

GLAUCOMA SURGICAL TREATMENTS

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[Instructions for Use](#) ⓘ

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Related Policy

- [Corneal Hysteresis and Intraocular Pressure Measurement](#)

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ²
Precertification with Medical Director Review Required	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Office, Outpatient
Special Considerations	<p>¹Precertification with review by a Medical Director or their designee is required.</p> <p>²Participating Providers in the Office Setting: Precertification is required for services performed in the office of a participating provider. Non-Participating/ Out-of-Network Providers in the Office Setting: Precertification is not required, but is encouraged for out-of-network services performed in the office. If precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered.</p>

COVERAGE RATIONALE

Glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Moltano 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 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, 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 the treatment of 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 may apply.

CPT Code	Description
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0376T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft

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HCPCS Code	Description
L8612	Aqueous shunt

DESCRIPTION OF SERVICES

Glaucoma refers to a group of eye diseases in which vision is lost due to damage of the optic nerve. The 2010 American Academy of Ophthalmology (AAO) Preferred Practice Patterns Guidelines report on POAG 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 2 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.

Glaucoma drainage devices, such as iStent®, Eyepass, or DeepLight SOLX® Gold Shunt (suprachoroidal shunt); divert aqueous fluid from the anterior chamber directly into Schlemm's canal (Samuelson, 2008). The CyPass® Micro-Stent increases aqueous flow via implantation in the suprachoroidal space between the sclera and the ciliary body (Hayes, 2017). The Xen® Gel Stent is for use in patients with refractory glaucoma. A gelatin tube is implanted into the subconjunctival space and is proposed as a less traumatic alternative to an external procedure such as trabeculectomy and shunt implantation (AqueSys, Inc., 2017). These stenting/shunting procedures are similar to viscocanalostomy in that they lower IOP without the formation of a filtering bleb.

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 IOP 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 (National Institute for Health and Care Excellence (NICE), 2008; updated 2017). 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 IOP 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.

CLINICAL EVIDENCE

Glaucoma Drainage Devices Approved by the U.S. Food and Drug Administration (FDA)

iStent[®]

Arriola-Vilaobos et al. (2013) conducted a prospective, non-comparative, uncontrolled, interventional case study to evaluate the mid-term efficacy and safety of the GTS-400- iStent[®] (Glaukos Corporation, Laguna Hills, CA) combined with phacoemulsification in patients with cataract and open glaucoma (OAG) or ocular hypertension. Subjects underwent phacoemulsification and 2 GTS-400 implantations. Efficacy outcomes measured included IOP and antiglaucoma medications. Safety outcomes included complications, best-corrected visual acuity and endothelial cell count (ECC). Follow-up was 1 year. 20 patients were enrolled. 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% from baseline washout IOP. Mean number of medications fell from 1.3 ± 0.66 to 0.3 ± 0.57. 75% of patients were off medications at 1 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 safe and effective.

Arriola-Villalobos et al. (2012) also evaluated the long-term efficacy and safety of combined cataract surgery and Glaukos iStent[®] implantation for coexistent OAG and cataract. This prospective case series included 19 patients. Mean follow-up was 53.68 months. Mean IOP was reduced from 19.42 mm Hg at the end of follow up to 16.26 mm, representing a 16.33% decrease. 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 OAG and cataract.

Samuelson et al. (2011) assessed the safety and efficacy of the iStent® trabecular micro-bypass stent in combination with cataract surgery in a prospective, open-label, multicenter randomized controlled trial (RCT). A total of 240 eyes with mild to moderate OAG with 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 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 (AEs) was similar between groups with no unanticipated adverse device effects. The investigators concluded that pressure reduction on fewer medications was clinically and statistically better 1 year after iStent® 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 (53 eyes) to treat 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.

An interventional procedure guidance published by NICE concluded that after systematic review and meta-analysis of multiple clinical studies on almost 3100 participants, current evidence demonstrated that trabecular stent bypass microsurgery for OAG is safe and effective (2017).

After examination of 1 systematic review, 6 controlled trials, and 6 case series reporting on more than 3,000 patients, a 2017 ECRI report concluded that the iStent® system implanted during cataract surgery reduces both IOP and postoperative glaucoma medication use. Results are reported as sustained for 1-4 years and AEs have been reported in no more than 12% of study participants. Additional long-term comparative data and more data on vision loss are needed.

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 OAG who do not achieve adequate control of 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 significantly fewer ocular hypotensive medications (2017).

Several registered ongoing clinical trials relevant to the iStent® are in progress, including 2 large trials (n=860) assessing 3 to 5-year outcomes with the device. For more information, please go to www.clinicaltrials.gov.

CyPass®

A 2017 Hayes search of published peer reviewed literature on the use of the CyPass® Micro-Stent identified 5 abstracts (1 RCT (the COMPASS trial), 1 prospective uncontrolled study, and 3 uncontrolled postmarket registry studies) with a combined total of 825 participants. It was concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the CyPass® Micro-Stent for the treatment of glaucoma in adults.

A 2017 ECRI review of peer-reviewed literature assessing the CyPass® Micro-Stent cites the COMPASS RCT as well as 2 case series (total participants=729) published between January 1, 2012 and May 11, 2017. The reviewers concluded that the evidence appears favorable relating to the use of the CyPass® implantation system during cataract surgery, and that both long term and more comparative data are needed.

In a multicenter interventional randomized clinical trial, Vold et al. evaluated 2-year safety and efficacy of supraciliary microstenting (CyPass® Micro-Stent; Transcend Medical, Inc., Menlo Park, CA) for treating mild-to-moderate POAG in patients undergoing cataract surgery. Subjects had POAG with mean diurnal unmedicated IOP of 21–33 mmHg and

were undergoing phacoemulsification cataract surgery. Of 505 subjects, 131 were randomized to the control group and 374 to the microstent group. There was early and sustained IOP reduction, with 60% of controls versus 77% of microstent subjects achieving $\geq 20\%$ unmedicated IOP lowering versus baseline at 24 months. Mean 24-month medication use was 67% lower in microstent subjects; 59% of control versus 85% of microstent subjects were medication free. No vision-threatening microstent-related AEs 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 OAG (Shaffer Grade 3 and 4) and uncontrolled medicated 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. AEs, 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 AEs. 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).

There are 3 clinical trials in progress relating to the CyPass[®] Micro-Stent implantation system. For more information, please go to www.clinicaltrials.gov.

XEN[®] Glaucoma Treatment System

Schlenker et al. (2017) conducted an investigator-initiated, international, multicenter, retrospective cohort study of consecutive patients who underwent either standalone microstent insertion with mitomycin C (MMC) or trabeculectomy with MMC. A total of 354 eyes of 293 patients (185 microstent and 169 trabeculectomy) participated in the study that extended between January 1, 2011, and July 31, 2015. Eligibility criteria included patients with multiple types of glaucoma and above-target IOP on maximum medical therapy. Participants were between the ages of 30-90 years with no history of previous incisional surgery for their eye disease. The authors concluded that there was no detectable difference in risk of failure and safety between standalone microstent with MMC and trabeculectomy with MMC. However, further research was believed to be warranted to further investigate these procedures.

Grover et al. evaluated the performance and safety of the XEN[®] 45 Gel Stent (Allergan, Irvine, CA) for the treatment of refractory glaucoma in a prospective, single-arm, open-label, multicenter clinical study sponsored by the manufacturer. Selection criteria included individuals with refractory glaucoma, defined as prior failure of a filtering or cilioablative procedure and/or uncontrolled IOP on maximally tolerated medical therapy. A total of 65 patients 45 years of age and older were implanted. No intraoperative complications or unexpected postoperative AEs were reported. During the 1 year of follow up, most AEs were considered mild/moderate and resolved with no sequelae. The authors concluded that the gel stent safely reduced both IOP and medication use and offer a less invasive surgical option for this subset of patients. Potential study limitations include the absence of comparator and open-label study design, which could have impacted the outcomes (2017).

De Gregorio et al. (2017) conducted a nonrandomized prospective clinical study to assess safety and efficacy of the XEN[®] 45 Gel Stent when combined with microincisional cataract surgery (MICS). Forty-one eyes of 33 patients with OAG underwent the combination surgery, and there were no major intra- or postoperative complications noted. Complete success was achieved in 80.4% and a qualified success reported in 97.5% after 12 months of follow-up. The authors concluded that the XEN[®] 45 gel implant is statistically effective in reducing IOP and medication use with minimal complications in glaucoma patients.

A review of published literature by Kerr et al. (2017) concluded that a growing body of evidence suggests that primary minimally invasive glaucoma surgery (including but not limited to the XEN[®] Glaucoma Treatment System) may be a viable initial treatment option to non-surgical intervention. However, further investigator-initiated randomized trials of sufficient size and duration are necessary to better evaluate efficacy.

Vinod and Gedde (2017) reviewed published literature from 2015 through 2016, commenting that findings are notable regarding new and emerging glaucoma procedures. While the data on newer techniques (including but not limited to the XEN[®] Gel Stent) are promising, the opinion of the authors was that further studies by means of RCTs with extended follow-up periods continue to be necessary to better evaluate long-term efficacy.

A 2017 ECRI review of peer-reviewed literature assessing the XEN[®] gel stent implantation system cites the studies of Grover and De Gregorio (above) as well as 2 other small single center case series (total n=134) published between January 1, 2012, and June 1, 2017. While most patients experienced a reduction in both IOP and glaucoma medication use post-implantation, the reviewers found the evidence in the 4 small case series to be inconclusive for both safety and efficacy. Larger, longer-term, controlled studies comparing XEN[®] with trabeculectomy are needed (2 of which are currently in progress).

There are 3 clinical trials in progress relating to the XEN[®] Glaucoma Treatment System. For more information, please go to www.clinicaltrials.gov.

EX-PRESS™

A 2017 Hayes report of published literature on the use of the EX-PRESS™ Glaucoma Filtration Device (EGFD) for the treatment of IOP in patients with OAG yielded 7 RCTs reported in 10 publications with participants ranging from 15-120 patients. They concluded that a moderate-quality body of evidence suggested that EGFD results in similar outcomes when compared with trabeculectomy (the current standard of care), citing few differences between the 2 procedures relative to reduction of IOP, medication use, and the return of visual acuity in both the short and long term (up to 5 years).

de Jong (2009) conducted a prospective RCT of 78 patients (80 eyes) with primary open-angle, pseudoexfoliative, 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% of patients receiving trabeculectomy achieved complete success (defined as an IOP of >4 mmHg ≤18 mmHg without the use of antiglaucoma medications). The respective proportions of patients achieving an 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. 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 RCT (i.e., up to 5 years in the patients who received either the EX-PRESS™ device (n=39) or who underwent 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%) posttreatment. 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 2 groups were not significant.

Ates et al. (2010) evaluated 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 IOP control and safety (Minkler, 2006). Only RCTs and quasi-RCTs 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 2 had adequate allocation concealment. Data collection and follow-up times were variable. Meta-analysis of 2 trials comparing Ahmed implant with trabeculectomy found trabeculectomy resulted in lower mean IOPs 11 to 13 months. 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 between the 2 treatments. 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 IOP.

Budenz et al. (2011) evaluated the relative efficacy and complications of the Ahmed glaucoma valve (AGV) (New World Medical, Rancho Cucamonga, CA) and the Baerveldt glaucoma implant (BGI) (Abbott Medical Optics, Abbott Park, IL) in refractory glaucoma in a multicenter, RCT. The study included 276 patients (143 = AGV, 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 in the

AGV and BGI groups at 1 year were 16.4% and 14%, respectively. More patients experienced early postoperative complications in the BGI group (58%) compared to 43% in the AGV group. Serious postoperative complications also were more frequent in the BGI group than in the AGV group, at 34% versus 20%, respectively. 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 RCT (known as the Tube versus Trabeculectomy (TVT) Study). A total of 212 eyes of 212 patients with uncontrolled glaucoma were enrolled (tube group = 107, 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 in the tube group versus trabeculectomy was 1.3 and 1.0, respectively. 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 39% and 60% in the tube and trabeculectomy groups, respectively. The investigators concluded that while tube shunt surgery had a higher success rate compared to trabeculectomy during the first 3 years of follow-up, both procedures were nearly equal with regard to IOP reduction and use of supplemental medication 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, finding 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 explanation. 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 November 8, 2017)

Viscocanalostomy

A Cochrane review analyzed data from RCTs and quasi-RCTs 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. AEs, such as choroidal detachment, shallow anterior chamber and hyphema, were reported from 4 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, stating that more research is needed to determine which of the many surgeries performed for PCG are effective (Ghate et al., 2015).

Another Cochrane review conducted by Eldaly et al. included relevant RCTs and quasi-RCTs on participants undergoing standard trabeculectomy for OAG compared to non-penetrating glaucoma surgery (NPGS), specifically viscocanalostomy or deep sclerectomy, with or without adjunctive measures. Included were 5 studies with a total of 311 eyes (participants = 247), of which 133 eyes (133 participants) were quasi-randomized. Eyes having trabeculectomy (n=160) were compared to those having NPGS (deep sclerectomy = 101 eyes, and 50 eyes had viscocanalostomy). The authors concluded that this review provided limited evidence that control of IOP is better with trabeculectomy than viscocanalostomy, although there is uncertainty about trabeculectomy versus deep sclerectomy. AEs appeared more common in the trabeculectomy arm, as cataract was more commonly reported in addition to OAG. However, overall AEs were rare. Study limitations identified included absence of quality of life measurement, poor quality evidence and high risk of bias. Further RCTs are needed. (2015).

Chai et al. (2010) conducted a meta-analysis to compare the efficacy and safety profile of viscocanalostomy versus trabeculectomy. Ten RCTs 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 AEs. The reviewers concluded that trabeculectomy had a greater pressure-lowering effect compared with viscocanalostomy. However, viscocanalostomy had a significantly better risk profile.

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

Cheng et al. (2011) evaluated the IOP-lowering effects achieved by NPGS in patients with OAG in a systematic review of RCTs. The pooled estimates were calculated using the random effects model. Both deep sclerectomy and viscocanalostomy were less effective than trabeculectomy in lowering IOP, with the percentage IOP reductions at 2 years being 35%, 30%, and 46% for deep sclerectomy, viscocanalostomy, and trabeculectomy, respectively. The complete success rates at 4 years were 35% for deep sclerectomy, and 23% for viscocanalostomy, both lower than that of trabeculectomy (48%). According to the authors, primary deep sclerectomy and primary viscocanalostomy were associated with fewer complications than trabeculectomy. However, trabeculectomy was superior to NPGS in reduction of IOP and overall success.

In a guidance on the diagnosis and management of chronic OAG and ocular hypertension, NICE concluded from the evidence (low to moderate quality) that trabeculectomy is more effective than non-penetrating surgery (e.g., viscocanalostomy) in reducing IOP from baseline at 6- 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 6- and 12-months (2009, updated 2017).

Canaloplasty

Rękas et al. (2015) conducted a prospective, randomized trial comparing safety and efficacy of non-penetrating deep sclerectomy (NPDS) using a viscoelastic compound versus canaloplasty in 29 eyes of individuals with uncontrolled POAG and a cataract. Outcomes measured included corrected distance visual acuity, IOP, and number of medications required postoperatively. Complete and qualified success was an IOP ≤ 18 mmHg. Follow-up examinations were performed on days 1 and 7, and at 1, 3, 6, and 12 months. Both groups had similar IOPs preoperatively. At 12 months, there were no statistical differences identified either in IOP or number of medications utilized. Complete and qualified success rates for the canaloplasty and NPDS groups were 79% and 77%, respectively. With these findings, the authors concluded that neither procedure is superior to the other in providing safe and effective treatment to the glaucoma patient with cataracts. However, over 50% of the NPDS group required intervention for AEs occurring in the postoperative period, while the canaloplasty group required no postoperative management.

Matlach et al. conducted a prospective, comparative RCT known as the TVC study, where participants received trabeculectomy (n=32) or canaloplasty (n=30) and were followed for 2 years. Primary outcomes included complete success (without medication) and qualified success (with or without medication), defined as IOP of ≤ 18 mmHg (definition 1) or IOP ≤ 21 mmHg and $\geq 20\%$ IOP reduction (definition 2), IOP ≥ 5 mmHg, no vision loss and no further glaucoma surgery. Each surgical intervention resulted in significantly reduced IOP. Complete success was achieved in 74% and 39% (definition 1), and 68% and 39% (definition 2) at 2 years in the trabeculectomy and canaloplasty groups, respectively. Mean absolute IOP reduction was slightly better at 2 years with trabeculectomy (10.8 ± 6.9 mmHg) versus canaloplasty (9.3 ± 5.7 mmHg). AEs were more frequent following trabeculectomy. The authors concluded that trabeculectomy is associated with a better reduction in IOP and less need for medication, but has a higher complication rate. If target IOP is attainable by moderate reduction, canaloplasty may be considered for its ease of postoperative care and lack of complications (2015).

Koerber et al. (2012) compared the safety and efficacy of canaloplasty in one eye with viscocanalostomy 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 viscocanalostomy procedure. At 18-month follow-up, both procedures canaloplasty and viscocanalostomy were successful in reducing IOP. The percentage reduction in IOP was significantly higher in the canaloplasty eyes (approximately 44%), as compared with the viscocanalostomy eyes (approximately 33%), at both 12 and 18 months. Final absolute IOP was not significantly different, although lower, in the canaloplasty group versus the viscocanalostomy 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. ; tThe viscocanalostomy group achieved complete success in 35.7% of eyes, and complete or qualified success in 36% and 50.0% of eyes, respectively. Complications were minimal in both groups. According to the authors, canaloplasty and viscocanalostomy were safe and effective in the surgical management of OAG open-angle glaucoma. The authors also stated that canaloplasty procedures showed superior efficacy to viscocanalostomy in the reduction of IOP.

Grieshaber et al. (2010b) compared the safety and efficacy of 2 polypropylene (Prolene) sutures for tensioning of the inner wall of Schlemm's canal (SC) in patients with POAG undergoing canaloplasty. This prospective RCT included 90

patients. . The mean preoperative 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. Mean IOP at 15 months for group 1 was 19.2 mm Hg and 16.4 mm Hg in group 2. Pressures equal or less than 21, 18, and 16 mm Hg without medications (complete success) at 12 months were 51%, 34%, and 21% in group 1, and 77%, 69%, and 54% 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 POAG. Sixty randomly selected eyes of 60 consecutive patients with POAG were included in this prospective study. The mean preoperative 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), 16.3 mm Hg at 24 months (n = 51), and 13.3mm Hg at 36 months (n=49). For IOP ≤ 21 mm Hg, complete success rate was 77.5% and qualified success rate was 82% 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%) had canaloplasty alone, while 36 eyes (23%) 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% 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 89% of eyes with phacocanaloplasty. The authors concluded that canaloplasty led to a significant and sustained IOP reduction in adult patients with OAG 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, multi-center, interventional study of 109 eyes of 109 adult OAG patients undergoing canaloplasty or combined cataract-canaloplasty surgery. IOP 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 OAG.

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 POAG. 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 2 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.
- RCTs comparing viscocanalostomy with trabeculectomy generally suggest greater IOP reduction with trabeculectomy, but fewer complications with viscocanalostomy. No randomized clinical trials comparing trabeculectomy and canaloplasty exists.

On the topic of combining glaucoma and cataract surgery, the AAO Preferred Practice Patterns Guidelines states:

- 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 2 approaches (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 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 OAG (e.g., iStent[®], EX-PRESS[™] mini glaucoma shunt, SOLX[®] Gold Shunt). The authors concluded that the novel glaucoma surgeries studied all showed some promise as alternative treatments to lower IOP in the treatment of OAG. 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

This society's 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 (2009).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Glaucoma Drainage Devices

The EXPRESS[™] Mini Glaucoma Shunt, indicated for use in reduction of IOP in patients with glaucoma where medical and conventional surgical treatments have failed, received 501(k) approval on March 13, 2003. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030350.pdf. (Accessed November 8, 2017)

Predicate 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>. (Accessed November 8, 2017)

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 IOP in adult patients with mild to moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce IOP. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080030b.pdf. (Accessed November 8, 2017)

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 IOP in adults with mild-to-moderate POAG. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150037b.pdf. (Accessed January 8, 2018)

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/pmn.cfm> under product codes HMX (cannula, ophthalmic), MPA (endoilluminator), or MRH (pump, infusion, ophthalmic). (Accessed November 8, 2017)

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 August 2006. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf6/k062259.pdf. (Accessed November 8, 2017)

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:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K062259>. (Accessed November 8, 2017)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2018	<ul style="list-style-type: none"> • Reorganized policy template: <ul style="list-style-type: none"> ○ Simplified and relocated <i>Instructions for Use</i> ○ Removed <i>Benefit Considerations</i> section • Updated conditions of coverage/special considerations; modified notation to clarify: <ul style="list-style-type: none"> ○ For participating providers in the office setting: Precertification is required for services performed in the office of a participating provider ○ For non-participating/out-of-network providers in the office setting: Precertification is not required, but is encouraged for out-of-network services performed in the office; if precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered • Updated coverage rationale; modified language to clarify the listed services are: <ul style="list-style-type: none"> ○ Proven and medically necessary (as described) ○ Unproven and not medically necessary (as described) ○ Investigational, unproven and not medically necessary (as described) • Archived previous policy version VISION 023.20 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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