed Baerveldt Comparison Study Group. The Ahmed Baerveldt Comparison Study methodology, baseline patient characteristics, and intraoperative complications. *Ophthalmology.* 2011 Mar;118(3):435-42. Epub 2010 Oct 8.
11. Broadway DC, Iester M, Schulzer M, Douglas GR. Survival analysis for success of Molteno tube implants. *Br J Ophthalmol.* 2001 Jun;85(6):689-95.
12. Brusini P. Canaloplasty in open-angle glaucoma surgery: a four-year follow-up. *ScientificWorldJournal.* 2014 Jan 16;2014:469609.
13. Budenz DL, Barton K, Feuer WJ, Schiffman J, Costa VP, Godfrey DG, Buys YM; Ahmed Baerveldt Comparison Study Group. Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. *Ophthalmology.* 2011 Mar;118(3):443-52.
14. Bull H, von Wolff K, Körber N, Tetz M. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. *Graefes Arch Clin Exp Ophthalmol.* 2011 Oct;49(10):1537-45.
15. Burr J, Azuara-Blanco A, Avenell A, Tuulonen A. Medical versus surgical interventions for open angle glaucoma. *Cochrane Database of Systematic Reviews* 2012, Issue 9. Art. No.: CD004399. DOI: 10.1002/14651858.CD004399.pub3.
16. Carassa RG, Bettin P, Fiori M, Brancato R. Visco canalostomy versus trabeculectomy in white adults affected by open-angle glaucoma: a 2-year randomized, controlled trial. *Ophthalmology.* 2003;110(5):882-7.
17. Centers for Disease Control and Prevention. Social Determinants of Health, Health Equity, and Vision Loss. Aug 28, 2023. Accessed Mar 6, 2024. Available at URL address: <https://www.cdc.gov/visionhealth/determinants/index.html>

18. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Apr 11, 2023. Available at URL address: <https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx>
19. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Apr 11, 2023. Available at URL address: <https://www.cms.gov/medicare-coverage-database/search.aspx>
20. Chai C, Loon SC. Meta-analysis of viscocanalostomy versus trabeculectomy in uncontrolled glaucoma. *Glaucoma*. 2010 Oct-Nov;19(8):519-27.
21. Chatzara A, Chronopoulou I, Theodossiadis G, Theodossiadis P, Chatziralli I. XEN Implant for Glaucoma Treatment: A Review of the Literature. *Semin Ophthalmol*. 2019;34(2):93-97.
22. Chaudhary A, Salinas L, Guidotti J, Mermoud A, Mansouri K. XEN Gel Implant: a new surgical approach in glaucoma. *Expert Rev Med Devices*. 2018 Jan;15(1):47-59.
23. Chen TC, Chen PP, Francis BA, Junk AK, Smith SD, Singh K, Lin SC. Pediatric glaucoma surgery: a report by the American Academy Of Ophthalmology. *Ophthalmology*. 2014 Nov;121(11):2107-15.
24. Chen G, Li W, Jiang F, Mao S, Tong Y. Ex-PRESS implantation versus trabeculectomy in open-angle glaucoma: a meta-analysis of randomized controlled clinical trials. *PLoS One*. 2014 Jan 23;9(1):e86045.
25. Cheng JW, Ma XY, Wei RL. Efficacy of non-penetrating trabecular surgery for open angle glaucoma: a meta-analysis. *Chin Med J (Engl)*. 2004 Jul;117(7):1006-10.
26. Chopra V, Takusagawa HL, Rosdahl JA, Sit AJ, Richter GM, Ou Y, Kim SJ, WuDunn D. Aqueous Shunts with Extraocular Reservoir for Open-Angle Adult Glaucoma: A Report by the American Academy of Ophthalmology. *Ophthalmology*. 2024 Feb;131(2):227-239. doi: 10.1016/j.opht.2023.10.007. Epub 2023 Dec 8. PMID: 38069945.
27. Christakis PG, Kalenak JW, Zurakowski D, Tsai JC, Kammer JA, Harasymowycz PJ, Ahmed II. The Ahmed Versus Baerveldt study: one-year treatment outcomes. *Ophthalmology*. 2011 Nov;118(11): 2180-9.
28. Colby A, Shane H. A Review of the Data on the Recently Approved Xen Surgical Gel Stent in the Management of Glaucoma. *JOJ Ophthal*. 2017; 3(4): 555617
29. Dahan E, Carmichael TR. Implantation of a miniature glaucoma device under a scleral flap. *J Glaucoma*. 2005 Apr;14(2):98-102.
30. Dahan E, Ben Simon GJ, Lafuma A. Comparison of trabeculectomy and Ex-PRESS implantation in fellow eyes of the same patient: a prospective, randomised study. *Eye (Lond)*. 2012 May;26(5):703-10. doi: 10.1038/eye.2012.13.
31. Davids AM, Pahlitzsch M, Boeker A, Winterhalter S, Maier-Wenzel AK, Klamann M. Ab interno canaloplasty (ABiC)-12-month results of a new minimally invasive glaucoma surgery (MIGS). *Graefes Arch Clin Exp Ophthalmol*. 2019 Sep;257(9):1947-1953. doi: 10.1007/s00417-019-04366-3. Epub 2019 Jun 8. PMID: 31175444.

32. De Gregorio A, Pedrotti E, Russo L, Morselli S. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. *Int Ophthalmol*. 2018 Jun;38(3):1129-1134.
33. de Jong L, Lafuma A, Aguadé AS, Berdeaux G. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. *Clin Ophthalmol*. 2011;5:527-33.
34. de Jong LA. The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: a prospective randomized study. *Adv Ther*. 2009 Mar;26(3):336-45.
35. de Jong L, Lafuma A, Aguadé AS, Berdeaux G. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. *Clin Ophthalmol*. 2011;5:527-33. doi: 10.2147/OPHTH.S18565. Epub 2011 Apr 29.
36. Do A, McGlumphy E, Shukla A, Dangda S, Schuman JS, Boland MV, Yohannan J, Panarelli JF, Craven ER. Comparison of Clinical Outcomes with Open Versus Closed Conjunctiva Implantation of the XEN45 Gel Stent. *Ophthalmol Glaucoma*. 2021 Jul-Aug;4(4):343-349. doi: 10.1016/j.ogla.2020.12.003. Epub 2020 Dec 13. PMID: 33321200; PMCID: PMC8197767.
37. Eldaly MA, Bunce C, ElSheikha OZ, Wormald R. Non-penetrating filtration surgery versus trabeculectomy for open-angle glaucoma. *Cochrane Database of Systematic Reviews* 2014, Issue 2. Art. No.: CD007059. DOI: 10.1002/14651858.CD007059.pub2.
38. Estermann S, Yuttitham K, Chen JA, Lee OT, Stamper RL. Comparative In Vitro Flow Study of 3 Different Ex-PRESS Miniature Glaucoma Device Models. *J Glaucoma*. 2012 Jan 20. [Epub ahead of print]
39. Every SG, Molteno AC, Bevin TH, Herbison P. Long-term results of Molteno implant insertion in cases of neovascular glaucoma. *Arch Ophthalmol*. 2006 Mar;124(3):355-60.
40. Fea AM, Spinetta R, et al. Evaluation of Bleb Morphology and Reduction in IOP and Glaucoma Medication following Implantation of a Novel Gel Stent. *J Ophthalmol*. 2017;2017:9364910
41. Fellman RL, Mattox C, Singh K, Flowers B, Francis BA, Robin AL, Butler MR, Shah MM, Giaconi JA, Sheybani A, Song BJ, Stein JD. American Glaucoma Society Position Paper: Microinvasive Glaucoma Surgery. *Ophthalmol Glaucoma*. 2020 Jan-Feb;3(1):1-6. doi: 10.1016/j.ogla.2019.12.003. PMID: 32672638; PMCID: PMC7531041.
42. Fingeret M, Dickerson JE Jr. The Role of Minimally Invasive Glaucoma Surgery Devices in the Management of Glaucoma. *Optom Vis Sci*. 2018 Feb;95(2):155-162.
43. Francis BA, Singh K, Lin SC, Hodapp E, Jampel HD, Samples JR, Smith SD. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2011 Jul;118(7):1466-80.
44. Galal A, Bilgic A, Eltanamly R, Osman A. XEN Glaucoma Implant with Mitomycin C 1-Year Follow-Up: Result and Complications. *J Ophthalmol*. 2017;2017:5457246. Epub 2017 Mar 1.

45. Gallardo MJ, Sarkisian SR Jr, Vold SD, Singh IP, Flowers BE, Campbell A, Dhamdhare K, Samuelson TW; GEMINI study group. Canaloplasty and Trabeculotomy Combined with Phacoemulsification in Open-Angle Glaucoma: Interim Results from the GEMINI Study. *Clin Ophthalmol*. 2021 Feb 10;15:481-489. doi: 10.2147/OPTH.S296740. PMID: 33603325; PMCID: PMC7882439.
46. Gallardo MJ, Supnet RA, Ahmed IIK. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. *Clin Ophthalmol*. 2018 Oct 23;12:2149-2155. doi: 10.2147/OPTH.S177597. PMID: 30425450; PMCID: PMC6205145.
47. Gedde SJ, Herndon LW, Brandt JD, Budenz DL, Feuer WJ, Schiffman JC; Tube Versus Trabeculectomy Study Group. Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. *Am J Ophthalmol*. 2012a May;153(5):804-814.e1. doi: 10.1016/j.ajo.2011.10.024.
48. Gedde SJ, Panarelli JF, Banitt MR, Lee RK. Evidenced-based comparison of aqueous shunts. *Curr Opin Ophthalmol*. 2013 Jan 2. [Epub ahead of print].
49. Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL; Tube versus Trabeculectomy Study Group. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. *Am J Ophthalmol*. 2012b May;153(5):789-803.e2. doi: 10.1016/j.ajo.2011.10.026.
50. Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL; Tube Versus Trabeculectomy Study Group. Three-year follow-up of the tube versus trabeculectomy study. *Am J Ophthalmol*. 2009 Nov;148(5):670-84.
51. Gillmann K, Aref A, Niegowski LJ, Baumgartner JM. Combined Ab interno viscocanaloplasty (ABiC) in open-angle glaucoma: 12-month outcomes. *Int Ophthalmol*. 2021 Oct;41(10):3295-3301. doi: 10.1007/s10792-021-01891-1. Epub 2021 May 20. PMID: 34014461.
52. Gilmour DF, Manners TD, Devonport H, Varga Z, Solebo AL, Miles J. Viscocanalostomy versus trabeculectomy for primary open angle glaucoma: 4-year prospective randomized clinical trial. *Eye*. 2009 Sep;23(9):1802-7.
53. Goldberg L. Canaloplasty: A Promising New Extension to Non-Penetrating Surgery. *Ophthalmology Management*. 10(3), March 2006.
54. Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after Ex-PRESS drainage device implantation versus trabeculectomy. *Am J Ophthalmol*. 2011 Mar;151(3):507-13.e1.
55. Grabska-Liberek I, Duda P, Rogowska M, Majszyk-Ionescu J, Skowrya A, Kozirowska A, Kane I, Chmielewski J. 12-month interim results of a prospective study of patients with mild to moderate open-angle glaucoma undergoing combined viscodilation of Schlemm's canal and collector channels and 360° trabeculotomy as a standalone procedure or combined with cataract surgery. *Eur J Ophthalmol*. 2022 Jan;32(1):309-315. doi: 10.1177/1120672121998234. Epub 2021 Feb 24. PMID: 33626924; PMCID: PMC8777320.

56. Grieshaber MC, Fraenkl S, Schoetzau A, Flammer J, Orgül S. Circumferential viscocanalostomy and suture canal distension (canaloplasty) for whites with open-angle glaucoma. *J Glaucoma*. 2011 Jun-Jul;20(5):298-302.
57. Grieshaber MC, Pienaar A, Olivier J, Stegmann R. Canaloplasty for primary open-angle glaucoma: long-term outcome. *Br J Ophthalmol*. 2010 Nov;94(11):1478-82.
58. Grieshaber MC, Pienaar A, Olivier J, Stegmann R. Clinical evaluation of the aqueous outflow system in primary open-angle glaucoma for canaloplasty. *Invest Ophthalmol Vis Sci*. 2010 Mar;51(3):1498-504.
59. Grover DS, Flynn WJ, Bashford KP, Lewis RA, Duh YJ, Nangia RS, Niksch B. Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months. *Am J Ophthalmol*. 2017 Nov;183:25-36.
60. HaiBo T, Xin K, ShiHeng L, Lin L. Comparison of Ahmed glaucoma valve implantation and trabeculectomy for glaucoma: a systematic review and meta-analysis. *PLoS One*. 2015 Feb 26;10(2):e0118142.
61. Hammel N, Lusky M, Kaiserman I, Robinson A, Bahar I. Changes in Anterior Segment Parameters After Insertion of Ex-PRESS Miniature Glaucoma Implant. *J Glaucoma*. 2012 Mar 7. [Epub ahead of print]
62. Health Canada. Medical Devices Active Licence Listing (MDALL). 2023. Accessed on Apr 11, 2023. Available at URL address: <https://health-products.canada.ca/mdall-limh/index-eng.jsp>
63. Hengerer FH, Kohnen T, Mueller M, Conrad-Hengerer I. Ab Interno Gel Implant for the Treatment of Glaucoma Patients With or Without Prior Glaucoma Surgery: 1-Year Results. *J Glaucoma*. 2017 Dec;26(12):1130-1136.
64. Hirsch L, Cotliar J, Vold S, Selvadurai D, Campbell A, Ferreira G, Aminlari A, Cho A, Heersink S, Hochman M, Gallardo M, Williamson B, Phan R, Nelson C, Dickerson JE Jr. Canaloplasty and trabeculectomy ab interno with the OMNI system combined with cataract surgery in open-angle glaucoma: 12-month outcomes from the ROMEO study. *J Cataract Refract Surg*. 2021 Jul 1;47(7):907-915. doi: 10.1097/j.jcrs.0000000000000552. PMID: 33315733.
65. Hohberger B, Welge-Lüssen UC, Lämmer R. MIGS: therapeutic success of combined Xen Gel Stent implantation with cataract surgery. *Graefes Arch Clin Exp Ophthalmol*. 2018 Jan 15.
66. Hoffman RS, Crandall AS, Crandall DA, Fine IH, Packer M, Sims AC. Minimally Invasive External Mini-Glaucoma Shunt Implantation Without Conjunctival Dissection. *J Glaucoma*. 2012 Aug 23. [Epub ahead of print]
67. Hondur A, Onol M, Hasanreisoglu B. Nonpenetrating glaucoma surgery: meta-analysis of recent results. *J Glaucoma*. 2008 Mar;17(2):139-46.
68. Ivantis. Hydrus Microstent. 2023. Accessed Apr 11, 2023. Available at URL address: <https://www.myalcon.com/professional/cataract-surgery/hydrus-microstent/>
69. Jacobs DS. Open-angle glaucoma: Treatment. In: UpToDate, Givens J, ed. Jan 29, 2024. UpToDate, Waltham, MA. Accessed Mar 6, 2024.

70. Jonescu-Cuypers C, Jacobi P, Konen W, Krieglstein G. Primary viscocanalostomy versus trabeculectomy in white patients with open-angle glaucoma: a randomized clinical trial. *Ophthalmology*. 2001;108(2):254-8.
71. Junk AK, Katz LJ. Ch 17. Tube shunts for refractory glaucoma. In: *Duane's Ophthalmology*. Philadelphia. Lippincott Williams & Wilkins. 2011.
72. Kammer JA, Mundy KM. Suprachoroidal devices in glaucoma surgery. *Middle East Afr J Ophthalmol*. 2015 Jan-Mar;22(1):45-52.
73. Kanner EM, Netland PA, Sarkisian SR Jr, Du H. Ex-PRESS miniature glaucoma device implanted under a scleral flap alone or combined with phacoemulsification cataract surgery. *J Glaucoma*. 2009 Aug;18(6):488-91.
74. Kazerounian S, Zimbelmann M, Lörtscher M, Hommayda S, Tsirkinidou I, Müller M. Canaloplasty ab interno (AbiC) - 2-Year-Results of a Novel Minimally Invasive Glaucoma Surgery (MIGS) Technique. *Klin Monbl Augenheilkd*. 2021 Oct;238(10):1113-1119. English, German. doi: 10.1055/a-1250-8431. Epub 2020 Nov 17. PMID: 33202434.
75. Kim WI, Aref AA, Moore DB. Canaloplasty. *American Academy of Ophthalmology, EyeWiki*. Feb 9, 2024. Accessed on Mar 7, 2024. Available at URL address: <https://eyewiki.aao.org/Canaloplasty>
76. King AJ, Shah A, Nikita E, Hu K, Mulvaney CA, Stead R, Azuara-Blanco A. Subconjunctival draining minimally-invasive glaucoma devices for medically uncontrolled glaucoma. *Cochrane Database of Systematic Reviews* 2018, Issue 12. Art. No.: CD012742. DOI: 10.1002/14651858.CD012742.pub2.
77. Kobayashi H, Kobayashi K. Randomized comparison of the intraocular pressure-lowering effect of phacoviscocanalostomy and phacotrabeulectomy. *Ophthalmology*. 2007 May;114(5):909-14.
78. Kobayashi H, Kobayashi K, Okinami S. A comparison of the intraocular pressure-lowering effect and safety of viscocanalostomy and trabeculectomy with mitomycin C in bilateral open-angle glaucoma. *Graefes Arch Clin Exp Ophthalmol*. 2003;241(5):359-66.
79. Koerber, N. Canaloplasty-a new approach to nonpenetrating glaucoma surgery. *Techniques in Ophthalmology*. 5(3):102-106, September 2007.
80. Le JT, Bicket AK, Wang L, Li T. Ab interno trabecular bypass surgery with iStent for open-angle glaucoma. *Cochrane Database of Systematic Reviews* 2019, Issue 3. Art. No.: CD012743. DOI: 10.1002/14651858.CD012743.pub2.
81. Lenzhofer M, Strohmaier C, Hohensinn M, Hitzl W, Sperl P, Gerner M, Steiner V, Moussa S, Krall E Reitsamer HA. Longitudinal bleb morphology in anterior segment OCT after minimally invasive transscleral ab interno Glaucoma Gel Microstent implantation. *Acta Ophthalmol*. 2019 Mar;97(2):e231-e237.
82. Lewis RA. Ab interno approach to the subconjunctival space using a collagen glaucoma stent. *J Cataract Refract Surg*. 2014 Aug;40(8):1301-6.

83. Lewis RA, von Wolff K, Tetz M, Koerber N, Kearney JR, Shingleton BJ, Samuelson TW. Canaloplasty: circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: two-year interim clinical study results. *J Cataract Refract Surg.* 2009 May;35(5):814-24.
84. Lewis RA, von Wolff K, Tetz M, Korber N, Kearney JR, Shingleton B, Samuelson TW. Canaloplasty: circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: interim clinical study analysis. *J Cataract Refract Surg.* 2007 Jul;33(7):1217-26.
85. Lewis RA, von Wolff K, Tetz M, Koerber N, Kearney JR, Shingleton BJ, Samuelson TW. Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg.* 2011 Apr;37(4):682-90.
86. Liu H, Zhang H, Li Y, Yu H. Safety and efficacy of canaloplasty versus trabeculectomy in treatment of glaucoma. *Oncotarget.* 2017 Jan 19. doi: 10.18632/oncotarget.14757. [Epub ahead of print].
87. Lüke C, Dietlein TS, Jacobi PC, Konen W, Krieglstein GK. A prospective randomized trial of viscocanalostomy versus trabeculectomy in open-angle glaucoma: a 1-year follow-up study. *J Glaucoma.* 2002;11(4):294-9.
88. Mansouri K, Guidotti J, Rao HL, Ouabas A, D'Alessandro E, Roy S, Mermoud A. Prospective Evaluation of Standalone XEN Gel Implant and Combined Phacoemulsification-XEN Gel Implant Surgery: 1-Year Results. *J Glaucoma.* 2018 Feb;27(2):140-147.
89. Mansouri K, Shaarawy T. Update on Schlemm's canal based procedures. *Middle East Afr J Ophthalmol.* 2015 Jan-Mar;22(1):38-44.
90. Maris PJ Jr, Ishida K, Netland PA. Comparison of trabeculectomy with Ex-PRESS miniature glaucoma device implanted under scleral flap. *J Glaucoma.* 2007 Jan;16(1):14-9.
91. Marzette L, Herndon LW. A comparison of the Ex-PRESS™ mini glaucoma shunt with standard trabeculectomy in the surgical treatment of glaucoma. *Ophthalmic Surg Lasers Imaging.* 2011 Nov-Dec;42(6):453-9.
92. Matlach J, Dhillon C, Hain J, Schlunck G, Grehn F, Klink T. Trabeculectomy versus canaloplasty (TVC study) in the treatment of patients with open-angle glaucoma: a prospective randomized clinical trial. *Acta Ophthalmol.* 2015 Dec;93(8):753-61.
93. Melamed S, Ben Simon GJ, Goldenfeld M, Simon G. Efficacy and safety of gold micro shunt implantation to the supraciliary space in patients with glaucoma: a pilot study. *Arch Ophthalmol.* 2009 Mar;127(3):264-9.
94. Minckler D, Baerveldt G, Ramirez MA, Mosaed S, Wilson R, Shaarawy T, Zack B, Dustin L, Francis B. Clinical results with the Trabectome, a novel surgical device for treatment of open-angle glaucoma. *Trans Am Ophthalmol Soc.* 2006;104:40-50.
95. Minckler DS, Francis BA, Hodapp EA, Jampel HD, Lin SC, Samples JR, Smith SD, Singh K. Aqueous shunts in glaucoma: a report by the American Academy of Ophthalmology. *Ophthalmology.* 2008 Jun;115(6):1089-98. Reviewed for currency: 2014.

96. Molteno AC, Bevin TH, Herbison P, Husni MA. Long-term results of primary trabeculectomies and Molteno implants for primary open-angle glaucoma. *Arch Ophthalmol*. 2011 Nov;129(11):1444-50.
97. Molteno AC, Whittaker KW, Bevin TH, Herbison P. Otago Glaucoma Surgery Outcome Study: long term results of cataract extraction combined with Molteno implant insertion or trabeculectomy in primary glaucoma. *Br J Ophthalmol*. 2004 Jan;88(1):32-5.
98. National Institute of Health (NIH): National Eye Institute. Eye Health Among Black/African American People. Feb 9, 2023. Accessed on Mar 6, 2024. Available at URL address: <https://www.nei.nih.gov/learn-about-eye-health/outreach-resources/eye-health-among-african-americans>
99. National Institute of Health (NIH): National Eye Institute. Glaucoma. Nov 15, 2023. Accessed Mar 6, 2024. Available at URL address: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/glaucoma>
100. Netland PA, Sarkisian SR Jr, Moster MR, Ahmed II, Condon G, Salim S, Sherwood MB, Siegfried CJ. Randomized, prospective, comparative trial of EX-PRESS glaucoma filtration device versus trabeculectomy (XVT study). *Am J Ophthalmol*. 2014 Feb;157(2):433-440.e3
101. New World Medical Inc. Ahmed™ glaucoma valve. 2024. Accessed Mar 7, 2024. Available at URL address: <https://www.newworldmedical.com/ahmed-glaucoma-valve/>
102. Nichamin LD. Glaukos iStent Trabecular Micro-Bypass. *Middle East Afr J Ophthalmol*. 2009 Jul;16(3):138-40.
103. Nova Eye Medical Limited. Molteno3® Glaucoma Drainage Device. Accessed on Mar 7, 2024. Available at URL address: <https://nova-eye.com/us/physicians/molteno3/>
104. O'Brart DP, Rowlands E, Islam N, Noury AM. A randomized, prospective study comparing trabeculectomy augmented with antimetabolites with a viscocanalostomy technique for the management of open angle glaucoma uncontrolled by medical therapy. *Br J Ophthalmol*. 2002;86(7):748-54.
105. O'Brart DP, Shiew M, Edmunds B. A randomized, prospective study comparing trabeculectomy with viscocanalostomy with adjunctive antimetabolite usage for the management of open angle glaucoma uncontrolled by medical therapy. *Br J Ophthalmol*. 2004;88:1012-7.
106. Olate-Pérez Á, Pérez-Torregrosa VT, Gargallo-Benedicto A, Neira-Ibáñez P, Cerdà-Ibáñez M, Osorio-Alayo V, Barreiro-Rego A, Duch-Samper A. Prospective study of filtering blebs after XEN45 surgery. *Arch Soc Esp Oftalmol*. 2017 Aug;92(8):366-371.
107. Optonol Ltd. Ex-PRESS™ Mini Glaucoma Shunt. 2024. Accessed Mar 7, 2024. Available at URL address: <http://www.opthalmologyweb.com/5588-Glaucoma-Shunt-Valve/51952-Ex-PRESS-Mini-Glaucoma-Shunt/>
108. Panarelli JF, Yan DB, Francis B, Craven ER. XEN Gel Stent Open Conjunctiva Technique: A Practical Approach Paper. *Adv Ther*. 2020 May;37(5):2538-2549. doi: 10.1007/s12325-020-01278-1. Epub 2020 Mar 21. PMID: 32200534; PMCID: PMC7467501.



109. Park J, Rittiphairoj T, Wang X, E J-Y, Bicket AK. Device-modified trabeculectomy for glaucoma. *Cochrane Database of Systematic Reviews* 2023, Issue 3. Art. No.: CD010472. DOI: 10.1002/14651858.CD010472.pub3.
110. Park M, Hayashi K, Takahashi H, Tanito M, Chihara E. Phaco-viscocanalostomy versus phaco-trabeculotomy: a middle-term study. *J Glaucoma*. 2006 Oct;15(5):456-61.
111. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M, Gargallo-Benedicto A, Osorio-Alayo V, Barreiro-Rego A, Duch-Samper A. Combined phacoemulsification and XEN45 surgery from a temporal approach and 2 incisions. *Arch Soc Esp Ophthalmol*. 2016 Sep;91(9):415-21.
112. Rabin RL, Rabin AR, Zhang AD, Burney EN, Rhee DJ. Co-management of cataract and glaucoma in the era of minimally invasive glaucoma surgery. *Curr Opin Ophthalmol*. 2018 Jan;29(1):88-95.
113. Razeghinejad MR, Spaeth GL. A history of the surgical management of glaucoma. *Optom Vis Sci*. 2011 Jan;88(1):E39-47.
114. Reitsamer H, Sng C, Vera V, Lenzhofer M, Barton K, Stalmans I; Apex Study Group. Two-year results of a multicenter study of the ab interno gelatin implant in medically uncontrolled primary open-angle glaucoma. *Graefes Arch Clin Exp Ophthalmol*. 2019 May;257(5):983-996.
115. Rhee DR. Which therapy to use in glaucoma? In: Yanoff and Duker, editors. *Yanoff Ophthalmology*, 4<sup>th</sup> ed. Saunders, an imprint of Elsevier, 2013.
116. Richter GM, Coleman AL. Minimally invasive glaucoma surgery: current status and future prospects. *Clin Ophthalmol*. 2016 Jan 28;10:189-206.
117. Rulli E, Biagioli E, Riva I, Gambirasio G, De Simone I, Floriani I, Quaranta L. Efficacy and safety of trabeculectomy vs nonpenetrating surgical procedures: a systematic review and meta-analysis. *JAMA Ophthalmol*. 2013 Dec;131(12):1573-82.
118. Salim S. Current variations of glaucoma filtration surgery. *Curr Opin Ophthalmol*. 2012 Jan 13. [Epub ahead of print].
119. Sarkisian SR. The ex-press mini glaucoma shunt: technique and experience. *Middle East Afr J Ophthalmol*. 2009 Jul;16(3):134-7.
120. Sarkisian SR Jr, Grover DS, Gallardo MJ, Brubaker JW, Giamporcaro JE, Hornbeak DM, Katz LJ, Navratil T; iStent infinite Study Group. Effectiveness and Safety of iStent Infinite Trabecular Micro-Bypass for Uncontrolled Glaucoma. *J Glaucoma*. 2023 Jan 1;32(1):9-18. doi: 10.1097/IJG.0000000000002141. Epub 2022 Oct 20. PMID: 36260288; PMCID: PMC9722368.
121. Schlenker MB, Gulamhusein H, Conrad-Hengerer I, Somers A, Lenzhofer M, Stalmans I, Reitsamer H, Hengerer FH, Ahmed IIK. Efficacy, safety, and risk factors for failure of standalone ab interno gelatin microstent implantation versus standalone trabeculectomy. *Ophthalmology*. 2017 Nov;124(11):1579-1588.
122. Schwartz KS, Lee RK, Gedde SJ. Glaucoma drainage implants: a critical comparison of types. *Curr Opin Ophthalmol*. 2006 Apr;17(2):181-9.

123. Seider MI, Rofagha S, Lin SC, Stamper RL. Resident-performed Ex-PRESS shunt implantation versus trabeculectomy. *J Glaucoma*. 2012 Sep;21(7):469-74.
124. Shaarawy T, Nguyen C, Schnyder C, Mermoud A. Five year results of viscocanalostomy. *Br J Ophthalmol*. 2003;87(4):441-5.
125. Sheybani A, Dick HB, Ahmed II. Early clinical results of a novel ab internogel stent for the surgical treatment of open-angle glaucoma. *J Glaucoma* 2016; 25:e691–e696.
126. Sheybani A, Lenzhofer M, Hohensinn M, et al. Phacoemulsification combined with a new abinternogel stent to treat open-angle glaucoma: pilot study. *J Cataract Refract Surg* 2015; 41:1905–1909.
127. Shingleton B, Tetz M, Korber N. Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract: one-year results. *J Cataract Refract Surg*. 2008 Mar;34(3):433-40.
128. Shoji T, Tanito M, Takahashi H, Park M, Hayashi K, Sakurai Y, Nishikawa S, Chihara E. Phacoviscocanalostomy versus cataract surgery only in patients with coexisting normal-tension glaucoma: midterm outcomes. *J Cataract Refract Surg*. 2007 Jul;33(7):1209-16.
129. Sight Sciences. OMNI® Surgical System. 2024. Accessed Mar 6, 2024. Available at URL address: <https://www.sightsciences.com/us/>
130. Singh D, Singh K. Transciliary filtration using the fugo blade™. *An Ophthalmol*. 2002;34(3):183-187.
131. Sng CC, Wang J, Hau S, Htoon HM, Barton K XEN-45 collagen implant for the treatment of uveitic glaucoma. *Clin Exp Ophthalmol*. 2018 May;46(4):339-345.
132. Stangos AN, Whatham AR, Sunaric-Megevand G. Primary viscocanalostomy for juvenile open-angle glaucoma. *Am J Ophthalmol*. 2005 Sep;140(3):490-6.
133. Sugiyama T, Shibata M, Kojima S, Ueki M, Ikeda T. The first report on intermediate-term outcome of Ex-PRESS glaucoma filtration device implanted under scleral flap in Japanese patients. *Clin Ophthalmol*. 2011;5:1063-6.
134. Tan NE, Tracer N, Terraciano A, Parikh HA, Panarelli JF, Radcliffe NM. Comparison of Safety and Efficacy Between Ab Interno and Ab Externo Approaches to XEN Gel Stent Placement. *Clin Ophthalmol*. 2021 Jan 26;15:299-305. doi: 10.2147/OPHTH.S292007. PMID: 33531795; PMCID: PMC7847364.
135. Tran DH, Souza C, Ang MJ, Loman J, Law SK, Coleman AL, Caprioli J. Comparison of long-term surgical success of Ahmed Valve implant versus trabeculectomy in open-angle glaucoma. *Br J Ophthalmol*. 2009 Nov;93(11):1504-9.
136. Tseng VL, Coleman AL, Chang MY, Caprioli J. Aqueous shunts for glaucoma. *Cochrane Database of Systematic Reviews* 2017, Issue 7. Art. No.: CD004918. DOI: 10.1002/14651858.CD004918.pub3.

137. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. EX-PRESS. K012852. Mar 26, 2002. Accessed Mar 7, 2024. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
138. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. Fugo Blade. K041019. Oct 8, 2004. Accessed Mar 7, 2024. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
139. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. Product code KYF. Accessed Mar 7, 2024. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
140. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. Visco™ 360. K171905. Jul 27, 2017. Accessed Mar 7, 2024. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
141. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. XEN Glaucoma Treatment System. K161457. Nov 21, 2016. Accessed Mar 7, 2024. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
142. U.S. Food and Drug Administration (FDA). 510(k) premarket notification. Guidance for industry and for FDA reviewers/staff: aqueous shunts - 510(k) submissions. Nov 16, 1998. Updated Mar 13, 2018. Accessed Mar 7, 2024. Available at URL address: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/aqueous-shunts-510k-submissions-guidance-industry-and-fda-reviewersstaff>
143. Vera V, Gagne S, Myers JS, Ahmed IIK. Surgical Approaches for Implanting Xen Gel Stent without Conjunctival Dissection. *Clin Ophthalmol*. 2020 Aug 17;14:2361-2371. doi: 10.2147/OPTH.S265695. PMID: 32903875; PMCID: PMC7445523.
144. Vold SD. Ab interno trabeculotomy with the trabectome system: what does the data tell us? *Int Ophthalmol Clin*. 2011 Summer;51(3):65-81.
145. Vold SD, Williamson BK, Hirsch L, Aminlari AE, Cho AS, Nelson C, Dickerson JE Jr. Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study. *Ophthalmol Glaucoma*. 2021 Mar-Apr;4(2):173-181. doi: 10.1016/j.ogla.2020.10.001. Epub 2020 Oct 9. PMID: 33045423.
146. Walland MJ, Carassa RG, Goldberg I, Grehn F, Heuer DK, Khaw PT, Thomas R, Parikh R. Failure of medical therapy despite normal intraocular pressure. *Clin Experiment Ophthalmol*. 2006 Dec;34(9):827-36.
147. Wang W, Zhou M, Huang W, Zhang X. Ex-PRESS implantation versus trabeculectomy in uncontrolled glaucoma: a meta-analysis. *PLoS One*. 2013 May 31;8(5):e63591.
148. Widder RA, Dietlein TS, Dinslage S, Kühnrich P, Rennings C, Rössler G. The XEN45 Gel Stent as a minimally invasive procedure in glaucoma surgery: success rates, risk profile, and rates of re-surgery after 261 surgeries. *Graefes Arch Clin Exp Ophthalmol*. 2018 Apr;256(4):765-771.
149. Wilson MR, Mendis U, Paliwal A, Haynatzka V. Long-term follow-up of primary glaucoma surgery with Ahmed glaucoma valve implant versus trabeculectomy. *Am J Ophthalmol*. 2003 Sep;136(3):464-70.

150. Wishart MS, Dages E. Seven-year follow-up of combined cataract extraction and viscocanalostomy. *J Cataract Refract Surg.* 2006 Dec;32(12):2043-9.
151. Wishart PK, Choudhary A, Wong D. Ahmed glaucoma valves in refractory glaucoma: a 7-year audit. *Br J Ophthalmol.* 2010 Sep;94(9):1174-9.
152. Wishart PK, Wishart MS, Choudhary A, Grierson I. Long-term results of viscocanalostomy in pseudoexfoliative and primary open angle glaucoma. *Clin Experiment Ophthalmol.* 2008 Mar;36(2):148-55.
153. Wishart PK, Wishart MS, Porooshani H. Viscocanalostomy and deep sclerectomy for the surgical treatment of glaucoma: a long term follow-up. *Acta Ophthalmol Scand.* 2003;81(4):343-8.
154. Woodcock MG, Richards JC, Murray AD. The last 11 years of Molteno implantation at the University of Cape Town. Refining our indications and surgical technique. *Eye (Lond).* 2008 Jan;22(1):18-25.
155. Yalvac IS, Eksioglu U, Satana B, Duman S. Long-term results of Ahmed glaucoma valve and Molteno implant in neovascular glaucoma. *Eye (Lond).* 2007 Jan;21(1):65-70.
156. Yalvac IS, Sahin M, Eksioglu U, Midillioglu IK, Aslan BS, Duman S. Primary viscocanalostomy versus trabeculectomy for primary open-angle glaucoma: Three-year prospective randomized clinical trial. *J Cataract Refract Surg.* 2004;30:2050-7.
157. Yarangumeli A, Gureser S, Koz OG, Elhan AH, Kural G. Viscocanalostomy versus trabeculectomy in patients with bilateral high-tension glaucoma. *Int Ophthalmol.* 2004 Jul;25(4):207-13. Epub 2005 Sep 29.
158. Yildirim Y, Kar T, Duzgun E, Sagdic SK, Ayata A, Unal MH. Evaluation of the long-term results of trabectome surgery. *Int Ophthalmol.* 2016 Oct;36(5):719-26.
159. Yook E, Vinod K, Panarelli JF. Complications of micro-invasive glaucoma surgery. *Curr Opin Ophthalmol.* 2018 Mar;29(2):147-154.
160. Zhang B, Kang J, Chen X. A System Review and Meta-Analysis of Canaloplasty Outcomes in Glaucoma Treatment in Comparison with Trabeculectomy. *J Ophthalmol.* 2017;2017:2723761

## Revision Details

Type of Revision	Summary of Changes	Date
Focused review	<ul style="list-style-type: none"> <li>• Removed policy statements for Glaukos iStent Trabecular Micro Bypass Stent, Glaukos iStent Inject, Ivantis Hydrus™ Microstent, ab interno suprachoroidal microstent (i.e., ab interno suprachoroidal microstent, drug-eluting ocular devices, Goniotomy (i.e. trabeculotomy, trabeculotomy ab interno), and excimer laser trabeculostomy (ie, ExTra ELT).</li> </ul>	10/15/2024

Annual review	• No policy statement changes.	4/15/2024
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