Medical Coverage Policy

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Glaucoma Surgical Procedures

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Related Coverage Resources

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The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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, 2024). 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 (2024), 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, 2025). 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, Goinioscopy Assisted Transluminal Trabeculotomy [GATT], TRAB 360/OMNI); enhancing aqueous outflow through Schlemn'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, transciliary 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 [Johnson & Johnson, Irvine, CA], Krupin [Hood Laboratories, Pembroke, MA], 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, Ltd., 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 (Johnson & Johnson, Irvine, CA): 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 subconjuctival 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, 2024).

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: ≥ 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 ≥ 18 and ≤ 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 ≥ 3 in the target quadrant. Postoperative change in mean IOP and medication usage were the primary outcome measures. Clinical success was defined as achieving ≥ 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 < 6mm 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 ≥ 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 ≥ 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 reinitiate 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 ≥ 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 ± 2.8 preoperatively and patients were on a mean of 3.1 ± 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 ± 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, 2025). Proposed advantages of canaloplasty over trabeculectomy include: no subconjuctival 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 successful 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 ≤ 18 mmHg or IOP decreased by ≥ 20% and to ≤ 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 ≤ 21 mmHg and ≥20% IOP reduction but was statistically significant for IOP ≤ 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 ≤21mmHg, ≤18mmHg, and ≤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., 2025) 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. 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 transciliary 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.

Transciliary Fistulization

Transciliary fistulization, transciliary 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 trabeculopasty have failed" (FDA, 2004).

Literature Review: There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of transciliary 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 canula 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 ≤ 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 ≤ 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 transciliary 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 (≤ 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 2024) glaucoma summary benchmarks for the management of primary open-angle glaucoma (OAG) stated that medical therapy is the most common 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

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determinations found.	
LCD	NGS	Microinvasive Glaucoma Surgery (MIGS) (L37244)	11/17/2024
LCD	Palmetto	Microinvasive Glaucoma Surgery (MIGS) (L37531)	11/17/2024
LCD	CGS	Microinvasive Glaucoma Surgery (MIGS) (L37578)	11/17/2024
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	Microinvasive Glaucoma Surgery (MIGS) (L39907)	11/17/2024

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:

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

CPT®* Codes	Description
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:

CPT®* Codes	Description
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:

CPT®* Codes	Description
66999†	Unlisted procedure, anterior segment of eye

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

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No policy statement changes.	4/15/2025
Focused review	• 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).	10/15/2024
Annual review	• No policy statement changes.	4/15/2024