INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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BENEFIT CONSIDERATIONS
Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE
Glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant, are proven and medically necessary for treating refractory glaucoma when conventional medical or surgical treatments have failed or are inappropriate.
The iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma and a cataract in adults currently being treated with ocular hypotensive medication.

The CyPass® Micro-Stent System is unproven and not medically necessary when used in combination with cataract surgery for treating mild-to-moderate primary open-angle glaucoma (POAG).

The Xen Glaucoma Treatment System is unproven and is not medically necessary for treating refractory glaucoma when conventional medical or surgical treatments have failed, or in patients with primary open-angle glaucoma, pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

Glaucoma drainage devices, such as Eyepass, DeepLight SOLX® Gold Shunt and other shunts that do not have FDA approval are investigational and unproven and not medically necessary for treating glaucoma. Clinical evidence is limited to small studies; therefore, additional studies are needed to establish the safety and efficacy of these devices.

Canaloplasty is proven and medically necessary for treating primary open-angle glaucoma.

Viscocanalostomy is unproven and not medically necessary for treating glaucoma. Evidence from the majority of available randomized controlled trials indicates that viscocanalostomy is not as effective as trabeculectomy in reducing intraocular pressure (IOP).

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion</td>
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<tr>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space</td>
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<tr>
<td>0376T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)</td>
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<td>0449T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device</td>
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<tr>
<td>0450T</td>
<td>Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)</td>
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<td>0474T</td>
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<td>66174</td>
<td>Transluminal dilation of aqueous outflow canal; without retention of device or stent</td>
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<tr>
<td>66175</td>
<td>Transluminal dilation of aqueous outflow canal; with retention of device or stent</td>
</tr>
<tr>
<td>66179</td>
<td>Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft</td>
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<tr>
<td>66180</td>
<td>Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)</td>
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<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
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<tr>
<td>66184</td>
<td>Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft</td>
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Glaucoma Surgical Treatments
UnitedHealthcare Commercial Medical Policy

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DESCRIPTION OF SERVICES

Glaucoma refers to a group of eye diseases in which vision is lost due to damage of the optic nerve. The 2015 American Academy of Ophthalmology (AAO) Preferred Practice Patterns Guidelines report on primary open-angle glaucoma states that the severity of glaucoma damage can be estimated using the following:

- Mild: Optic nerve abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry
- Moderate: Optic nerve abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with standard automated perimetry
- Severe: Optic nerve abnormalities consistent with glaucoma as and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with standard automated perimetry

Glaucoma drainage devices include the ExPRESS Mini Glaucoma Shunt, the Molteno implant, the Baerveldt tube shunt, or the Ahmed glaucoma valve implant. The ExPRESS Mini Glaucoma Shunt is a small stainless steel device that is placed beneath the scleral flap into the anterior chamber instead of creating a punch or excisional sclerostomy, thereby bypassing the trabecular meshwork and directing aqueous fluid to form a perilimbal conjunctiva-covered bleb. The Molteno, Baerveldt and Ahmed glaucoma implants consist of a length of flexible plastic tubing that is inserted into anterior or posterior chamber and connect to a plastic or silicone plate with a large surface area that is secured to the posterior sclera between two of the extraocular muscles, and covered by conjunctiva. The plate acts as a physical barrier to scarring of the conjunctiva to the sclera providing a large surface area bleb posterior to the limbus.

Viscocanalostomy is a procedure used to treat glaucoma that involves surgical incisions and injection of a viscous, elastic material into the eye. The goal of this procedure is to reduce intraocular pressure by creating a channel that allows excess fluid to drain from the eye.

Canaloplasty is a surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye (NICE, 2008). Canaloplasty involves viscodilation of the Schlemm's canal with an illuminated tipped microcatheter. The microcatheter is used to place an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening the Schlemm's canal.

The difference between a viscocanalostomy and a canaloplasty is that the canaloplasty aims at opening the entire length of the canal, not just one section of it. Canaloplasty and viscocanalostomy are referred to as nonpenetrating procedures.

Trabeculectomy is a surgical procedure that removes part of the eye’s trabecular meshwork and adjacent structures to reduce intraocular pressure in patients with glaucoma. For the majority of patients it is the most common surgery that allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is absorbed.

GLAUCOMA DRAINAGE DEVICES APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

iStent

Arriola-Vilaobos er al. (2013) conducted a prospective, non-comparative, uncontrolled, interventional case study to evaluate the mid-term efficacy and safety of the GTS-400- iStent combined with phacoemulsification in patients with cataract and open glaucoma (OAG or ocular hypertension. Prospective, non-comparative, uncontrolled, interventional case series study. Subjects underwent phacoemulsification and two GTS-400 implantation. Efficacy outcomes: intraocular pressure (IOP) and antiglaucoma medications. Safety outcomes: complications, best-corrected visual acuity and endothelial cell count (ECC). Follow-up was 1 year. 20 patients were enrolled (mean age: 75.1 ± 8.6 years). Mean medicated baseline IOP was 19.95 ± 3.71 mm Hg and 26 ± 3.11 mm Hg without medication. Mean final IOP was 16.75 ± 2.24, determining a final IOP decrease of 35.68% (9.42 ± 3 mm Hg; p<0.001), from baseline washout IOP. Mean number of medications fell from 1.3 ± 0.66 to 0.3 ± 0.57 (P<0.001). 75% of patients were off medications at one year. Mean ECC decreased from 2289.64 ± 393.5 cells/mm(2) to 1986.95 ± 520.58 cells/mm(2). The authors concluded that combined cataract surgery with implantation of GTS-400-iStent appeared to be an effective and safe service.

Glaucoma Surgical Treatments
UnitedHealthcare Commercial Medical Policy

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Arriola-Villalobos et al. (2012) also evaluated the long-term efficacy and safety of combined cataract surgery and Glaukos iStent implantation for coexistent open-angle glaucoma and cataract. This prospective case series included 19 patients. Mean follow-up was 53.68 months. Mean intraocular pressure (IOP) was reduced from 19.42 mm Hg at the end of follow up, indicating a 16.33% to 16.26 mm decrease in IOP. The mean number of pressure-lowering medications used by the patients fell from 1.32 to 0.84. In 42% of patients, no antiglaucoma medications were used at the end of follow-up. Mean best-corrected visual acuity significantly improved from 0.29 to 0.62. The authors concluded that combined cataract surgery and Glaukos iStent implantation seems to be an effective and safe procedure to treat coexistent open-angle glaucoma and cataract.

Samuelson et al. (2011) assessed the safety and efficacy of the iStent trabecular micro-bypass stent (Glaukos Corporation, Laguna Hills, CA) in combination with cataract surgery in a prospective, randomized, open-label, controlled, multicenter clinical trial. A total of 240 eyes with mild to moderate open-angle glaucoma with intraocular pressure (IOP) ≤24 mmHg controlled on 1 to 3 medications were randomized to undergo cataract surgery with iStent implantation (treatment group) or cataract surgery only (control). Fifty additional patients were enrolled to undergo cataract surgery with iStent implantation under protocol expansion. The primary efficacy measure was unmedicated IOP ≤21 mmHg at 1 year. The study met the primary outcome, with 72% of treatment eyes versus 50% of control eyes achieving the criterion. At 1 year, IOP in both treatment groups was statistically significantly lower from baseline values. Sixty-six percent of treatment eyes versus 48% of control eyes achieved 20% or more IOP reduction without medication. The overall incidence of adverse events was similar between groups with no unanticipated adverse device effects. The investigators concluded that pressure reduction on fewer medications was clinically and statistically significantly better 1 year after stent plus cataract surgery versus cataract surgery alone, with an overall safety profile similar to that of cataract surgery alone.

In a prospective case series, Belovay et al. (2012) evaluated the efficacy and safety of multiple trabecular micro-bypass stents in 47 cataract patients (mean age 77.2 years) (53 eyes) to treat primary open-angle glaucoma (POAG). Either 2 (n=26) or 3 (n=23) stents were implanted along with concurrent cataract surgery. Efficacy measures were IOP and topical ocular hypotensive medication use. Patients were followed for 1 year. The overall mean 1-year postoperative IOP was 14.3 mm Hg, which was significantly lower than preoperative IOP overall and in each group. The target IOP was achieved in a significantly higher proportion of eyes at 1 year versus preoperatively (77% versus 43%). Overall, 83% of eyes had a decrease in topical ocular hypotensive medication at 1 year from preoperatively, with a 74% decrease in the mean number of medications (from 2.7 to 0.7) at 1 year. The 3-stent group was on significantly fewer medications than the 2-stent group at 1 year. The authors concluded that the use of multiple micro-bypass stents with concurrent cataract surgery led to a mean postoperative IOP of less than 15 mm Hg and allowed patients to achieve target pressure control with significantly fewer medications through 1 year.

A National Institute for Health and Care Excellence (NICE) interventional procedure guidance for Trabecular Stent Bypass Microsurgery for Open Angle Glaucoma states that current evidence on trabecular stent bypass microsurgery for open angle glaucoma raises no major safety concerns. There is evidence of efficacy in the short term but this is based on small numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2011).

A Hayes report concluded that the iStent Trabecular Micro-Bypass device, when used in combination with cataract surgery, appears to be an efficacious and safe treatment for patients with open-angle glaucoma who do not achieve adequate control of intraocular pressure (IOP) on ocular hypotensive medications. The report also evaluated the use of multiple stents in conjunction with phacoemulsification. Results suggest that overall stent implantation was successful in reducing IOP from baseline measurements. No statistically significant differences were seen between groups having 2 or 3 stents at 12 months; however, those with 3 stents were using statistically significantly fewer ocular hypotensive medications (2016).

Several registered ongoing clinical trials relevant to the iStent can be reviewed on ClinicalTrials.gov.

*CyPass®*

In a multicenter interventional randomized clinical trial, Vold et al. evaluated 2-year safety and efficacy of suprachoroidal microstenting (CyPass Micro-Stent; Transcend Medical, Inc., Menlo Park, CA) for treating mild-to-moderate primary open-angle glaucoma (POAG) in patients undergoing cataract surgery. Subjects had POAG with mean diurnal unmedicated intraocular pressure (IOP) 21–33 mmHg and were undergoing phacoemulsification cataract surgery. Of 505 subjects, 131 were randomized to the control group and 374 were randomized to the microstent group. There was early and sustained IOP reduction, with 60% of controls versus 77% of microstent subjects achieving ≥20% unmedicated IOP lowering versus baseline at 24 months. Mean 24-month medication use was 67% lower in microstent subjects (P < 0.001); 59% of control versus 85% of microstent subjects were medication free. No vision-threatening microstent-related adverse events occurred. Visual acuity was high in both groups through 24 months; >98% of all subjects achieved 20/40 best-corrected visual acuity or better. The authors concluded that
microinterventional surgical treatment for mild-to-moderate POAG was safe and the technology’s use resulted in a sustained 2-year reduction in IOP and glaucoma medication use (2016).

A multicenter, single-arm interventional study was conducted by García-Feijoo et al. to evaluate the safety and efficacy of a supraciliary micro-stent (CyPass Micro-Stent) for surgical treatment of glaucoma in patients refractory to topical medications. Patients with open-angle glaucoma (Shaffer Grade 3 and 4) and uncontrolled medicated intraocular pressure (IOP) >21 mm Hg at baseline and candidates for conventional glaucoma surgery were enrolled. CyPass Micro-Stent implantation was completed in all patients using a standard clear corneal approach. Adverse events, postoperative IOP changes, and need for IOP-lowering medications during the first 12 postoperative months (12M) were monitored. Sixty-five eyes were enrolled, and 55 were available at 12M. There were no serious intraoperative events or major adverse events. At 12M, mean IOP was reduced by 34.7% and mean medication usage also decreased. In eyes originally indicated for conventional glaucoma surgery, no secondary surgery was performed in 83% (53/64). The authors concluded that supraciliary stenting with the CyPass Micro-Stent effectively lowers IOP as a surgical treatment for glaucoma, precluding the need for more invasive glaucoma surgery in >80% of patients at 1 year, thereby reducing postoperative glaucoma surgical complications (2015).

**Xen Glaucoma Treatment System**

New studies have shown that minimally invasive glaucoma surgery (MIGS) using drainage devices such as the ab interno gel implant (XEN, Allergan, Dublin, Ireland) may lower the IOP and/or topical medication burden in phakic or pseudophakic patients with glaucoma. This effect seems to last at least 12 months, but reliable cost-effectiveness and quality of life indicators have not yet been established by investigator-initiated randomized trials of sufficient size and duration. Further research is needed to determine the clinical relevance of these findings (Kerr et al. 2016).

Vinode and Gedde (2016) evaluated literature from the 2015 to 2016. Abundant data regarding new and emerging glaucoma procedures was reviewed with notable findings from recent randomized clinical trials being identified. Early studies of investigational subconjunctival filtering devices which included XEN Gel Stent (AqueSys, Inc., Aliso Viejo, California, USA) were found to offer promising evidence, but late complications are as yet unknown. The authors concluded that newer glaucoma procedures targeting different aqueous outflow pathways have improved the safety profile of glaucoma surgery while preserving modest efficacy. Most can be combined with phacoemulsification, allowing for simultaneous treatment of comorbid cataract and glaucoma. Well-designed randomized clinical trials with extended follow-up remain necessary to evaluate the long-term efficacy and late complications of these novel procedures.

Two clinical trials associated with the Xen Glaucoma Treatment System are active but not recruiting. They can be reviewed on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).

**Ex-PRESS**

De Jong (2009) conducted a prospective, randomized trial of 78 patients (80 eyes) with primary open-angle, pseudoxefoliatative, or pigmentary glaucoma to compare the Ex-PRESS mini glaucoma shunt with trabeculectomy. A total of 84.6% of patients receiving Ex-PRESS and 60.0% of patients receiving trabeculectomy achieved complete success. Complete success was defined as an IOP of >4 mmHg <=18 mmHg without the use of antiglaucoma medications. The respective proportions of patients achieving an intraocular pressure (IOP) >4 mmHg and <=15 mmHg were 76.9% and 50.0%. At 1-year follow-up, complete success rates were 81.8% for Ex-PRESS and 47.5% for trabeculectomy, and 71.7% and 37.5%, respectively, for the more stringent target. The authors concluded that the Ex-PRESS mini glaucoma shunt implanted under a superficial scleral flap produces significantly higher success rates compared with trabeculectomy.

In follow up to the above study de Jong et al. (2011) reported on outcomes at 4 years beyond those in the original randomized controlled trial, i.e., up to 5 years in the 78 patients who received either the Ex-PRESS device (n=39) or who underwent a trabeculectomy (n=39). Compared with trabeculectomy, the Ex-PRESS device controlled IOP more effectively without medication in a higher percentage of patients from year 1 (86.8% versus 61.5%) to year 3 (66.7% versus 41.0%) after treatment. At 1 year posttreatment, only 12.8% of patients required IOP medication after Ex-PRESS implantation, compared with 35.9% after trabeculectomy; however, the proportions became closer each year and at 5 years were 41% versus 53.9%, respectively. Up to the end of the third year after surgery, IOP remained better controlled by Ex-PRESS devices than by trabeculectomy. In the fourth and fifth years, the differences in IOP control between the two groups were not significant.

Ates et al. (2010) evaluated intraocular pressure (IOP) control and graft survival after Ex-PRESS mini glaucoma shunt implantation in 15 patients. IOP decreased from 41.46 mm Hg to 12.06 mm Hg over a mean follow-up of 12.2 months. Neither biomicroscopy nor pachymetry showed worsening of preoperatively opaque grafts. The investigators concluded that the Ex-PRESS mini glaucoma shunt implantation may be an effective procedure for refractory post-penetrating keratoplasty glaucoma with acceptable graft failure rates in short term.
**Molteno Implant, Baerveldt Tube Shunt and Ahmed Glaucoma Valve Implant**

A Cochrane review compared various aqueous shunts for intraocular pressure (IOP) control and safety (Minkler, 2006). Only randomized and quasi-randomized trials were included. This included 15 trials with a total of 1153 participants with mixed diagnoses. Five studies reported details sufficient to verify the method of randomization but only two had adequate allocation concealment. Data collection and follow-up times were variable. Meta-analysis of two trials comparing Ahmed implant with trabeculectomy found trabeculectomy resulted in lower mean IOPs 11 to 13 months later. One study concluded there were outcome advantages with a double versus a single-plate Molteno implant and one trial comparing the 350 mm² and 500 mm². Baerveldt shunts found no clinically significant advantage of the larger device but neither of these trials included all patients randomized. One study comparing endocyclophotocoagulation (ECP) with Ahmed implant in complicated glaucomas found no evidence of better IOP control with Ahmed implant over ECP. The authors concluded that there are relatively few randomized trials that have been published on aqueous shunts, therefore methodology and data quality among them is poor. To date there is no evidence of superiority of one shunt over another. This meta-analysis was a review of comparative studies and did not evaluate whether aqueous shunts could lower intraocular pressure.

Budenz et al. (2011) evaluated the relative efficacy and complications of the Ahmed glaucoma valve (AGV) (New World Medical, Ranchos Cucamonga, CA) and the Baerveldt glaucoma implant (BGI) (Abbott Medical Optics, Abbott Park, IL) in refractory glaucoma in a multicenter, randomized, controlled clinical trial. The study included 276 patients (143=AGV group and 133 =BGI). Preoperative IOP was 31.2±11.2 mmHg in the AGV group and 31.8±12.5 mmHg in the BGI group. At 1 year, mean±SD IOP was 15.4±5.5 mmHg in the AGV group and 13.2±6.8 mmHg in the BGI group. The mean±SD number of glaucoma medications was 1.8±1.3 in the AGV group and 1.5±1.4 in the BGI group. The cumulative probability of failure was 16.4% in the AGV group and 14.0% in the BGI group at 1 year. More patients experienced early postoperative complications in the BGI group (n = 77; 58%) compared with the AGV group (n = 61; 43%). Serious postoperative complications associated with reoperation, vision loss of ≥2 Snellen lines, or both occurred in 29 patients (20%) in the AGV group and in 45 patients (34%) in the BGI group. The investigators concluded that although the average IOP after 1 year was slightly higher in patients who received an AGV, there were fewer early and serious postoperative complications associated with the use of the AGV than the BGI.

Gedde et al. (2009) evaluated the use of the Baerveldt glaucoma implant or trabeculectomy with mitomycin C in a multicenter randomized clinical trial (Tube versus Trabeculectomy (TVT) Study). A total of 212 eyes of 212 patients with uncontrolled glaucoma were enrolled, including 107 in the tube group and 105 in the trabeculectomy group. At 3 years, IOP was 13.0 mm Hg in the tube group and 13.3 mm Hg in the trabeculectomy group. The number of glaucoma medications was 1.3 in the tube group and 1.0 in the trabeculectomy group. The cumulative probability of failure during the first 3 years of follow-up was 15.1% in the tube group and 30.7% in the trabeculectomy group. Postoperative complications developed in 42 patients (39%) in the tube group and 63 patients (60%) in the trabeculectomy group. The investigators concluded that tube shunt surgery had a higher success rate compared to trabeculectomy during the first 3 years of follow-up in the TVT Study. Both procedures were associated with similar IOP reduction and use of supplemental medical therapy at 3 years. While the incidence of postoperative complications was higher following trabeculectomy with MMC relative to tube shunt surgery, most complications were transient and self-limited.

**Glaucoma Drainage Devices Not Approved by the U.S. Food and Drug Administration (FDA)**

**Eyepass**

Dietlein et al. (2008) conducted a small study to evaluate the safety and pressure-reducing efficacy of the Y-shaped Eyepass glaucoma implant in 12 glaucoma and cataract patients and found that combined cataract surgery with Eyepass shunt implantation was safe and appeared to be beneficial in glaucomatous eyes with cataract not requiring a low target IOP. Perforation of the trabecular meshwork during Eyepass implantation occurred in 2 eyes requiring explantation. In the remaining 10 eyes, the mean maximum IOP was 30.4 mm Hg preoperatively, 12.0 mm 1 day postoperatively, 17.2 mm Hg at 4 weeks, and 18.3 mm at the end of the preliminary follow-up.

**SOLX Gold Shunt**

2 clinical trials are listed for the Solx Gold Shunt. One Phase III trial has been completed, but no data has yet been published (http://clinicaltrials.gov/ct2/show/NCT01282346). The other trial has suspended participant recruitment (http://clinicaltrials.gov/ct2/show/NCT00382395). (Accessed December 13, 2016)

A detailed search of the medical peer-reviewed literature on December 13, 2016 did not identify that the above glaucoma drainage devices have been approved by the FDA. They remain unproven and not medically necessary for treating glaucoma.

**Viscocanalostomy**

A Cochrane review analyzed data from randomized and quasi-randomized trials where surgical techniques were utilized to treat primary congenital glaucoma (PCG). The rationale for the analysis was to compare the efficacy and
safety of different surgical techniques in children diagnosed at age one and younger and having surgical therapy before 5 years of age (N=61). Due to the limited sample sizes for all trials (average of 10 children per trial), the evidence as to whether a particular surgical technique is effective and which surgical technique is better still remains uncertain. Adverse events, such as choroidal detachment, shallow anterior chamber and hyphema, were reported from four trials. None of the trials reported quality of life or economic data. These trials were neither designed nor reported well overall. Due to poor study design and reporting, the reliability and applicability of evidence remain unclear. The author states that no conclusions could be drawn from the trials included in this review due to paucity of data. The reviewer concluded that more research is needed to determine which of the many surgeries performed for PCG are effective (Ghate et al. 2015).

Chai et al. (2010) conducted a meta-analysis to compare the efficacy and safety profile of viscocanalostomy versus trabeculectomy. Ten randomized controlled trials were selected and included in the meta-analysis with a total of 458 eyes of 397 patients with medically uncontrolled glaucoma. Trabeculectomy was found to have a significantly better pressure-lowering outcome. Viscocanalostomy had a significantly higher relative risk of intraoperative perforation of the Descemet membrane, whereas trabeculectomy had significantly more postoperative adverse events. The reviewers concluded that trabeculectomy had a greater pressure-lowering effect compared with viscosanalostomy. However, viscosanalostomy had a significantly beter risk profile.

A meta-analysis by Hondur et al. (2008) evaluated the efficacy of nonpenetrating glaucoma surgery for open angle glaucoma with respect to target intraocular pressure (IOP) and severity of glaucoma. The studies reviewed included deep sclerectomy (DS) and viscosanalostomy (VC). With lower set IOP targets, the rates of success varied between 35% and 86% for DS, and between 10% and 67% for VC. Mean follow-up was mostly in the range of 3 years. The authors concluded that nonpenetrating glaucoma surgery seems to provide IOP reduction into the high teens. Its potential to achieve lower target IOPs seems to be lower. Longer-term studies, with data related to glaucoma severity and proper target IOPs are required.

Cheng et al. (2011) evaluated the intraocular pressure (IOP)-lowering effects achieved by nonpenetrating glaucoma surgery (NPGS) in patients with open angle glaucoma in a systematic review of randomized controlled trials. The pooled estimates were calculated using the random effects model. Both deep sclerectomy (DS) and viscosanalostomy (VCO) were less effective than trabeculectomy (TE) in lowering IOP, with the percentage IOP reductions at 2 years being 35.2% for DS, 30.2% for VCO, and 45.6% for TE. The complete success rates at 4 years were 35.4% for DS, and 22.7% for VCO, lower than that of TE (47.6%). According to the authors, primary deep sclerectomy and primary viscosanalostomy, which can significantly lower IOP, were associated with fewer complications than was TE. However, the IOP-lowering effects of both nonpenetrating glaucoma surgeries seem to be lower than that of primary TE.

Koerber et al. (2012) compared the safety and efficacy of canaloplasty in one eye with viscosanalostomy in the contralateral eye in 15 patients (30 eyes) with bilateral primary open-angle glaucoma (POAG). Sixty percent of patients had the canaloplasty procedure first, followed by the viscosanalostomy procedure. At 18-month follow-up, both canaloplasty and viscosanalostomy were successful in reducing IOP. The percentage reduction in IOP was significantly higher in the canaloplasty eyes (approximately 44%), as compared with the viscosanalostomy eyes (approximately 33%), at both 12 and 18 months. Final absolute IOP was not significantly different, although lower, in the canaloplasty group versus the viscosanalostomy group at 18 months. Using the criteria for complete success defined as an IOP of ≤ 18 mm Hg without antiglaucoma medication, and qualified success as an IOP of ≤ 18 mm Hg with 1 or 2 antiglaucoma medications, the canaloplasty cohort achieved complete success in 60.0% of eyes, and complete or qualified success in 86.7% of eyes; the viscosanalostomy group achieved complete success in 35.7% of eyes, and complete or qualified success in 50.0% of eyes. Complications were minimal in both groups. According to the authors, canaloplasty and viscosanalostomy were safe and effective in the surgical management of open-angle glaucoma. The authors also stated that canaloplasty procedures showed superior efficacy to viscosanalostomy in the reduction of IOP.

In a guidance on the diagnosis and management of chronic open-angle (OAG) and ocular hypertension, the National Institute for Health and Care Excellence (NICE) concluded from the evidence (low to moderate quality) that trabeculectomy is more effective than non-penetrating surgery (e.g., viscosanalostomy) in reducing IOP from baseline at six- and 12-month follow-ups, but the effect size may be too small to be clinically significant. Trabeculectomy is also more effective in reducing the number of eyes with unacceptable IOP at six- and 12-month follow-ups (NICE 2009).

**Canaloplasty**

Grieshaber et al. (2010) compared the safety and efficacy of two polypropylene (Prolene) sutures for tensioning of the inner wall of Schlemm's canal (SC) in patients with primary open-angle glaucoma (POAG) undergoing canaloplasty. This prospective randomized trial included 90 patients. The mean preoperative intraocular pressure (IOP) was 42.7 mm Hg in group 1 and 45.0 mm Hg in group 2. The mean postoperative IOP without medications was 18.4 mm Hg in group 1 and 16.4 mm Hg in group 2 at 1 month, and 19.2 mm Hg in group 1 and 16.4 mm Hg in group 2 at 15...
months. Pressures equal or less than 21, 18, and 16 mm Hg without medications (complete success) at 12 months were 51.0%, 34.1%, and 21.2% in group 1, and 76.9%, 68.8%, and 53.6% in group 2, respectively. The investigators concluded that IOP reduction was substantial in canaloplasty. Younger age, but not the level of IOP at surgery, had a positive effect on the amount of IOP reduction, thus suggesting that an early surgical intervention to re-establish physiological outflow offers the best prognosis.

Grieshaber et al. (2010a) evaluated the safety and effectiveness of 360° visco-dilation and tensioning of Schlemm canal (canaloplasty) in patients with primary open-angle glaucoma (POAG). Sixty randomly selected eyes of 60 consecutive patients with POAG were included in this prospective study. The mean preoperative intraocular pressure (IOP) was 45.0 mm Hg. The mean follow-up time was 30.6 months. The mean IOP at 12 months was 15.4 mm Hg (n=54), at 24 months 16.3 mm Hg (n = 51) and at 36 months 13.3 mm Hg (n=49). For IOP ≤ 21 mm Hg, complete success rate was 77.5% and qualified success rate was 81.6% at 36 months. Complication rate was low. The investigators conclude that canaloplasty produced a sustained long-term reduction of IOP in patients with POAG independent of preoperative IOP. As a bleb-independent procedure, canaloplasty may be a true alternative to classic filtering surgery, in particular in patients with enhanced wound healing and scar formation.

Lewis et al. (2011) conducted a multicenter clinical trial that included 157 eyes in 157 patients (140 patients with POAG, 17 patients with other glaucoma diagnoses) who underwent canaloplasty or combined cataract-canaloplasty surgery. A total of 121 eyes (77.1%) had canaloplasty alone, while 36 eyes (22.9%) with visually significant cataracts had canaloplasty combined with cataract extraction (phacocanaloplasty). Complete success (defined as attaining an IOP of ≤ 18 mm Hg without antiglaucoma medication) at 3-year follow-up was achieved in 36% of eyes receiving canaloplasty alone with successful suture placement, and 70.4% of eyes having the combined phacocanaloplasty procedure with successful suture placement. Complete or qualified success (defined as attaining an IOP of ≤ 18 mm Hg with 1 or 2 antiglaucoma medications) was achieved in 77.5% of eyes with canaloplasty alone, and 88.9% of eyes with phacocanaloplasty. The authors concluded that canaloplasty led to a significant and sustained IOP reduction in adult patients with open-angle glaucoma and had an excellent short- and long-term postoperative safety profile.

Bull et al. (2011) reported 3-year results investigating the safety and efficacy of canaloplasty in a prospective, multicenter, interventional study of 109 eyes of 109 adult, open-angle glaucoma patients undergoing canaloplasty or combined cataract-canaloplasty surgery. Intraocular pressure and medication use results for all study eyes were significantly decreased from baseline. According to the authors, canaloplasty demonstrated significant and sustained IOP reductions accompanied by an excellent short- and long-term safety profile in adult patients with open-angle glaucoma.

**Professional Societies**

**American Academy of Ophthalmology (AAO)**

The AAO Preferred Practice Patterns Committee and Glaucoma Panel (2015) considered viscocanalostomy and canaloplasty in their report on primary open-angle glaucoma. The following statements were made regarding these alternatives to current glaucoma surgery: The precise role of nonpenetrating surgery in the surgical management of glaucoma remains to be determined. The two main types of nonpenetrating glaucoma surgery are viscocanalostomy and nonpenetrating deep sclerectomy. The rationale for nonpenetrating glaucoma surgery is that by avoiding a continuous passageway from the anterior chamber to the subconjunctival space, the incidence of complications such as bleb-related problems and hypotony can be reduced. The nonpenetrating procedures have a higher degree of surgical difficulty compared with trabeculectomy and require special instrumentation. Randomized clinical trials comparing viscocanalostomy with trabeculectomy generally suggest greater intraocular pressure (IOP) reduction with trabeculectomy, but fewer complications with viscocanalostomy. No randomized clinical trials comparing trabeculectomy and canaloplasty exists (AAO 2015).

On the topic of combining glaucoma and cataract surgery, the AAO Preferred Practice Patterns Guidelines state that the decision of which procedure(s) to perform first or whether to combine cataract and glaucoma surgery is determined by the ophthalmologist and patient. Generally, combined cataract and glaucoma surgery is not as effective as glaucoma surgery alone in lowering IOP, so patients who require filtration surgery who also have mild cataract may be better served by filtration surgery alone and cataract surgery later. A systematic review published in 2002 found moderate quality evidence that separating the cataract and glaucoma incisions results in lower IOP than a one-site combined procedure, but the differences in outcomes were small. Subsequent publications have found no difference between the two approaches (AAO 2015).

An AAO Ophthalmic Technology Assessment by Minckler et al. (2008) provided an evidence-based summary of commercially available aqueous shunts currently used in substantial numbers (Ahmed, Baerveldt, Krupin, and Molteno) that are used to control intraocular pressure (IOP) in various glaucomas. Although the primary indication for aqueous shunts is when prior medical or surgical therapy has failed, they may be used as primary surgical therapy for selected conditions such as trauma, chemical burns, or pemphigoid (level III evidence - case series, case reports, and poor quality cohort and case-control studies). Based on level I evidence, aqueous shunts seem to have benefits (IOP
control, duration of benefit) comparable with those of trabeculectomy in the management of complex glaucomas (phakic or pseudophakic eyes after prior failed trabeculectomies). Level I evidence indicates that there are no advantages to the adjunctive use of anti-fibrotic agents or systemic corticosteroids with currently available shunts. Too few high-quality direct comparisons of various available shunts have been published to assess the relative efficacy or complication rates of specific devices beyond the implication that larger-surface-area explants provide more enduring and better IOP control. Long-term follow-up and comparative studies are encouraged.

An AAO technology assessment on novel glaucoma procedures (Francis et al, 2011) provided an evidence-based summary of clinically relevant information on novel devices for treating open-angle glaucoma (e.g., iStent, ExPRESS™ mini glaucoma shunt, SOLX® Gold Shunt). The authors concluded that the novel glaucoma surgeries studied all showed some promise as alternative treatments to lower intraocular pressure in the treatment of open-angle glaucoma. However, their report states that it is not possible to conclude whether these novel procedures are superior, equal to, or inferior to surgery such as trabeculectomy or to one another.

AAO references do not reflect that the organization has taken a position on the CyPass® Micro-Stent System or the Xen Glaucoma Treatment System.

**Canadian Ophthalmological Society**

The Canadian Ophthalmological Society guidelines for the management of glaucoma in the adult eye lists viscocanalostomy under other strategies for the surgical management of coexisting cataract and glaucoma, but the guideline developers report that there is insufficient scientific evidence comparing these procedures to phaco-trabeculectomy (Canadian Ophthalmological Society, 2009).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

**Glaucoma Drainage Devices**


Predicte Devices include the Molteno Implant (K890598 and K902489), the Baerveldt Glaucoma Implant (K905129 and K955455), the Krupin Eye Valve (K885125 and K905703), the Ahmed Glaucoma Valve Implant (K925636), and the Xen Glaucoma Treatment System (K161457). Additional information is available at: [http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073806.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073806.pdf). (Accessed December 5, 2016)

iStent Trabecular Micro-Bypass Stent System, Model GTS100R/L, was approved by the FDA on June 25, 2012. This device is approved for use in combination with cataract surgery to reduce pressure inside the eye (intraocular pressure) in adult patients with mild to moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce intraocular pressure. Additional information is available at: [http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080030b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080030b.pdf). (Accessed December 13, 2016)

CyPass® System, Model 241-S, was approved by the FDA on July 29, 2016. This device is approved for microinvasive glaucoma surgery (MIGS) in combination with cataract surgery, and is indicated to reduce intraocular pressure (IOP) in adults with mild-to-moderate primary open-angle glaucoma. Additional information is available at: [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm513982.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm513982.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery). (Accessed December 13, 2016)

**Viscocanalostomy and Canaloplasty**

Specialized devices used for viscocanalostomy and canaloplasty are regulated by the FDA as Class II devices. Additional information may be obtained at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncf](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncf) under product codes HMX (cannula, ophthalmic), MPA (endoilluminator), or MRH (pump, infusion, ophthalmic). (Accessed December 13, 2016)

The Canaloplasty Ophthalmic Microcannula, or iTRACK, is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye such as the anterior chamber and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The FDA approved the Ophthalmic Microcannula in June 2004. See the following website for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf4/k041108.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf4/k041108.pdf). (Accessed December 13, 2016)
The iScience Surgical Fiberoptic Illuminator provides localization of the Schlemm’s canal and was approved by the FDA in August 2006. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062259.pdf. (Accessed December 13, 2016)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for surgical treatments for glaucoma (e.g., glaucoma drainage devices, viscocanalostomy and canaloplasty). Local Coverage Determinations (LCDs) exist; see the LCDs for Category III Codes, Category III CPT® Codes, Glaucoma Treatment with Aqueous Drainage Device and Non Covered Services. (Accessed December 14, 2016)

REFERENCES


Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. 2012 Feb;21(2):129-34.


**POLICY HISTORY/REVISION INFORMATION**

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