Glaucoma Surgical Treatments (for Idaho Only)

Policy Number: CS050ID.C
Effective Date: June 1, 2026

➲ Instructions for Use

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Related Policy

- Outpatient Surgical Procedures – Site of Service (for Idaho Only)

Application

This Medical Policy only applies to the state of Idaho, including Idaho Medicaid Plus plans.

Coverage Rationale

The following are proven and medically necessary:

- Goniotomy, trabeculotomy, canaloplasty (ab interno), or combined canaloplasty (ab interno) and trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and cataract in individuals currently being treated with ocular hypotensive medication
- iStent®, iStent inject®, or Hydrus® Microstent when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and a cataract in individuals currently being treated with ocular hypotensive medication
- Drainage devices (e.g., XEN® System, EX-PRESS™, Molteno implant, Baerveldt tube shunt, Ahmed glaucoma valve implant, and Krupin-Denver valve implant) for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate
- Laser trabeculoplasty (e.g., Argon, Selective)
- Laser iridotomy/iridectomy (e.g., Nd: YAG)
- Laser iridoplasty
- Laser ciliary body destruction

All other FDA-approved types of laser procedures are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety.

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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
*0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
*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
*0621T	Trabeculostomy ab interno by laser
*0622T	Trabeculostomy ab interno by laser; with use of ophthalmic endoscope
*0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
*0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
*1012T	Motorized ab interno trephination of sclera (sclerostomy), or trabecular meshwork (trabeculostomy), 1 or more, including injection of antifibrotic agents, when performed
65820	Goniotomy
65855	Trabeculoplasty by laser surgery
66174	Transluminal dilation of aqueous outflow canal (e.g., canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (e.g., canaloplasty); 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
66710	Ciliary body destruction; cyclophotocoagulation, transscleral
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens
66761	Iridotomy/iridectomy by laser surgery (e.g., for glaucoma) (per session)
66762	Iridoplasty by photocoagulation (1 or more sessions) (e.g., for improvement of vision, for widening of anterior chamber angle)
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

HCPCS Code	Description
L8612	Aqueous shunt

Codes that are labeled with an asterisk (*) are not on the State of Idaho Medicaid Fee Schedule and therefore may not be covered by the State of Idaho Medicaid Program. For additional information on non-covered and excluded services, refer to the Idaho Medicaid Provider Handbook, General Information, General Information and Requirements for Providers: Non-Covered and Excluded Services.

Description of Services

Glaucoma refers to a group of eye diseases characterized by elevated intraocular pressure (IOP) which results in visual field loss and irreversible blindless if left untreated. The 2020 American Academy of Ophthalmology (AAO) Preferred Practice Patterns Guidelines on primary open-angle glaucoma (POAG) defines the disease as a chronic, progressive optic neuropathy in which there is atrophy of the optic nerve and loss of retinal ganglion cells and their axons. POAG is associated with the following characteristics:

- Evidence of optic nerve damage from either, or both, of the following:
  - Optic disc or retinal nerve fiber layer (RNFL) structural abnormalities
  - Reliable and reproducible visual field abnormality
- Adult onset
- Open anterior chamber angles
- Absence of other known explanations for progressive glaucomatous optic nerve change

The severity of glaucoma damage can be estimated according to the following categories:

- Mild: Definite optic disc, RNFL or macular imaging abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry (SAP)
- Moderate: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with SAP
- Severe: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with SAP
- Indeterminate: Definite optic disc, RNFL, or macular imaging abnormalities consistent with glaucoma, inability to perform visual field testing, unreliable/uninterpretable visual field test results, or visual fields not yet performed

Canaloplasty is a surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye . It was historically performed using an ab externo (from the outside) approach or more recently, an ab interno (from the inside) approach. Both approaches involve viscodilation of Schlemm's canal (SC) to restore normal aqueous outflow. With an ab externo approach, the microcatheter is inserted through cuts in the conjunctiva and sclera and then uses an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening the SC. With an ab interno approach, the microcatheter is inserted through either a clear corneal or limbal micro-incision, through the trabecular meshwork and then, into SC. Once in the canal, a viscoelastic gel is used to dilate it. [National Institute for Health and Care Excellence (NICE), 2017, 2022]

Laser ciliary body destruction, also known as cyclophotocoagulation (CPC), is a surgical procedure used to treat glaucoma. CPC is the most common procedure to perform cyclodestruction. It can be performed using different laser wavelengths. In cyclodestructive procedures, the secretory epithelium of the ciliary epithelium is damaged, which leads to reduced aqueous humor secretion and lower intraocular pressure (IOP) (AAO, 2023e).

Laser iridoplasty is a procedure that can be performed by using a low energy argon laser photocoagulation to contract peripheral iris tissue away from the trabecular meshwork, thereby opening the anterior chamber angle and lowering IOP (AAO, 2025).

Laser peripheral iridotomy (LPI), also described as laser iridotomy is a procedure that uses a laser device to create a hole in the iris, thereby allowing aqueous humor to traverse directly from the posterior to the anterior chamber and consequently, relieve a pupillary block (AAO, 2023b).

Laser trabeculoplasty both argon laser trabeculoplasty (ALT) and selective laser trabeculoplasty (SLT) types, is used to increase aqueous outflow facility through the trabecular meshwork (TM) in order to lower intraocular pressure (IOP) in cases of ocular hypertension and glaucoma (AAO, 2023c).

Trabeculectomy is described as a surgical procedure that removes part of the eye's trabecular meshwork and adjacent structures to reduce IOP in individuals with glaucoma. For the majority of individuals, it is the most common surgery that allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is absorbed.

Trabeculotomy is performed in patients with glaucoma to reduce the IOP by reducing the resistance to aqueous flow by incising the trabecular meshwork and the inner wall of the Schlemm Canal (Miura, 2022).

Goniotomy is described as a surgical procedure where the trabecular meshwork is incised and/or excised with a blade or other surgical instrument for a least several clock hours to create an opening into the SC from the anterior chamber (AC),

via an internal approach through the AC (AAO, 2023a). Examples of devices which may be used during the goniotomy (also known as ab interno trabeculotomy) may include the Kahook Dual Blade (KDB) or Trabectome.

Gonioscopy-assisted transluminal trabeculotomy (GATT) is a refinement of circumferential ab interno trabeculotomy. With GATT, a temporal corneal wound is made and direct gonioscopy is used to visualize the nasal angle structures. A goniotomy is created and microsurgical forceps are used to guide an illuminated microcatheter or suture into SC. The forceps are used to progress the microcatheter or suture circumferentially until the tip is identified at the original goniotomy site and retrieved. Then, traction on the suture or catheter used to create a 360-degree trabeculotomy (Baykara, 2019; SooHoo, 2015).

Canaloplasty (ab interno) and trabeculotomy involves the use of two different mechanistic modalities successively to address multiple points of outflow resistance in the conventional outflow pathway, both proximal and distal. First, canaloplasty is performed to open a distal outflow pathway including a collector channel ostium then, trabeculotomy removes the resistance residing in the trabecular meshwork (Vold, 2021).

Glaucoma drainage devices (GDDs), also known as aqueous shunts include the Ex-PRESS™ Mini Glaucoma Shunt, the Molteno implant, the Baerveldt tube shunt, Ahmed glaucoma valve implant, and the Krupin-Denver valve implant. The Ex-PRESS™ Mini Glaucoma Shunt is a small stainless-steel device that is placed beneath the scleral flap into the AC 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. The Krupin-Denver value implant has a pressure sensitive unidirectional valve to provide filtration restriction and the implant is designed to open when IOP is > 11 mmHg (Krupin, 1988).

GDDs such as iStent® and iStent *Inject*® Trabecular Micro-Bypass systems, divert aqueous fluid from the AC directly into SC (Samuelson, 2008). The Xen® Gel Stent is for use in individuals with refractory glaucoma. A gelatin tube is implanted into the subconjunctival space and is proposed as a less traumatic alternative to ab externo procedures 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.

Microinvasive or minimally invasive glaucoma surgery (MIGS) constitutes a group of newer surgical interventions that are typically performed via an ab interno approach usually combined with phacoemulsification surgery that allow for minimal disruption of normal ocular anatomy. When compared to traditional incisional surgeries MIGS carry a lower risk of complications however, the level of IOP reduction is often inferior to traditional filtering surgery. These procedures should offer at least 20% IOP reduction or alternatively, an IOP reduction of at least one medication. MIGS are often conducted on candidates who have mild to moderate glaucoma and are not suitable for those with more advanced disease who require a low IOP goal. The current approaches include but are not limited to: trabecular meshwork bypass by stent placement (e.g., iStent, iStent inject, Hydrus Microstent); trabecular meshwork bypass by tissue excision (e.g., KDB Goniotomy, Trabectome, GATT, TRAB 360/OMNI); enhancing aqueous outflow through Schlemm's canal [e.g., Visco 360/OMNI, Ab Interno Canaloplasty (ABiC), Streamline Surgical System]; enhancing aqueous outflow through the suprachoroidal space (e.g., CyPass microstent); and shunting aqueous outflow into the subconjunctival space (e.g., XEN Gel Stent); and reducing aqueous production by ciliary body ablation [e.g., endocyclophotocoagulation (ECP)]. The Cypass Micro-Stent was withdrawn from the market in August 2018. (AAO, 2023d).

Clinical Evidence

iStent® and iStent *inject*®

Kahale et al. (2023) performed a systematic review and meta-analysis comparing the effect of iStent insertion at the time of phacoemulsification with phacoemulsification alone in patients with OAG. The results included ten comparative studies, reporting on 1453 eyes (853 eyes were subjected to combined surgery and 614 eyes underwent phacoemulsification alone) with a mean follow-up period of 21.9 months. The results demonstrated IOP reduction was higher in the combined surgery at 4.7 ±2mm Hg compared to 2.8 ±1.9mm Hg in phacoemulsification alone. A greater decrease in postoperative eye drops was noted in the combined group having a decrease of 1.2 ±0.3 eye drops versus 0.6 ±0.6 drops in isolated phacoemulsification. The quality effect model showed an IOP reduction weighted mean difference (WMD) of 1.22 mm Hg [confidence interval (CI): (–0.43, 2.87); Q = 315.64; p < 0.01; I2 = 97%] and decreased eye drops WMD 0.42 drops [CI: (0.22, 0.62); Q = 42.6; p < 0.01; I2 = 84%] between both surgical groups. The authors concluded the findings support the use of iStent in combination with cataract surgery when further IOP reduction is desired in OAG. The iStent second-

generation seems more effective in lowering the IOP. Although the results were statistically significant with iStent showing a good safety protocol and offering the benefit of decreasing the dependence of glaucoma eye drops, the clinical implications are still debatable. Further studies are still needed to assess the long term IOP lowering effect of iStent, the protective effect on the optic nerve, and how long it may delay the need for future, more invasive, glaucoma surgeries. Limitations of the study include small sample size, the heterogeneity between studies, duration of follow-up and possible publication bias.

Healey et al. (2021) conducted a systematic review and meta-analysis to evaluate the efficacy of iStent devices (iStent® and iStent *inject*®) when performed independently of cataract surgery in patients with OAG. A search was conducted using Embase.com (EMBASE and MEDLINE) as well as the Cochrane Library. All RCTs were considered as well as non-randomized studies that included at least 6 months of follow-up or more than 10 eyes. Efficacy analyses included post-operative IOP and medication use, and the proportion of eyes free of ocular medication. Post-operative AEs were descriptively summarized. The literature search yielded a total of 760 citations and after further review, a total of 13 studies were included in the analysis. Those included 4 RCTs and 9 non-randomized or single-arm studies providing data for 778 eyes. In eyes implanted with iStent devices, a weighted mean IOP reduction of 31.1% was observed at 6-12 months. In studies reporting longer-term outcomes (36-48 months or 60 months), the weighted mean IOP reduction was 30.4% and 32.9%, respectively. The pooled weighted mean reduction in IOP from baseline across all studies at 6-12 months and 36-60 months post-stent implantation was 7.01 mmHg (95% CI: 5.91 to 8.11) and 6.59 mmHg (95% CI: 5.55 to 7.63), respectively. Medication burden was reduced by approximately 1.0 medication at 6-18 months and 1.2 medications at 36-60 months. AEs reported in more than 5% of participants included progression of pre-existing cataract/cataract surgery and loss of BCVA but these rates were no different to those reported in comparator medical therapy study arms. The authors concluded that these results support the independent effect of the iStent trabecular bypass devices on IOP and medication burden for up to five years after treatment, and without the potential for confounding from cataract surgery.

An ECRI review, iStent inject trabecular micro-bypass system for treating OAG during cataract surgery (2019), evaluated 7 studies (5 full text and 2 abstracts) with a total of 1,112 eyes. Those included 1 multicenter RCT, 1 single-center RCT, and 5 non-randomized comparison studies. Evidence from those studies showed that iStent *inject* implantation during cataract surgery reduced IOP (> 20%) and use of glaucoma medication for patients with mild-to-moderate primary OAG through two years of follow-up. Serious AEs did not differ statistically between iStent *inject* plus cataract surgery or cataract surgery alone. The authors concluded that the evidence is somewhat favorable.

Samuelson et al. (2019a) evaluated the safety and effectiveness of the iStent *inject*® trabecular micro-bypass system (Glaukos Corporation, San Clemente, CA, USA) in combination with cataract surgery in subjects with mild to moderate POAG through a prospective, single-masked, concurrently controlled, multicenter RCT (NCT00323284). After uncomplicated cataract surgery, eyes were randomized 3:1 intraoperatively to ab interno implantation (single or multiple) of iStent *inject*® (Model G2-M-IS; treatment group, n = 386) or no stent implantation (control group, n = 118). Subjects were followed for 2 years post-implant. At 24 months, 75.8% of treatment eyes versus 61.9% of control eyes experienced ≥ 20% reduction from baseline in unmedicated diurnal IOP (DIOP), and mean reduction in unmedicated DIOP from baseline was greater in treatment eyes (7.0 ±4.0 mmHg) than in control eyes (5.4 ±3.7 mmHg). Of the subjects who were responders (e.g., 24-month unmedicated mean DIOP reduced by ≥ 20% from baseline in the absence of IOP-affecting surgery during the study), 84% of treatment eyes and 67% of control group eyes were not receiving ocular hypotensive medication at 23 months. In addition, 63% of treatment eyes and 50% of control eyes had medication-free DIOP ≤ 18 mmHg at 2 years. The overall safety profiles were highly favorable and similar in both groups throughout the follow-up period. The researchers concluded that clinically and statistically greater reductions in IOP without medication were achieved after iStent *inject*® implantation with cataract surgery versus cataract surgery alone. Additionally, the pivotal study's findings support the consideration of this second-generation trabecular micro-bypass stent system as a safe, durable, and less compliance-dependent treatment modality for additional unmedicated IOP reduction in POAG eyes undergoing cataract surgery. This study was included in the ECRI review.

In a single-center, longitudinal, retrospective, comparative study, Guedes et al. (2019) performed a side-by-side comparison of the iStent® and iStent *inject*® trabecular micro-bypass stent systems. The study evaluated performance and safety in consecutive eyes following implantation of either device with concomitant cataract surgery. Performance outcomes included IOP reduction; glaucoma medication reduction; proportions of eyes achieving an IOP of < 18, < 16, < 14, or < 12 mmHg; and proportions of eyes on 0, 1, 2, or ≥ 3 medications. Safety outcomes included AEs, secondary surgeries, and BCVA. The follow up period was 6 months. A total of 73 eyes with OAG and cataract were included in the study; of these, 38 eyes were implanted with the iStent® device and 35 were implanted with the iStent *inject*® device. At 6 months post-surgery, mean IOP had fallen in both groups; however, the reduction was significantly greater in the iStent *inject*® eyes versus the iStent® eyes (26.6 vs. 15.8%). All who received the iStent *inject*® device achieved an IOP of < 18 mmHg at 6 months compared to 86.8% of the iStent® recipients, and > 70% of eyes in both groups became medication-

free by 6 months post implantation. AEs occurred in 2 iStent® eyes which resulted in no sequelae; and 2 iStent® eyes underwent non-penetrating deep sclerectomy during follow-up. No complications or secondary surgeries occurred in the iStent Inject® group. All eyes in both groups maintained or showed improved BCVA versus baseline. The authors concluded that significant and safe IOP and medication reductions were observed after iStent® or iStent *inject*® implantation with concomitant cataract surgery. However, compared with the iStent®, trends toward greater effectiveness and fewer AEs were observed with the iStent *inject*®. This advantage may be attributed to device design: each individual iStent *inject*® stent has four lateral outflow lumens and uses two stents versus one in the trabecular meshwork which allows for greater IOP-reducing potential. Several limitations to the study include a modest number of eyes in each group, relatively short follow up period and lack of randomization. A prospective study with a larger population and longer follow-up is necessary to validate these findings. This study was included in the ECRI review.

The aim of a prospective, non-randomized, consecutive case series by Hengerer et al. (2018) was to assess 36-month outcomes after cataract surgery and implantation of two second-generation trabecular micro-bypass stents (iStent *inject*®). Participants (81 eyes of 55 consecutive patients) presented with cataract plus varying types of glaucoma [POAG/n = 60, pseudoexfoliative (PEX)/n = 5, appositional narrow-angle/n = 4, pigmentary/n = 1 or neovascular (secondary)/n = 1]. Following cataract surgery, all eyes underwent ab interno iStent *inject*® implantation. Effectiveness endpoints included IOP, number of medications, and proportion of eyes with ≥ 20% IOP reduction, IOP ≤ 18 mmHg, and IOP ≤ 15 mmHg. Safety measures included corrected distance visual acuity, AEs, and secondary surgeries. Outcomes were evaluated for the overall cohort, and for the POAG and PEX subgroups. In the overall cohort, substantial reductions in both IOP and medication use were observed for 36 months postoperatively. With regards to the POAG and PEX subgroups, the outcomes in PEX eyes were similarly favorable to those in POAG eyes, thereby corroborating prior studies showing iStent® technology to be a highly suitable and effective treatment option in patients with this condition. The authors concluded that the study demonstrated substantial reductions in both IOP and medication burden along with favorable safety through 36 months following the implantation of iStent *inject*®. While there were several limitations in this unmasked, single arm study, these outcomes were interpreted as significant and future studies are encouraged.

Popovic et al. (2018) conducted a systematic review and meta-analysis on the efficacy and adverse event (AE) profile of the iStent in the treatment of OAG. Using predetermined search terms, a systematic review was performed using Ovid MEDLINE and Ovid EMBASE. A total of 28 studies were included in the meta-analysis. The main analysis was performed based on whether patients had 1, 2 or 3 iStents implanted and whether they did or did not receive combined phacoemulsification and iStent. The mean age was 71.4 ±5.4 years, and 44.9% of patients were male. There was a significantly greater IOP reduction after the use of two first-generation stents compared to one, irrespective of phacoemulsification status ($p < 0.001$). Additionally, there was a significantly greater IOP reduction following iStent alone relative to phaco-iStent for the first-generation iStent ($p < 0.001$) and the iStent *inject* ($p < 0.001$). For the first-generation stent, combined phaco-iStent provided a greater level of IOP reduction ($p < 0.001$) and reduction in the number of medication classes relative to phacoemulsification alone ($p < 0.001$). In total, 22.5% of eyes that received iStent implantation sustained some type of AE. The most common AEs were IOP elevation, stent blockage or obstruction, stent malposition and hyphema. The authors concluded that there may be differences in treatment response for the iStent due to varying parameters, including the number of iStents and phaco-iStent compared to either iStent alone or phacoemulsification alone. In their analysis, two stents delivered a greater response in terms of IOP reduction relative to one and iStent alone had a significantly greater IOP reduction compared to phaco-iStent. Combined phaco-iStent was statistically superior relative to phacoemulsification alone in the reduction of IOP and medication classes pre- to post-operatively.

A retrospective, intraindividual eye study was conducted on 27 patients (54 eyes) with cataract and OAG to compare the safety and efficacy of combined micro-incision cataract surgery (MICS) in one eye with the ab interno trabeculectomy (AIT) with Trabectome® versus MIGS with two iStent *inject*® devices in the contralateral eye. Patients were followed for 6 weeks, 3, 6, and 12 months post-implantation. The authors concluded that the trabeculectomy and iStent *inject*® were both effective in lowering IOP with a favorable and comparable safety profile, citing no significant difference between the 2 approaches. Further research would be necessary to determine long-term outcomes and evaluate significant differences (Gonnermann et al., 2017). This study was included in the ECRI review.

Hydrus® Microstent

Hu et al. (2022) conducted a systematic review and network meta-analysis to compare the efficacy and safety of two Schlemm's canal-based microinvasive glaucoma surgery (MIGS) devices, the Hydrus Microstent and the iStent Trabecular Bypass combined with phacoemulsification for treatment of OAG. Literature searches were conducted on PubMed, Web of Science, Cochrane Library and ClinicalTrials.gov to identify RCTs assessing the Hydrus or the iStent implantation combined with phacoemulsification for treatment of OAG. Risk of bias was assessed using a six-item modified Jadad scale. Effects were estimated using the IOP reduction (IOPR), the percentage of IOPR and the proportion of medication-free participants at follow-up end. Safety was estimated using the proportions of adverse events. The

network meta-analysis was conducted within a Bayesian framework using the Markov Chain Monte Carlo method in ADDIS software. Six prospective RCTs comprising 1397 participants were identified. Regarding the absolute value and the percentage of IOPR, the Hydrus and 2-iStent implantation combined with phacoemulsification were more effective than phacoemulsification alone. Rank probability analysis suggested that Hydrus might be the best choice to lower IOP. There was no difference in the proportion of medication-free patients among groups. The Hydrus and 2-iStent implantation had a higher probability of achieving medication-free status versus the 1-iStent implantation and phacoemulsification alone. Overall safety profiles were good for each device with the focal peripheral anterior synechiae more frequently reported in Hydrus eyes. The authors concluded that the Hydrus implantation may have a slight advantage over the 1-iStent or 2-iStent implantation in combination with phacoemulsification to treat OAG. The findings might be of some uncertainty due to the limited included data. This systematic review and network meta-analysis has limitations, including the indirectness of the comparisons. The number of studies is relatively small, and the sample size of the included studies varied ranging from 33 to 556 eyes, which may potentially bias the results. Further research is necessary to add to this meta-analysis and offer a more convincing conclusion. Second, the details of adverse events were not always reported in each study, and due to the limited data, the authors did not perform statistical analysis to compare the difference in treatment safety among groups. It is unclear whether there is difference in efficacy between two first-generation stents and double iStent inject, as few studies have been conducted to compare these two stents. Further studies are needed to investigate whether these findings are robust, including high-quality RCTs, to directly compare these MIGS devices.

Ahmed et al. (2021) reported 3-year outcomes of the HORIZON study (Samuelson 2019b) which compared cataract surgery performed with Hydrus Microstent (HMS) implantation (n = 369) to that of cataract surgery (CS) alone (n = 187). The authors found the results suggested that combining the Hydrus Microstent implantation at the time of the cataract surgery improved the patient's chances of remaining medication free and reduced the risk of needing additional glaucoma surgery. No differences were found when it came to safety outcomes or long-term endothelial cell loss. Despite some limitations which included the exclusion of patients with secondary open angle glaucoma (SOAG) and limitation of only one comorbidity (POAG) for patients, the authors felt the study sufficiently demonstrated the difference in long-term IOP and medication reduction. In a 2022 update by Ahmed et al., after a five-year follow-up, outcomes measured IOP, glaucoma medication usage, repeat glaucoma surgery, visual acuity, visual field, AEs and corneal endothelia cell counts. The outcomes showed the HMS group included a higher proportion of eyes with IOP of 18 mmHg or less without medications than the CS group as well as greater likelihood of IOP reduction of 20% or more without mediations than the CS group and 66% of eyes in the HMS group were medication free compared with 46% in the CS group. The authors concluded the microstent in conjunction with CS was safe, resulted in lowered IOP, medication use and reduced the need for postoperative incisional glaucoma filtration surgery compared with CS after 5 years. Study limitations included inability to mask the surgeon to treatment group during examinations, limited experience by the surgeons with the HMS implantation technique, exclusion of patients with SOAG, inclusion limitations to only POAG eyes with age-related cataract and possibly medication introduction bias.

Otarola et al. (2020) conducted a systematic review of RCTs to evaluate the efficacy and safety of ab interno trabecular bypass surgery with the Hydrus Microstent in treating patients with OAG. A search was conducted using the CENTRAL, Ovid MEDLINE, Ovid Embase, the International Standard Research Clinical Trial Number (ISRCTN) registry, the U.S. National Institutes of Health Ongoing Trials Register, and the World Health Organization (WHO) International Clinical Trials Registry Platform. A total of 209 publications were screened, and 3 studies (4 publications, Ahmed 2019, Jones 2018, Samuelson 2018, Pfeiffer 2015), with 808 randomized subjects were included in the review. Two studies compared the Hydrus Microstent combined with cataract surgery to cataract surgery alone, in participants with visually significant cataracts and OAG and the other study reported short-term data for the Hydrus Microstent compared with the iStent trabecular micro-bypass stent. The authors concluded that in patients with cataracts and mild to moderate OAG, there is moderate-certainty evidence that the Hydrus Microstent with cataract surgery compared to cataract surgery alone, likely increases the proportion of participants who do not require IOP lowering medication, and may further reduce IOP at short- and medium-term follow-up. The authors also stated that there is moderate-certainty evidence that the Hydrus Microstent is probably more effective than the iStent in lowering IOP of patients with OAG in the short-term, complications may be rare using the Hydrus Microstent, as well as the iStent, and that because only a few Hydrus Microstent studies exist, additional larger studies are needed to fully investigate its safety.

An ECRI Evidence Analysis (2019, updated 2024) of the Hydrus Microstent for Treating OAG during cataract surgery, revised their recommendation after reviewing additional literature. The review evaluated two systematic reviews that included RCTs. Evidence from those studies were considered to be favorable and showed that Hydrus implantation is safe and effective in normalizing IOP in patients with OAG up to five-year follow-up. Hydrus is more effective than phacoemulsification alone for reducing IOP and medication use. It also appears to normalize IOP and reduce OAG medication use as well as or better than trabeculectomy, selective laser trabeculoplasty, iStent, and other MIGS devices, such as OMNI Xen Gel stents, and Cypass; however, studies provide very low-quality evidence that does not enable firm

conclusions. Additional RCTs are needed to validate findings, and RCTs compareing Hydrus with other OAG microstents and glaucoma surgery would be useful.

Fea et al. (2017a) conducted a prospective interventional cohort study comparing the reduction of IOP and glaucoma medications following selective laser trabeculoplasty (SLT) versus stand-alone placement of the Hydrus® Microstent. Participants with uncontrolled POAG (n = 56 eyes/56 patients) received either SLT (n = 25) or Hydrus® implantation (n = 31) at 2 centers. Patients were evaluated at baseline and 1 day, 7 days, 1, 3, 6 and 12 months post-surgery. Primary outcome measures were IOP and use of glaucoma medications. There were no significant differences at baseline between groups. After 12 months, the Hydrus® group had significant decreases in both IOP and medication use compared with baseline. In the SLT group, while there was a significant decrease in IOP, there was a 3-fold greater reduction in medication use in the Hydrus® group compared with SLT. At 12 months, 47% of patients versus 4% were medication-free in the Hydrus and SLT groups, respectively. In the SLT group, members were complication-free. Three patients In the Hydrus® group experienced a temporary reduction of visual acuity post-operatively, and 2 patients had post-operative IOP spikes that resolved within one week. The authors concluded that while both procedures are safe, the use of the Hydrus® implant led to a significant and further reduction in medication dependence at 12 months. The study is however limited by the lack of randomization.

Fea et al. (2017b) also conducted a multisite retrospective case series, evaluating the safety and efficacy of the Hydrus® Microstent combined with cataract surgery in routine clinical practice. The study included 92 eyes and analyzed outcomes based on IOP, number of glaucoma medications, incidence of complications and baseline and at 2 years post procedure. The researchers concluded that combined phacoemulsification and implantation of the Hydrus® Microstent is an effective surgical treatment option in patients with OAG, including patients with previously failed incisional glaucoma surgeries. The combined surgery led to a significant reduction in IOP and a high medication-free rate 24 months postoperatively. The findings are however limited by the lack of a comparison group.

Glaucoma Drainage Devices

EX-PRESS™

Sun et al. (2019) conducted a meta-analysis of RCTs to compare the efficacy and safety of trabeculectomy and EX-PRESS implantation in OAG. The search was conducted using PubMed, Web of Science, Embase, and the Cochrane Library. Articles that met the predetermined search terms and published up to November 2018, were included. IOP reduction and antiglaucoma medication reduction were considered continuous variables with the mean difference (MD) measured. Complication, postoperative success, and intervention were considered dichotomous variables measured as the odds ratio (OR). Complete success was defined as target endpoint IOP without antiglaucoma medication, while qualified success was defined as target endpoint IOP with or without antiglaucoma medication. All outcomes were reported with a 95% confidence interval (CI). Data were pooled using a random effects model. A total of 8 RCTs were included in the final analysis (223 eyes in the EX-PRESS group and 217 eyes in the trabeculectomy group). EX-PRESS device implantation had a better IOPR% at 12 months postoperatively compared with trabeculectomy. There was no difference in the antiglaucoma medication reduction and qualified success between the groups. Complete success at 1 year postoperatively was higher in the EX-PRESS group (OR = 3.26, 95% CI = 1.24-8.55, p = 0.02). EX-PRESS was associated with a lower frequency of increased IOP (OR = 0.15, 95% CI = 0.03-0.93, p = 0.04) and hyphema (OR = 0.20, 95% CI = 0.05-0.74, p = 0.02). Less postoperative intervention was needed in the EX-PRESS group (OR = 0.43, 95% CI = 0.20-0.94, p = 0.04). The authors concluded that for OAG patients, EX-PRESS implantation provided better efficacy in IOP control and complete success at 1 year postoperatively, with fewer patients with increased IOP and hyphema as well as requiring postoperative interventions. The EX-PRESS device and trabeculectomy were similar in the qualified success and antiglaucoma medication reduction.

De Jong et al. (2011) published results from a 5-year extension of a prospective RCT conducted to establish the efficacy and safety of the EX-PRESS mini glaucoma shunt in OAG. In the original study (De Jong 2009), enrolled patients were randomly assigned to either EX-PRESS implantation under a scleral flap, or trabeculectomy. The main outcome measures included: mean IOP, postoperative medication use, visual acuity, and incidence of complications. Complete success was defined as an IOP of > 4 mmHg and ≤ 18 mmHg without the use of antiglaucoma medications. A more stringent target of IOP > 4 mmHg and ≤ 15 mmHg was also noted. A total of 78 patients (80 eyes) with primary open-angle, pseudoexfoliative, or pigmentary glaucoma were enrolled. Of those, 84.6% of patients who were randomized to EX-PRESS and 60.0% of patients who were randomized to trabeculectomy achieved complete success (p = 0.0230). Patients who achieved an IOP > 4 mmHg and ≤ 15 mmHg were 76.9% and 50.0%, respectively (p = 0.0193). At 1-year of follow-up, complete success rates were 81.8% for Ex-PRESS and 47.5% for trabeculectomy (p = 0.0020), and 71.7% and 37.5% (p = 0.0070), respectively, for the more stringent target. There was a similar level of postoperative interventions and complications for each group. In the extension study, risk-benefit data for 78 patients who received either the EX-PRESS glaucoma filtration device or underwent a trabeculectomy were followed for up to an additional four years (five

years total) beyond the original study (39 eyes per treatment group). Outcome variables were IOP and IOP medications. Complete success was denoted by IOP values ≤ 18 mmHg without medication. The EX-PRESS glaucoma filtration device controlled IOP more effectively without medication for more patients from year 1 (86.8% versus 61.5%, p = 0.01) to year 3 (66.7% versus 41.0%, p = 0.02) than trabeculectomy. At year 1, only 12.8% of patients required IOP medication after EX-PRESS implantation, compared with 35.9% after trabeculectomy. The proportions became closer at year 5 (41% versus 53.9%). The responder rate was higher with EX-PRESS and time to failure was longer. In addition, surgical interventions for complications were fewer after EX-PRESS implantation. The authors concluded that the five-year analysis confirmed and extended the results reported after one year, and that compared with trabeculectomy, EX-PRESS provided better IOP control in the first three years, and patients required fewer IOP medications and fewer surgical interventions during the five-year study period. They also concluded that for patients with POAG, the EX-PRESS glaucoma filtration device produced significantly higher success rates than trabeculectomy, and therefore the EX-PRESS is an effective device for long-term treatment of POAG. de Jong (2011) was included in the Sun 2019 systematic review described above.

Molteno Implant, Baerveldt Tube Shunt, and Ahmed Glaucoma Valve and Krupin-Denver Value Implants

Luo et al. (2023) conducted a systematic review and meta-analysis to compare the efficacy and safety of tube shunt implantation with trabeculectomy in the treatment of patients with glaucoma. A systematic literature search was performed for studies comparing tube with trabeculectomy in patients with glaucoma. Comparisons between tube and trabeculectomy were grouped by the type of tube (Ahmed, Baerveldt, Ex-PRESS and XEN). The primary endpoints included IOP, IOP reduction (IOPR), IOPR percentage (IOPR%), complete success rate (CSR), qualified success rate (QSR) and adverse events (AEs). Forty-nine studies were included in this meta-analysis and data presented for 3795 eyes (Ahmed: 670, Baerveldt: 561, Ex-PRESS: 473, XEN: 199, trabeculectomy: 1892). Ahmed and Ex-PRESS were comparable to trabeculectomy in terms of IOP outcomes and success rate Ahmed vs trabeculectomy: IOPR%: mean difference (MD) = 1.34 (-5.35, 8.02), p = 0.69; Ex-PRESS vs trabeculectomy: IOPR%: MD = 0.12 (-3.07, 3.31), (p = 0.94). The IOP outcomes for Baerveldt were worse than those for trabeculectomy IOPR%: MD = -7.51 (-10.68, -4.35), (p < 0.00001), but the QSR was higher. No difference was shown for the CSR. XEN was worse than trabeculectomy in terms of IOP outcomes [IOPR%: MD = -7.87 (-13.55, -2.18), p = 0.007], while the success rate was similar. Ahmed and Ex-PRESS had a lower incidence of AEs than trabeculectomy. Baerveldt had a lower incidence of bleb leakage/wound leakage, hyphema and hypotonic maculopathy than trabeculectomy but a higher incidence of concurrent cataracts, diplopia/strabismus, and tube erosion. The incidence of AEs was similar for the XEN and trabeculectomy procedures. The authors concluded that compared with trabeculectomy, both Ahmed and Ex-PRESS appear to be associated with similar ocular hypotensive effects and lower incidences of AEs. However, Baerveldt and XEN did not achieve reductions in IOP similar to those of trabeculectomy. This systematic review and meta-analysis had limitations. Most of the studies were not RCTs. Instead, they were non-randomized, retrospective, or prospective studies with potential sources of selection bias. In addition, all the data were only from the final follow-up, which causes potential bias. As trabeculectomy can be easily distinguished from tube shunt implantation, it is difficult to mask the surgical procedures during the postoperative follow-up period, which may affect the results. Due to the limited number of study cases, further subgroup analysis could not be carried out. As the indications for various filtration surgeries differ, further studies should focus on comparing efficacy and safety among different surgeries according to the severity of glaucoma (e.g., grouped by IOP). Further research with RCTs is needed to validate these findings.

Islamaj et al. (2020) conducted an RCT to compare Baerveldt glaucoma implant (BGI) surgery and trabeculectomy (TE) in patients without previous ocular surgery. Inclusion criteria were age 18-75 years, primary OAG, normal-tension glaucoma (NTG), pseudo exfoliative glaucoma or pigmentary glaucoma and the need for IOP lowering surgery. Patients with a history of any ocular surgery, such as TE, strabismus surgery or cataract extraction were excluded from the study. Other exclusion criteria were history of active uveitis or diabetic retinopathy, pregnancy or lactation, anticipated glaucoma surgery combined with other ocular procedures (i.e., cataract surgery), narrow AC angle interfering with tube implantation, BCVA < 0.1 in the study eye or fellow eye and history of ocular motility disturbances. Primary outcomes were IOP and failure rate. The secondary outcomes were medication, AC laser flare value and complications. A total of 119 patients with glaucoma were included in the trial (60 patients received TE surgery and 59 received a BGI). After 5 years, an IOP of 12.7 ±3.9 mmHg (mean ±SD) was achieved in the TE group and 12.9 ±3.9 mmHg in the BGI group. There was no difference in the failure rate between the groups (p = 0.72). More BGI patients needed additional medication to control their IOP (85%; 1.9 ±1.2 types of glaucoma medication) compared to the TE patients (57%; 0.5 ±0.9 types of glaucoma medication). Diplopia was significantly more present in the BGI group than in the TE group (27% versus 4%; p < 0.001). The self-limiting complication rate was similar in both groups. The authors concluded that, in the long term, the final IOP and failure rate are similar after TE and BGI surgery, and that the need for additional medication after BGI surgery is higher than after TE. They also stated that the increased risk of developing diplopia after BGI surgery must be taken into consideration.

In a Cochrane Review conducted by Tseng et al. (2017) the objective was to assess the effectiveness and safety of aqueous shunts for reducing IOP in glaucoma. A search was conducted in CENTRAL, MEDLINE Ovid, Embase.com,

PubMed, LILACS (Latin American and Caribbean Health Sciences Literature Database), ClinicalTrials.gov and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and included RCTs that compared various types of aqueous shunts with standard surgery or to each other in eyes with glaucoma. The search resulted in 27 relevant trials, which included a total of 2,099 participants. Four trials compared an aqueous shunt (Ahmed or Baerveldt) with trabeculectomy, 2 trials that compared the Ahmed implant with the Baerveldt implant, 1 trial compared the Ahmed implant with the Molteno implant, 2 trials compared the double-plate Molteno implant with the Schocket shunt, and the remaining 18 trials evaluated modifications to aqueous shunts. The authors concluded that information was insufficient to conclude whether there are differences between aqueous shunts and trabeculectomy for glaucoma treatment. While the Baerveldt implant may lower IOP more than the Ahmed implant, the evidence was of moderate-certainty, and it is unclear whether the difference in IOP reduction is clinically significant. Overall, methodology and data quality among existing RCTs was heterogeneous across studies, and there are no well-justified or widely accepted generalizations about the superiority of one surgical procedure or device over another.

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, RCT. The study included 276 participants (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 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. This study was included in the Tseng (2017) systematic review described above.

XEN® Glaucoma Treatment System

A 2025 updated ECRI review of the XEN Gel Stent (Allergan plc.) for treating OAG, evaluated 16 studies (five systematic reviews, one RCT, four nonrandomized comparison studies, and six pre-post studies). The evidence indicated favorable results that Xen gel stent implants successfully lower IOP to clinically normal levels in most patients. The effect may last for up to five years, but most studies reported only to 12 or 24 months. These studies had a high risk of bias because most are retrospective. In studies comparing Xen with TRAB (one systematic review, one RCT, and four retrospective comparisons studies), both treatments were effective, with TRAB being somewhat more effective. The findings of five systematic reviews (three with meta-analysis) had different approaches to evaluating Xen implant safety and effectiveness. One examined only studies of Xen implants combined with mitomycin C injections, one compared TRAB with tube stents including Xen, one examined Xen implant complications, and two used different approaches to evaluate Xen's long-term safety and effectiveness. One RCT and four retrospective comparisons studies compared Xen and TRAB. The remaining six studies were single-arm (five retrospective and one prospective) pre-post studies with more than 100 patients and published between 2024 and 2025. No studies compared Xen with other tube stent devices.

Chen et al. (2022) conducted a systematic review on XEN gel stents used in the treatment of OAG. 56 studies published between September 2015 and December 2021, were included in the analysis and none of them were RCTs. The authors found the XEN gel stent lowered IOP by approximately 35% to a final average of 15 mmHg. In addition, the number of antiglaucoma medications also showed a significant decrease. The authors concluded the XEN gel stent was safe and effective, but further studies should be performed to investigate the impact of ethnicity on the success and failure rate after XEN implantation since most of the patients in the analysis were Caucasian. The publication is limited by only reporting findings based on before-after measurements without comparison to groups received different treatments. This systematic review included the following studies summarized below: Tan (2021), Rauchegger (2021), De Gregorio (2018), Grover (2017), Galal (2017) and Pérez-Torregrosa (2016).

A Hayes technology assessment (2019, updated April 2023) on the XEN Glaucoma Treatment System for treatment of OAG identified 7 studies (all observational) that evaluated the safety and efficacy of the XEN treatment system. Two publications compared XEN implantation with trabeculectomy, six studies compared stand-alone XEN implantation against XEN implantation combined with cataract surgery, three publications compared XEN implantation with that of patients with POAG and patients with pseudoexfoliative glaucoma and one study assessed the use of medication between patients with prior glaucoma surgery to patients who had no prior surgical intervention. While the low-quality evidence generally resulted in positive effects for the implantation of the XEN gel stent, the degree of impact varied across the studies, and it was concluded that the XEN system has potential but unproven benefit.

Rauchegger et al (2021) evaluated the 2-year efficacy of XEN Gel Stent implantation in 79 eyes of patients with POAG; 23 of these patients had pseudoexfoliation glaucoma (XFG). The primary outcome of the study was mean reduction in IOP along with a decrease in medication usage. Participants were evaluated preoperatively and day one postoperatively in addition to evaluations at 1 week and then every month up to 2 years. Overall, 28% of the patients completed postop visits through the 24-month follow-up. Needling was documented in 62% of the patients as an additional postoperative treatment to improve aqueous flow and lower IOP. Thirteen eyes needed a glaucoma-related secondary surgical intervention and therefore were considered complete surgical failures. The most common AE was hyphema which occurred in 5 patients and self-resolved within 7 days. The authors saw a meaningful drop of IOP from 23.4 ±7.9 mmHg preoperatively to 14.6 ±3.6 mmHg at month 12 and 14.8 ±4.4 mmHg at month 24 postoperatively. The results suggest the XEN gel stent significantly reduces the patient's IOP over a 2-year period. The findings are limited by the retrospective nature of the study, lack of comparison group and the low number of patients being seen at 24-months, but the authors contributed this to the number of patients that completed their follow-up with private practice ophthalmologists.

Tan et al. (2021) compared the safety and efficacy of two different techniques for implantation of the XEN Gel Stent. The chart review analyzed fifty eyes that underwent the ab interno placement and 30 eyes which underwent the ab externo placement. The cohort that received the ab interno procedure demonstrated a mean IOP reduction of 8.4 ±1.7 mmHg by 12 months; the ab externo group underwent a mean reduction of 12.8 ±3.0 mmHg. Average medications reduction in the ab interno group was 1.81 ±0.29 and in the ab externo group was 1.86 ±0.37. No statistically significant differences were found in IOP control, medication reduction, or AEs. The authors concluded there were no differences in outcomes between the two procedures and the insertion of the XEN Gel Stent. Limitations included retrospective review, lack of comparison group receiving treatments other than the XEN Gel Stent, small sample size, lack of long-term data beyond one year and differences in technique proficiency amongst surgeons.

Buffault et al. (2019) conducted a systematic review to analyze the change in IOP and glaucoma medications using the XEN® Gel Stent as a solo procedure or in association with phacoemulsification in patients with chronic OAG. Using predetermined search terms, a systematic review was performed using PubMed. A total of 8 case series or cohort studies (6 prospective and 2 retrospective) that were published between 2016 and 2018, were included. There were no RCTs included. Data was analyzed for 777 individuals or 958 eyes. The various studies showed a mean IOP at 12 months between 13 and 16 mmHg, which represented an IOP reduction between 25 and 56% (mean: 42%). This decrease was associated with a reduction in glaucoma medications in all studies. The decrease in IOP was significantly greater in XEN® implantation as a stand-alone procedure (44%) than in combined surgery (32%) ($p < 0.05$). Transient hypotony (< 1 month) (3%), choroidal detachment or choroidal folds (1.5%), hyphema (1.9%), bleb leak (1.1%) and shallow AC (1.1%) were the most frequent complications. As for severe complications, four cases of malignant glaucoma (0.4%) and one case of retinal detachment have been reported. In the follow-up period, needling was being required in 32% of cases, and a total of 55 eyes (5.7%) required repeat filtering surgery or cyclodestructive procedure. The authors concluded that the XEN® Gel Stent appears effective for reducing IOP and the number of medications in OAG patients within 1 year postoperatively, and with an acceptable safety profile. However, its use required vigilant postoperative follow-up and frequent postoperative interventions. While these results appear promising, RCTs are needed to confirm the XEN® Gel Stent's safety and efficacy.

De Gregorio et al. (2018) conducted a nonrandomized prospective clinical study to assess safety and efficacy of the XEN® 45 Gel Stent when combined with micro-incisional cataract surgery (MICS). Forty-one eyes of 33 patients with OAG underwent the combination surgery, and there were no major intra- or post-operative 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. The findings are limited by the lack of a comparison group. This study was included in the Buffault (2019) study.

Schlenker et al. (2017) conducted an investigator-initiated, international, multicenter, retrospective cohort study of consecutive patients who underwent either standalone microstent insertion (XEN 45 microstent) 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. As with any retrospective cohort studies, the risk for bias is elevated. Further research was believed to be warranted to further investigate these procedures. This study was included in the Buffault (2019) study.

Galal et al. (2017) conducted a prospective interventional case series of 13 eyes with POAG underwent XEN® implantation with subconjunctival mitomycin-C. Of those eyes, 3 were pseudophakic and 10 underwent simultaneous

phacoemulsification and XEN. Patients had uncontrolled IOP, intolerance to therapy, or maximal therapy but undergoing cataract extraction. One year of follow-up documentation of IOP, number of medications, visual acuity, and complications. Complete success was defined as IOP reduction ≥ 20% from preoperative baseline at 1 year without any glaucoma medications, while partial success as IOP reduction of ≥ 20% with medications. Results reflected a drop in IOP from 16 ±4 mmHg pre-op to 9 ±5, 11 ±6, 12 ±5, 12 ±4, and 12 ±3 mmHg at 1 week, 1, 3, 6, and 12 months, respectively. At 1 year, (BCVA improved from 0.33 ±0.34 to 0.13 ±0.11); and mean number of medications decreased from 1.9 ±1 preoperatively to 0.3 ±0.49. 42% of eyes achieved complete success and 66% qualified success. Complications included choroidal detachment in 2 eyes, implant extrusion in 1 eye, and 2 eyes underwent trabeculectomy. The authors concluded that the XEN implant is an effective surgical treatment for POAG, with significant reduction in IOP and glaucoma medications at 1 year, and state that longer follow-up is needed. The findings are limited by the lack of a comparison group. This study was included in the Buffault (2019) study.

Grover et al. (2017b) 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 case series 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 eyes in 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 XEN® 45 Gel Stent safely reduced both IOP and medication use and offers 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.

Laser Trabeculoplasty

Gazzard et al. (2022) conducted the LIGHT trial on the clinical effectiveness of selective laser trabeculoplasty (SLT) compared with IOP-lowering eye drops after six years of treatment for OAG and ocular hypertension (OHT). Patients were allocated randomly to initial SLT or eye drops. The study included 629 patients completing three years (91.5%) and 524 patients completing 6 years in the trial extension (82.8%). The results demonstrated at six years the SLT arm, 69.8% remained at or less than the target IOP without need for medical or surgical intervention. More eyes in the drop arm exhibited disease progression (26.8% vs. 19.6%, respectively; p = 0.006). The authors concluded SLT is a safe treatment for OAG and OHT provides better long-term disease control than drop therapy. The trial limitations were where no washout was performed, and a proportion of eyes were receiving IOP-lowering topical medical treatment. Success rates for SLT have been published using various definitions and success rates.

Laser Iridotomy/Iridectomy

Baskaran et al. (2022) conducted a multi-center RCT to examine the efficacy of laser peripheral iridotomy (LPI) in patients who received a diagnosis of primary angle-closure suspect (PACS). The study enrolled 480 participants older than 50 years with bilateral asymptomatic PACS followed up yearly for five years. Each participant underwent prophylactic LPI in one randomly selected eye, whereas the fellow eye served as the control. The primary outcome measure was in the development of primary angle closure (PAC); defined as presence of peripheral anterior synechiae, intraocular pressure [IOP] of > 21 mmHg, or both or acute angle closure [AAC] or primary angle-closure glaucoma (PACG). The results demonstrated Eyes treated with LPI reached the end point less frequently after 5 years [n = 24 (5.0%); incidence rate {IR}, 11.65 per 1000 eye-years] compared with control eyes [n = 45 (9.4%); IR, 21.84 per 1000 eye-years; p = 0.001]. The number needed to treat to prevent an end point was 22 (95% CI, 12.8-57.5). The authors concluded that eyes with untreated PACS showed twice the risk of end points developing, mostly peripheral anterior synechiae (PAS), over 5 years compared with eyes that underwent prophylactic LPI. The study limitations included baseline visual fields showed low mean deviation and high pattern standard deviation, increased patient drop-out due to cataract surgery and lack of masking for the intervention.

Laser Iridoplasty

Qin et al. (2023) conducted an RCT to explore the efficacy and safety of laser peripheral iridoplasty (LPIp) with different energy levels and locations in the treatment of primary angle closure disease (PACD) assessed by swept-source anterior segment optical coherence tomography (AS-OCT). Individuals with PACD following best-corrected visual acuity (BCVA), intraocular pressure (IOP), anterior chamber gonioscopy, ultrasound biomicroscopy (UBM), optic disc OCT, and visual field examinations were enrolled in this RCT. A total of 32 participants (64 eyes) included two men and 30 women with an average age of 61.80 ±9.79 (range, 42–77) years were enrolled and placed in one of four groups. The time of the last follow-up ranged from six months to two years. Each of the four study groups comprised eight patients (16 eyes). After Pentacam and AS-OCT measurements, the participants were randomly divided into four treatment groups for LPIp with two different energy levels (high vs. low energy) and two locations (far from the periphery vs. near the periphery) and combined with laser peripheral iridotomy. BCVA, IOP, pupil diameter, central anterior chamber depth, anterior chamber

volume, anterior opening distance (AOD)500, AOD750, trabecular iris angle (TIA)500, and TIA750 in four quadrants before and after laser treatment were compared. The authors followed up the 32 participants for up to two years. The IOP of all enrolled participants decreased after surgery compared to that before ($t = 3.297$, $p = 0.002$), the volume of the anterior chamber was increased ($t = -2.047$, $p = 0.047$), and AOD500, AOD750, TIA500, and TIA750 were increased (all $p < 0.05$). Within-group comparisons showed that BCVA in the low-energy/far-periphery group was improved after surgery ($p < 0.05$). After surgery, the IOP was decreased in the two high-energy groups, whereas the volume of the anterior chamber, AOD500, AOD750, TIA500, and TIA750 were increased in all groups (all $p < 0.05$). However, when comparing every two groups, the high-energy/far-periphery group showed a stronger effect on pupil dilation than the low-energy/near-periphery group ($p = 0.045$). The anterior chamber volume in the high-energy/near-periphery group was larger than that in the high-energy/far-periphery group ($p = 0.038$). The change in TIA500 was six points smaller in the low-energy/near-periphery group than in the low-energy/far-periphery group ($p = 0.038$). Per the authors, other parameters showed no significant group differences. The authors concluded that LPIp combined with iridotomy can effectively reduce IOP, increase anterior chamber volume, increase chamber angle opening distance, and widen the trabecular iris angle. Intraoperatively, high-energy laser spots positioned one spot diameter from the scleral spur can obtain the best effect and safety. Swept-source AS-OCT can safely and effectively quantify the anterior chamber angle. This study has limitations. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population. In addition, at the initial stage of enrollment, the participants were randomly enrolled, and the baseline conditions of the patients were not matched, so the baseline levels slightly differed among groups. Well designed, adequately powered, prospective, controlled clinical trials of LPIp are needed to further describe safety and clinical efficacy.

In a Cochrane systematic review conducted by Bayliss et al. (2021) the effectiveness of LPIp in the treatment of people with chronic angle closure, were compared to LPI, medical therapy or no further treatment. The study included four RCTs involving 252 participants (276 eyes) from various outpatient settings in the UK, Singapore, China, and Korea with either PACS, PAC or PACG. The results obtained from the four included RCTs do not provide enough evidence to suggest that argon LPIp confers any additional benefit to the use of peripheral iridotomy alone in reducing IOP and subsequently preventing the progression of the disease process, whether when used as a primary or secondary intervention. A low incidence of severe complications was reported by three RCTs across all groups. Findings suggest that anterior chamber morphology may be positively impacted by argon LPIp. However, there is no evidence of significant reduction in IOP. A meta-analysis was only possible for a limited number of outcomes due to the variation in study design and outcomes assessed. The authors stated LPIp is currently used a second-line treatment option in people with remaining appositional angle closure after LPI. All studies included in this assessment showed elements of high risk of bias. Due to the nature of the intervention assessed, a lack of masking of both participants and assessors was noted in all trials.

Laser Ciliary Destruction

In a Cochrane systematic review conducted by Chen et al. (2019) assessed the relative effectiveness and safety of cyclodestructive procedures compared with other procedures in people with refractory glaucoma of any type and to assess the relative effectiveness and safety of individual cyclodestructive procedures compared with each other. RCTs and quasi-randomized trials with any laser type, route of administration, and laser settings were included. The primary comparison was any cyclodestructive procedure versus another glaucoma treatment, and the secondary comparisons were individual cyclodestructive procedures versus another cyclodestructive procedure. The study included five trials reporting data for 330 eyes (326 participants). The results demonstrated no study reported data for the primary outcome. Three types of comparisons from four studies provided data for secondary comparisons. In the study that compared micropulse with continuous wave cyclophotocoagulation (CPC), median IOP was reported to be similar between the two groups at all time points. Two studies compared CPC using a semiconductor diode versus an Nd: YAG laser. At 12 months postintervention, the mean deviation in IOP was 1.02 mmHg (95% CI -1.49 to 3.53) in one study. The second study did not report mean IOP beyond three months of follow-up. Lastly, one study compared different energy settings of the same Nd: YAG laser. At 12-month follow-up, visual acuity was unchanged or improved in 21 of 33 participants in the 8J group and 20 of 27 participants in the 4J group (risk ratio 0.86, 95% CI 0.61 to 1.21). Meta-analysis of outcome data was limited to two studies due to various interventions. The authors concluded that the evidence in this review was inconclusive as to whether cyclodestructive procedures for refractory glaucoma result in better outcomes and fewer complications than other glaucoma treatments, and whether one type of cyclodestructive procedure is better than another. The most commonly reported adverse events across all five studies were hypotony and phthisis bulbi. Large well-designed randomized controlled trials are needed. The studies included in this review had the following limitations allocation concealment, lack of masking, lack of randomization, incomplete or missing data, small sample sizes, and possible conflict of interest. Also, no studies comparing cyclodestructive procedures to medical management were not included.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

Laser trabeculoplasty may be used as initial or adjunctive therapy in patients with POAG. Laser trabeculoplasty lowers IOP by improving aqueous outflow and can be performed using argon or solid-state lasers. Current literature shows laser trabeculoplasty to be safe and efficacious.

Cyclodestructive procedures have traditionally been used for refractory glaucomas, and success rates have been reported in the range of 34% to 94%. They have been associated with a subsequent decrease in visual acuity. The literature has shown that further trials are needed to further elucidate the merits of each type of cyclophotocoagulation relative to one another as well as to other types of glaucoma surgery. Therefore, the selection of cyclophotocoagulation over other procedures should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient.

A 2018 AAO Technology Assessment conducted by Radhakrishnan et al. examined the efficacy and complications of LPI in PAC. The literature demonstrated LPI increases angle width in all stages of primary angle closure and has a good safety profile. Most PACS eyes do not receive further intervention, whereas many PAC and acute PAC eyes, and most PACG eyes receive further treatment. Progression to PACG is uncommon in PACS and PAC. There is limited data on the comparative efficacy of LPI versus other treatments for the various stages of angle closure.

Canaloplasty (Ab Interno)

Goldberg et al. (2024) reported on interim results of the VENICE study multi-center RCT (NCT05280366) comparing Streamline Canaloplasty with iStent inject W (iStent W) implantation in patients with mild to moderate POAG undergoing phacoemulsification. Subjects (n = 72 eyes) were randomized; 35 underwent Streamline canaloplasty and 37 were implanted with the iStent W. Seventy eyes completed their six-month follow-up. The results showed both the mean morning post-washout Baseline IOP between Streamline 24.86 ±3.05 mmHg and iStent W 25.16 ±3.41 mmHg and the mean IOP at 6 months between Streamline eyes 16.52 ±3.63 mmHg and iStent W eyes 16.08 ±3.19 mmHg were not statistically significantly different (p = 0.691 and 0.596, respectively). At 6 months, more eyes were on zero glaucoma medications in the Streamline group (81.8%) compared to the iStent W group (78.4%). In medication-free eyes, the mean IOP was reduced from 24.80 ±2.79 mmHg to 16.00 ±3.40 mmHg and 24.60 ±3.18 mmHg to 15.80 ±2.21 mmHg in the Streamline and iStent W groups, respectively (p = 0.752). Both groups showed a reduction in IOP-lowering medications at every visit. The authors concluded that the IOP-lowering efficacy and reduction of IOP-lowering medications were similar between groups. Adverse effects were also similar between groups and generally categorized as minor and self-limiting. This study is on-going and twelve-month results for this cohort will be reported in the future to help better understand the long-term efficacy and safety for both Streamline canaloplasty and the iStent inject W. The limitations of the study include short-term follow-up, potential bias due to manufacturer sponsored study, analysis not designed to test non-inferiority (findings could be due to type 2 error), and a priori primary outcome not yet reported in the publication.

A Hayes Health Technology Assessment, Canaloplasty for OAG (2020, updated January 2023), states that there is insufficient evidence to assess the effectiveness and safety of ab interno canaloplasty.

Ondrejka and Körber (2019) conducted a retrospective case series of 106 eyes from 71 patients with mild to moderate POAG that underwent ab-interno canal viscodilation with the VISCO360 device. Patients were divided into two groups; group 1 had 72 eyes with a baseline IOP ≥ 18 mmHg and group 2 had 34 eyes with baseline IOP of < 18 mmHg. Twelve eyes received standalone ab-interno canal viscodilation (VISCO360-alone) and 94 eyes received ab interno canal viscodilation in conjunction with cataract extraction (CE) (VISCO360 + CE). Primary outcomes measured were the change in mean IOP and the mean number of IOP-lowering medications. Postoperatively, patients received topical tobramycin/dexamethasone medication five times each day for 1 week; then patients received dexamethasone drops four times daily for the second week. All patients had their fundus and anterior angle assessed and were evaluated for best corrected visual acuity, IOP, and medications. Follow up visits occurred on postop day 1, at one month, 3 months and then every 3 months thereafter. At 12 months, group 1 mean IOP reduced from 24.6 ±7.1 mmHg to 14.6 ±2.8 mmHg; group 2 had a mean IOP of 14.9 ±1.8 mmHg at baseline and at 12 months showed no significant difference with a mean IOP at 13.6 ±2.3 mmHg. The authors found that microcatheterization and viscodilation of SC with the VISCO360 Viscosurgical System with or without CE can be safely and consistently performed in patients with mild-moderate POAG. Limitations included lack of comparison group undergoing a different treatment approach, small sample size, lack of long-term effectiveness beyond a year. In a follow-up study Ondrejka et al. (2022) assessed the long-term safety and effectiveness of the VISCO360 and included the updated version the OMNI surgical system performing ab interno canaloplasty only or in conjunction with cataract extraction. The authors concluded both devices successfully performed canaloplasty and achieved statistically significant reductions in IOP and the use of medications, however further studies are warranted to confirm the benefit of this intervention in patients with OAG.

Gallardo et al. (2018a) conducted a retrospective single-center case series of patients with uncontrolled POAG who underwent ab-interno canaloplasty (ABiC) as a stand-alone procedure or in conjunction with cataract extraction. The primary outcomes were mean IOP and mean number of glaucoma medications. Secondary outcomes included surgical and postsurgical complications and secondary interventions. A subset analysis was conducted comparing the outcomes of patients who underwent ABiC and phacoemulsification vs. ABiC as a stand-alone procedure. A total of 68 patients (75 eyes) were included with a mean age of 73.7 ±9.9 years. At baseline, the mean IOP was 20.4 ±4.7 mmHg and mean medication use was 2.8 ±0.9. Twelve months postoperatively, the mean IOP reduced to 13.3 ±1.9 mmHg (n = 73) and mean medication use was reduced to 1.1 ±1.1 medications. At 12 months, 40% of eyes were medication free. In the ABiC/phacoemulsification subgroup (n = 34 eyes), the mean IOP and medication use decreased from 19.4 ±3.7 mmHg on 2.6 ±1.0 medications preoperatively to 13.0 ±1.8 mmHg on 0.8 ±0.2 medications at 12 months (both $p < 0.001$). In the stand-alone ABiC subgroup (n = 41), the mean IOP and medication use decreased from 21.2 ±5.3 mmHg on 3.0 ±0.7 medications preoperatively to 13.7 ±1.9 mmHg on 1.3 ±1.1 medications at 12 months ($p = 0.001$ and $p < 0.001$, respectively). No serious AEs were recorded. The authors concluded that their results demonstrate that ABiC was effective at reducing IOP and medication use in eyes with uncontrolled POAG with or without cataract surgery. However, limitations of this study should be noted. For example, all cases are from a single center, the study design, as a retrospective case series, is uncontrolled and subject to selection bias, the combination cataract surgery results are confounded by the IOP-lowering effect of cataract surgery and therefore, the precise mechanism of the ability of ABiC to reduce IOP is unclear, and only 12 months of follow-up. Longer-term, multicenter prospective randomized trials with a larger sample size are still needed to assess the safety and efficacy of ABiC.

Gallardo et al. (2018b) conducted a non-randomized, retrospective, single-center paired eye cohort study to assess the efficacy of ABiC vs. ab externo canaloplasty (CP) in reducing IOP and glaucoma medication dependence. Patients with PAOG underwent ABiC in one eye and CP in the other eye, either as stand-alone procedures or combined with cataract extraction. The primary outcomes included mean IOP and number of glaucoma medications at 12 months after surgery. Secondary outcomes included surgical complications and secondary interventions. A total of 12 patients (8 females and 4 males) with a mean age of 73.8 ±12.6 years were included. In the CP group, the mean preoperative IOP was 18.1 ±3.9 mmHg on 2.4 ±0.5 medications, which reduced to 13.5 ±2.2 mmHg ($p < 0.05$) on 0.9 ±0.9 medications ($p < 0.001$). In the ABiC group, the mean preoperative IOP was 18.5 ±3.4 mmHg on 2.4 ±0.5 medications and postoperative IOP was 13.8 ±2.2 mmHg ($p < 0.05$) on 0.8 ±0.8 medications ($p < 0.05$). There was no significant difference in IOP, and medication use between treatment groups at 12 months after surgery. No serious AEs were recorded in either group, though two patients in the CP group developed pressure spikes 10 mmHg beyond preoperative IOP. The authors concluded that in this small pilot paired eye study, ABiC was found to have comparable IOP lowering and glaucoma medication reduction to CP in OAG and that ABiC may be a suitable method for improving aqueous outflow via the trabecular pathway. Limitations of this study include lack of randomization and small sample size that may have been insufficient to detect clinically significant differences.

Combined; Canaloplasty (Ab Interno) and Trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) for Adults

An ECRI evidence analysis (2024) of the Streamline Surgical System for treating glaucoma evaluated only one available case series described in two publications. The study reported that Streamline reduced IOP at up to 12 months after surgery in patients and approximately half of the treated patients did not require IOP medication. However, the available study is at high risk of bias and does not permit conclusions on streamline's safety and effectiveness and how they compare with those of other ophthalmic infusion cannulas. RCTs that compare Streamline with other ophthalmic cannulas are needed; two ongoing trials may partially address evidence gaps.

Lazcano-Gomez et al. (2022) conducted a prospective single-arm case series to assess the clinical outcomes of the Streamline Surgical System for mild to severe POAG. The study included twenty eyes that underwent incisional goniotomies and SC viscodilation following phacoemulsification. Outcomes in this interim analysis included mean reduction in IOP and medications through six months of follow-up as well the proportion of yes achieving a reduction ≥ 20% from baseline. At six months mean IOP reduction of ≥ 20% from baseline was achieved in 89.5% of eyes. Mean IOP was significantly reduced from baseline through 6 months of follow-up to 14.7 (2.4) mmHg ($p < 0.001$), representing an IOP reduction of 8.8 mmHg (36.9%). Overall, 57.9% (11/19) of eyes decreased dependence on IOP-lowering medications by at least one medication, and 42.1% (8/19) were medication free. Mean medication use was reduced from 2.0 (0.8) at screening to 1.1 (1.1) at 6 months ($p < 0.001$). The authors concluded preliminary outcomes of incisional goniotomies and SC viscodilation compare favorably to outcomes with other TM bypass implants and commercialized forms of canaloplasty. The limitations of the study include study design (lack of contemporary controls), small sample size, no long-term outcomes, and possible conflict of interest in a manufacturer sponsored study.

In 2022, Toneatto et al. evaluated the effectiveness of ab-interno microcatheterization and 360 degrees viscodilation of SC performed with the OMNI surgical system in 73 patients with OAG. A total of 80 eyes were assessed and divided into

two groups. Group 1 had 50 eyes that underwent ab interno microcatheterization and SC viscodilation, while 30 eyes in group 2 underwent glaucoma surgery + cataract extraction. Preoperatively each patient underwent a complete baseline ophthalmologic examination and IOP was measured by the Goldmann applanation tonometry. The main primary outcome was defined as a reduction in IOP equal to or greater than 25% from baseline at the 12-month follow-up visit; and the eyes that reached this goal without any medical treatment were considered a complete success. Baseline IOP for all eyes had an average of 22.5 ±5.3 mmHg. The authors found after 12 months the mean IOP was reduced to 15.0 ±3.6 mmHg which was statistically significant. However, the reduction in medications at 12 months was not significantly significant between the two groups; the average for groups 1 and 2 were 3.0 ±1.1 and 3.4 ±0.8, respectively, and at 12 months decreased to 2.0 ±1.4 and 1.9 ±1.4, respectively. The authors found approximately 15% of eyes achieved an IOP of 18 mmHg or lower with no medications and an overall success rate of 71.8%. The authors concluded that SC viscodilation with the OMNI device appears to be promising at controlling IOP, however, further studies are needed to report long-term outcomes and complications. Limitations included lack of comparison to other glaucoma treatments, small sample size, lack of long-term outcomes and retrospective design.

An ECRI review (2021), Omni Surgical System (Sight Sciences, Inc.) for Treating OGA, evaluated 3 studies (4 publications), which reported on a total of 217 patients. Those included case series, 3 retrospective and 1 prospective. It was concluded that very-low-quality evidence suggests that the OMNI Surgical System is safe and reduces IOP and medication use up to 18 months of follow-up in patients with mild to moderate OAG when performed alone or during cataract surgery. No studies compared OMNI with other OAG treatments. RCTs comparing OMNI with other MIGSs and with long-term (> 12 months) outcomes are still needed to assess its safety and effectiveness (2021). This ECRI report includes the review of the studies by Hughes and Traynor (2020), Vold, et al. (2021) and Hirsch et al. (2021). In a 2023 update, which included a systematic review, the assessment showed Omni is safe and reduces IOP and medication use at up to 24-month follow-up when used alone or during cataract surgery in patients with mild or moderate OAG, based on low-quality evidence from 7 studies. Omni compared with other OAG treatments cannot be determined because comparative studies are at high risk of bias and provide very low-quality evidence.

Gallardo et al. (2021) conducted a multicenter case series to report 6 month safety and efficacy outcomes of 360° canaloplasty and 180° trabeculotomy using the OMNI® Surgical System concomitantly with phacoemulsification in patients with OAG. Eligible patients had cataract and mild-moderate OAG with IOP ≤ 33 mmHg on 1 to 4 hypotensive medications. Effective outcomes included mean IOP and medications. Safety outcomes included AEs, best corrected visual acuity (BCVA) and secondary surgical interventions (SSI). A total of 137 patients were enrolled and treated. The mean diurnal IOP after washout was 23.8 ±3.1 mmHg at baseline. At month 6, 78% (104/134) of patients were medication free with IOP of 14.2 mmHg, a mean reduction of 9.0 mmHg (38%). One hundred percent (104/104) had a ≥ 20% reduction in IOP and 86% (89/104) had IOP ≥ 6 and ≤ 18 mmHg. The mean number of medications at screening was 1.8 ±0.9 and 0.6 ±1.0 at month 6. AE included transient hyphema (4.6%) and IOP elevation ≥ 10 mmHg (2%). There were no AEs for loss of BCVA or recurring hyphema. There were no SSI. The authors concluded that canaloplasty followed with trabeculotomy and performed concomitantly with phacoemulsification has favorable intra and perioperative safety, significantly reduces IOP and anti-glaucoma medications through 6 months in eyes with mild-moderate OAG. Limitations of this study include its design, which lacks a comparison group and short follow-up period. Additional prospective, randomized studies are still needed to determine the efficacy and safety of this technology. A 2022 update by Gallardo et al. reported on the 12-month efficacy outcomes using the OMNI surgical system in combination with phacoemulsification in patients with mild-moderate OAG and cataracts. At month 12, 84.2% of eyes achieved IOP reductions > 20% from baseline, 80% of eyes were medication-free, and 76% of eyes achieved IOP between 6-18 mmHg inclusive. AEs were uncommon, mild and self-limited including transient hyphema and transient IOP elevations. The authors concluded that the OMNI surgical system at the time of phacoemulsification significantly reduces unmedicated mean diurnal IOP and medication use 12 months postoperatively, with an excellent safety profile. Limitations of this study include a lack of control group or comparison of OMNI to other procedures.

Grabska-Liberek et al. (2021) conducted a case series study to characterize clinical outcomes of combined viscodilation of SC and collector channels and 360° trabeculotomy using the OMNI surgical system as a standalone procedure or combined with cataract surgery in eyes with mild to moderate OAG. Eligible participants were adults aged 45 years or older, with either visually significant cataract or pseudophakia, and OAG (including primary, pigmentary, and pseudoexfoliative) with IOP > 21 mmHg using up to three topical IOP-lowering medications. The primary outcome was the proportion of eyes with IOP reduction ≥ 20% from baseline using the same number or fewer IOP-lowering medications compared to baseline at Month 24. Secondary outcomes included the proportion of eyes with IOP ≤ 18 mmHg and the proportion with IOP ≤ 15 mmHg (and IOP ≥ 6 mmHg in both cases) at Month 12; the proportion of eyes that were medication-free or on at least one fewer medication compared to baseline at Month 12; changes from baseline in IOP and the number of IOP-lowering medications at each visit; and the number of secondary surgical interventions performed for IOP control. Safety endpoints included the nature and incidence of ocular AEs. Participants were re-evaluated at 1 week and 1, 3, 6, 12, and 24 months postoperatively. Among 17 eyes of 15 subjects, mean IOP was reduced from 20.4 mmHg

to 12.7-13.7 mmHg through 12 months of follow-up ($p < 0.001$ at every time point) and mean medications reduced from 2.5 to 0.1-0.6 ($p < 0.001$ at every time point). IOP reductions in eyes undergoing standalone surgery were approximately 2-4 mmHg greater at each time point compared to eyes undergoing surgery combined with phacoemulsification; this may be related to a higher baseline IOP in the former eyes (22.1 vs. 18.5 mmHg). Six eyes developed hyphema, of which three required wash-out for elevated IOP on the first postoperative day; six additional eyes had IOP elevations that resolved with medical management. The authors concluded that viscodilation of SC and collector channels paired with ab interno trabeculotomy performed with a single integrated instrument (OMNI), whether as standalone or combined with phacoemulsification, effectively lowers both IOP and the need for IOP-lowering medications through 12 months of follow-up. The authors also mentioned that this study ongoing and 24-month data will be reported when available. Limitations of this study include its design, a case series lacking a contemporaneous comparison group, the small sample size, that all surgeries were performed by the same surgeon, and the unexpectedly high rate of hyphema. Additional randomized studies with larger sample sizes and longer follow-up periods are still needed to clarify efficacy and safety of this technology.

Klabe and Kaymak (2021) analyzed a case series of 27 patients that were approximately 67 years of age and underwent 360° viscodilation followed by up to 360° trabeculotomy as a standalone procedure. The primary goal of this analysis was to distinguish changes in IOP and IOP medication. 38 eyes underwent the surgical procedure; 30 eyes were available for analysis at one year; and 26 eyes were available for analysis at 2 years. The authors found at 24 months 88.5% (23/26) of eyes had shown an IOP below 18 mmHg; 14 (61%) of these without medication. In addition, 84.6% of eyes were using at least 1 less medication than at baseline, and 57.7% were medication-free. AEs included transient postoperative hyphema in 17 eyes; other AE included choroidal effusion, anterior synechiae, and transient lens-cornea touch associated with shallow AC. Limitations included study design, which was retrospective in nature and lacked a comparison group.

Pyfer et al. (2021) conducted a 12-month case series from the GEMINI study [Gallardo (2021)]. The OMNI device was used following phacoemulsification to perform a sequential ab interno canaloplasty followed by a trabeculotomy on 128 patients with OAG. IOP was measured at 9 AM (±1.5 hours), 12 PM (±1 hour), and 4 PM (±2 hours) using Goldmann applanation tonometry. Two measurements were taken from each eye with the mean value recorded as the IOP for that time point. Measurements were taken again at 12 months. The authors found 95% of patients experienced an overall reduction in IOP; 91% of the patients experienced an IOP reduction of at least 3 mmHg and 86% of patients experienced a reduction in IOP of at least 20%. It was concluded that patients with OAG can benefit from overall decrease IOP for 12 months after surgical treatment. Limitations included lack of comparison group and the inability to generalize the assessment to other minimally invasive glaucoma surgery procedures and implants.

Goniotomy or Trabeculotomy for Adults

Guedes et al. (2025) conducted a systematic review and meta-analysis comparing the outcomes of phacoemulsification combined with either the KDB goniotomy (phaco-KDB) or trabecular microbypass stent (iStent/iStent Inject) implantation (phaco-Stent). The main outcome measures were surgical success, IOP and medication number, and complication rates. Initial search yielded 223 articles, only 14 studies met criteria with a total of 1959 eyes (958 phaco-KDB, and 1000 phaco-Stent including 753 phaco-iStent and 207 phaco-iStent inject). The results demonstrated KDB-phaco group may offer better surgical success compared with the phaco-Stent group (OR: 0.75; 95% CI: 0.13 to 4.13; $p = 0.74$; $I^2 = 47\%$). However, by 12 and 24 months, the IOP reduction between the two groups became comparable. Meanwhile, both procedures demonstrated similar safety profiles including the rates of hyphema and IOP spikes. Using the Cochrane Risk of Bias assessment tool only one study was determined to have a low risk, one study was deemed to pose serious risk of bias regarding measurement outcomes and the remaining 12 studies were assessed at moderate risk of bias. All 13 observational studies were found to have risk of confounding, and seven of these studies had potential bias due to missing data and/or selection of reported results. The authors concluded that further large-scale RCTs comparing these two canal-based MIGS procedures are warranted. The limitations of the studies included in this analysis were only one RCT and the rest were retrospective observational studies which reduced the strength of evidence. In addition, definitions and follow-up among studies varied. The rate of surgical success was consolidated despite variations in endpoints. Finally, studies were included regardless of their quality assessment and limited data with possible conflict of interest due to manufacturer sponsored studies. (McNiel et al. 2022, Falkenberry et al. 2020, ElMallah et al. 2019, Dorairaj et al. 2018 and Le et al. 2018 in this policy are included in this review).

Radwan et al. (2024) conducted a systematic review and meta-analysis examining the IOP lowering effects of the KDB goniotomy combined with phacoemulsification and phacoemulsification alone in patients with OAG or OH. The review included 26 studies reporting on 1659 individuals, 684 individuals underwent phacoemulsification alone, and 975 underwent combined KDB goniotomy with phacoemulsification. The results showed a 9.62% mean reduction in IOP was observed following phacoemulsification compared with 22.74% after KDB combined with phacoemulsification. The heterogeneity was found to be significant among the studies considering phacoemulsification alone as an intervention ($I^2 = 95\%$, p-value for $Q < 0.01$) and those investigating the efficacy of phacoemulsification with KDB goniotomy ($I^2 = 98\%$, p-

value for Q < 0.01). In addition, as the points on the funnel plot are spread-out, it indicates that the variance between studies was larger than just random error. The mean reduction in the number of glaucoma eye drops per patient in phacoemulsification alone was 0.36 [95% CI (0.06, 0.66)] compared with a mean reduction in the number of glaucoma eye drops per patient of 1.35 [95% CI (1.08, 1.61)] based on KDB goniotomy with concurrent phacoemulsification. For both types of studies, the heterogeneity among studies is significant (type 1: I^2 = 84%, p-value for Q < 0.01; type 2: I^2 = 98%, p-value for Q < 0.01). The subgroup analysis result (p-value < 0.01) indicates a significant difference in the mean reduction of glaucoma eye drops used between studies reporting on phacoemulsification as a solo procedure and those reporting on combined strategy. The most common complications reported in patients who underwent the combination of procedures included postoperative IOP spikes and hyphema. The authors concluded KDB goniotomy, when combined with phacoemulsification, has a synergistic beneficial effect on both IOPR and glaucoma drop reduction. Despite the statistically significant outcomes indicating a favorable safety profile for KDB and a reduction in reliance on glaucoma eye drops, the clinical ramifications remain a subject of debate. Further investigations are warranted to evaluate the prolonged effectiveness of KDB in lowering intraocular pressure, its protective influence on the optic nerve, and the potential duration it can postpone the necessity for subsequent, more intrusive glaucoma surgical interventions. The limitations of the studies in this review include only one RCT, inherent biases of indirect comparison of single-arm observational studies, insufficient data, and statistical power to draw definitive conclusions, small sample sizes, and possible conflict of interest related to manufacturer sponsored studies. (Ventura-Abreu et al. 2021, Falkenberry et al. 2020, Le et al. 2019, Dorairaj et al. 2018, and Sieck et al. 2018 cited in this policy are included in this review)

Arimura et al. (2023) conducted an RCT comparing the KDB goniotomy and ab interno trabeculotomy with microhook for morphological changes of the trabecular meshwork. Secondary outcomes included IOP changes, the number of medications and complication rate. Participants with POAG and exfoliative glaucoma (EXG) eyes were randomized into two groups, KDB group (n = 27) and microhook group (n = 25) with a twelve-month follow-up. The incisional cross-sectional area of the KDB group was significantly larger at one week and at one, six and twelve months (p < 0.01) postoperatively. Despite the significant difference in incisional cross-sectional area between the groups, none of the rate of IOP changes, numbers of postoperative glaucoma medications and the usage rate per glaucoma medication type were found to show significant differences between the two groups. The postoperative complications included hyphema, transient IOP elevation, macular edema and ciliochoroidal detachment. The authors concluded the incisional cross-sectional area remains larger in the KDB group than those with microhook, whereas KDB did not have an advantage in controlling IOP postoperatively. The limitations of the study are small sample size and participant type included both with and without stable IOP control, as well as lack of comparison to glaucoma treatments other than goniotomy or trabeculotomy.

Bravetti et al. (2022) conducted a retrospective case series to investigate the surgical outcomes of excisional goniotomy using the KDB in patients with severe or refractory glaucoma. Over a twelve-month post-operative period, data were collected from eleven surgeons at eleven centers in the United States, Mexico and Switzerland. The study reported on forty eyes from a varied population with severe or refractory glaucoma that underwent standalone (52.5%) or combined KDB goniotomy (47.5%). The outcomes showed at twelve months 37.5% (n = 15) achieved an IOP reduction of 20% or more with fewer medications than preoperatively. Qualified success was achieved in 15% of eyes using 12 mmHg or less definition, while 67.5% and 82.5% of eyes achieved a medicated IOP ≤ 16 mmHg and ≤ 18 mmHg. In total 17.5% (n = 7) were classified as complete failure due to uncontrolled IOP above 18 mmHg despite medical treatment. The authors concluded that KDB is a favorable safety profile making it a potential useful primary or adjunctive procedure in high-risk eyes, however, its efficacy decreases over time and that further prospective and randomized studies are required to characterize long-term efficacy and safety of the dual-blade as a standalone procedure. The limitations of the study include lack of comparison group, lack of randomization, small sample size, and lack of standardized protocols.

NcNiel et al. (2022) conducted a retrospective study on the comparative benefits of post-operative IOP changes and ocular hypotensive medications with three surgical cohorts. The study included 138 eyes with OAG, comparing cataract surgery alone (n = 84), cataract with trabecular micro-bypass(cataract/trabecular) (n = 25) and cataract surgery with goniotomy (cataract/goniotomy) (n = 29). When compared with cataract surgery alone, cataract/trabecular and cataract/goniotomy had similar IOP lowering at one month postoperatively, and variable results at three and six months. The change in ocular hypotensive medications was not statistically different between the surgical groups at any postoperative visit. The authors concluded trabecular bypass, and goniotomy when added to cataract surgery resulted in a modest effect on IOP, and a minimal effect on medication burden when compared with cataract surgery alone in glaucoma patients. The study limitations include lack of randomization and small sample size.

Aktas et al. (2021) evaluated a retrospective case series of 15 patients with SOAG for long-term effects following GATT. These patients were enrolled between May 2014 and May 2019, at Gazi University Hospital for the treatment of medically uncontrolled SOAG after silicone oil (SO) removal. Baseline evaluation for all patients included a detailed ophthalmic examination and Goldmann applanation tonometry. Surgical success was defined as an IOP ≤ 21 and ≥ 6 mmHg. Post-op

visits were conducted the day after surgery, and then data was collected at first week, first month, third month and every 3 months. The authors concluded that GATT seems to be effective since the results showed a final mean IOP of 15.6 ±4.6 mmHg, however, the need for medication did increase over the follow-up period. Limitations included lack of comparison group undergoing a different treatment approach, retrospective design and small sample size.

Belkin et al. (2021) conducted a retrospective case series study to report on the efficacy and safety of GATT in patients with uveitic glaucoma. Thirty-three eyes of 32 patients were included with a mean patient age of 49 ±16 years. The data was collected through chart review and communication with eye health professionals involved in patient follow-up. Primary outcome was a reduction in IOP ≤ 18 mmHg and one of the following: IOP within one mmHg of baseline on fewer glaucoma medications as compared with baseline or a 30% IOP reduction from baseline on the same or fewer glaucoma medications. After review and analysis of the data, the authors found a 72% success rate. Limitations should be considered when evaluating these results. For example, the retrospective case series design lacks randomization or comparisons to other glaucoma surgical procedures; in addition, the sample size was small and lacked long-term outcomes.

A 2021 ECRI clinical evidence assessment of the Trabectome an electrosurgical platform intended to reduce IOP in patients with glaucoma. It includes a single-use handpiece with an electrode tip, an irrigation/aspiration unit, and a separately sold high-frequency generator. Using microscope visualization, an ophthalmic surgeon inserts the handpiece's tip via a small corneal incision, using continuous irrigation. The surgeon uses the electrode tip to ablate the trabecular meshwork, guiding it along the SC, up to 90° to the left and right of the incision. Trabectome can be performed alone or in combination with cataract surgery. The report concluded low-quality evidence from 2 systematic reviews and 6 additional nonrandomized comparison studies. Three other nonrandomized comparison studies are too high risk of bias to determine how well Trabectome works compared with ab externo trabeculectomy. Additional RCTs comparing Trabectome with MIGs are needed to validate findings. Evidence limitations include high risk of bias, small study size, retrospective design, single-center focus and lack of randomization and blinding.

Hu et al. (2021) conducted a search of the (CENTRAL), Ovid MEDLINE, Ovid Embase, the ISRCTN registry, ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) for RCTs of ab interno trabecular bypass surgery with the Trabectome procedure when compared to other MIGs, laser or medical treatment. The authors found no high-quality evidence to determine whether ab interno trabecular bypass surgery with the Trabectome procedure for OAG was better or worse than conventional surgery. It was concluded properly designed RCTs are needed to assess the long-term efficacy and safety of this technique.

Sharkawi et al. (2021) reported on outcomes from a non-comparative prospective case series of 103 eyes from 84 patients with pseudoexfoliative glaucoma. The patients underwent a 360-degree ab interno trabeculotomy procedure with gonioscopic assistance. Primary outcomes were IOP and the number of glaucoma medications. Combined cataract surgery with GATT was performed in 50 eyes while the other 53 eyes were already pseudophakic. The complication rate was minimal at 2.9% with only one patient experiencing transient hypertony. The combination of cataract surgery and GATT maintained the same effectiveness as GATT alone in pseudophakic patients. Postoperatively, IOP was reduced by 52%. The authors concluded the study demonstrated that GATT safely and effectively lowers IOP in PXG, whether performed alone or in addition to cataract surgery. Limitations included absence of a comparative group and lack of long-term outcomes.

A single-center longitudinal RCT was conducted by Ventura-Abreu et al. (2021) to evaluate the efficacy and safety of the KDB ab interno trabeculectomy combined with phacoemulsification (phaco) compared to stand-alone conventional cataract surgery. Forty-two eyes from 33 patients over the age of 18 years were randomly allocated to the combined cataract and KDB treatment (n = 21) or cataract alone (n = 21) groups. Preoperative and postoperative data were collected and analyzed at 1-, 3-, 6-, and 12-months post procedure. IOP decreased from 17.9 ±3.5 to 16.0 ±2.2 mmHg and from 17.3 ±2.5 to 15 ±3.2 mmHg at the last visit in the treatment and control groups (p = 0.47). The use of glaucoma medications was reduced from a median (IQR) 1 (1-2) to 0 (0-0) in the treatment group and from 1 (1-2) to 0 (0-1) in the control group, with no significant differences between groups at the 12-month visit (p = 0.47). The authors concluded the KDB ab interno trabeculectomy along with cataract surgery might not offer additional IOP and glaucoma medications reduction compared to stand-alone phacoemulsification. There were no significant major complications found for safety, however there was one case of corneal decompensation in the treatment group. Limitations in the study include small sample size, which could have been too small to detect clinically significant differences, and lack of investigation of systematic medications and medication wash-out.

A systematic review and meta-analysis by Guo et al. (2020) of ten studies evaluated the safety and efficacy of GATT in patients with open angle glaucoma; one study was not pooled for the meta-analysis due to a repeat in data. All studies were case series without a comparison group undergoing a different treatment. The primary outcome was a decrease of

IOP, and the authors found most patients following the surgery still needed anti-glaucoma medication, but the pooled results showed a significant decrease in medications. The most common complication seen was hyphema which was observed in all the studies. Limitations included lack of comparison group, variances amongst the studies including baseline IOP, patient follow up and primary diseases that could have impacted the results. While the authors identified that GATT could effectively lower IOP and decrease medications overall, they agreed RCTs with larger sample sizes should be conducted before drawing any final conclusions. (Rahmatnejad et al. 2017 and Grover et al. 2017a, previously cited in this policy is included in this meta-analysis).

Falkenberry et al. (2020) conducted a multicenter prospective RCT to compare reduction in IOP and IOP-lowering medication in eyes undergoing excisional goniotomy with KDB versus iStent (first generation) implantation both combined with phaco in eyes with mild to moderate OAG. The study included 164 eyes of 164 patients randomized to analyze visual acuity, IOP, IOP lowering medications and AEs postoperatively on day 1, week 1, and months 1, 3, 6, and 12. The primary outcome stated in clinicaltrial.gov was percent reduction in mean IOP at 12 months, but in the publication was the proportion of eyes at 12 months with IOP reduction of 20% or greater or IOP medication of 1 or more compared with baseline. The results showed the composite outcome was attained in 74 (93.7%) of 79 patients of KDB eyes and 65 (83.3%) of 78 patients of the iStent eyes (p = .04). As this outcome was not listed a priori in clinicaltrial.gov, these findings should be considered as resulting from post hoc analyses and should be taken cautiously. The mean percentage IOP reductions from 1 month onward were not significantly different at any point after day 1. The mean post-operative medications were not statistically different between groups beginning at 1 month. The most common AEs in the KDB-Phaco groups and iStent-Phaco groups were increasing IOP occurring in 31.7% (KDB) eyes and 33.3% (iStent) eyes, posterior capsule opacification in 8.5% (KDB) and 6% (iStent), and hyphema in 3.7% (KDB) and 1.2% (iStent) of eyes. The authors concluded both procedures lowered both IOP and the need for IOP lower medications. Significantly, more KDB-Phaco eyes than iStent-Phaco eyes met the primary outcome of 20% or greater IOP reduction or more than 1 medication reduction at 12 months. However, the mean IOP and medication reductions seen in the KDB-Phaco group in this study (approximately 17% and 80%) are likely the result of more eyes undergoing surgery with the goal of medication reduction rather than IOP reduction, as evidenced by the relatively low baseline IOP of the eyes in the KDB-Phaco group. Limitations in the study include relatively small sample size, study not designed to test for non-inferiority, lack of masking, which could have impacted the number of medications ordered, no long-term outcomes, and possible conflict of interest in a manufacturer sponsored study.

A 2019 retrospective cohort study by ElMallah et al. analyzed the efficacy and safety of combined cataract extraction with excisional goniotomy performed with the KDB (KDB; phaco-KDB group) compared to the single iStent trabecular bypass implantation (phaco-iStent group) in eyes with mild to moderate glaucoma and visually significant cataract. The study included 315 eyes from 230 adults treated with one or more IOP-lowering medications (190 eyes in phaco-KDB group and 125 eyes in the phaco-iStent group) that required no subsequent surgical intervention for IOP control through 12 months. Data included visual acuity, IOP and IOP-lowering medications preoperatively and postoperatively at week 1 and month 1, 3, 6, and 12 as well as AEs. The primary outcome was the proportion of subjects achieving ≥ 20% IOP reduction and ≥ 1 medication reduction at month 12. The results showed at month 12, IOP reductions ≥ 20% were achieved by 64.2% and 41.6% (p < 0.001) in the phaco-KDB and phaco-iStent groups, and IOP medication reductions of ≥ 1 medication were achieved by 80.4% and 77.4% (p = 0.522). However, baseline IOP was significantly higher in the phaco-KDB group compared with the phaco-iStent group [18.2 (0.3) vs. 16.7 (0.3) mmHg, p = 0.001]. AEs included transient IOP elevations, transient AC inflammation, corneal edema, and posterior capsule opacification. Transient blood reflux was seen in 38 eyes in the phaco-KDB group (19.8%) and in 5 eyes in the phaco-iStent group (4%). The authors concluded that statistically significant mean IOP and mean IOP medication reductions from baseline were achieved at all time points in both groups. Limitations in the study include study design, small sample size, lack of randomization of treatment groups, short-term outcomes and possible conflict of interest in manufacturer sponsored study. Furthermore, significant group differences existed at baseline (age, ethnicity, type of glaucoma) and no adjusted analyses are provided.

Le et al. (2019) conducted a retrospective single-center cohort study to analyze the surgical outcomes from 2011 to 2017, of patients with mild POAG after combined phacoemulsification with either iStent implantation (48 eyes) or goniotomy using KDB (29 eyes) with a minimum of 12 months follow-up. There was no difference in patients age, previous surgery, sex, preoperative or postoperative visual acuity or IOP between the 2 groups. The overall percentage of IOP reduction was 14.3% in the iStent group and 12.6% in the KDB group at 12 months of follow-up. Mean topical glaucoma medication use decreased from 2.0 ±0.9 to 0.7 ±1.1 in the iStent group and from 2.2 ±1.0 to 1.6 ±1.3 in the KDB group. Adjusted analyses failed to detect statistically significant group differences. The authors concluded phaco in combination with either iStent implantation or goniotomy using the KDB both achieved statistical significance in IOP reduction and number of glaucoma medications at 12-month follow-up. Limitations in the study include small sample size, which could have been insufficient to detect clinically significant group differences (type 2 error), and short-term follow-up.

A multicenter retrospective observational comparative study was conducted by Dorairaj et al. (2018) comparing IOP outcomes in eyes with cataract and glaucoma undergoing phaco in combination with goniotomy using the KDB or implantation of a single iStent trabecular bypass device. Preoperative, intraoperative and postoperative data of IOP and IOP lowering medications were collected through 6 months of follow-up in 435 yes of 318 subjects in phaco-goniotomy with KDB (n = 237) or phaco-iStent (n = 198). The results showed mean IOPs were not statistically different between groups at all time points (1 day, 1 week, and 1, 3, and 6 months) postoperatively. The percent change in IOP from baseline identified statistically significantly greater reduction in phaco-goniotomy with KDB group versus the phaco-iStent group at all time points ($p < 0.001$). Additionally, the proportion of eyes achieving IOP reduction ≥ 20% was statistically greater in the phaco-goniotomy with KDB group than in the phaco-iStent group at every time point after day 1 ($p \leq 0.011$). IOP-lowering medication reduction was greater in the phaco-goniotomy with KDB group compared to the phaco-iStent group p (1.1 vs. 0.9 medications, respectively; $p = 0.001$). The most common AE was IOP spikes occurring in 12.6% of phaco-iStent eyes and 6.3% of phaco-goniotomy with KDB eyes ($p = 0.024$). However, the phaco-iStent group had a lower baseline IOP than the phaco-goniotomy with KDB group thereby slightly reducing the dynamic range between the starting IOP and the episcleral pressure compared to the dynamic range for the phaco-goniotomy with KDB group. The authors concluded goniotomy with the KDB combined with cataract surgery significantly lowers both IOP and the need for IOP-lowering medications compared to cataract extraction with iStent implantation in glaucomatous eyes through 6 months. The authors noted some surgeons are implanting two iStent devices to optimize the IOP-lowering effect. Future studies comparing the use of double iStent implants with goniotomy using the KDB should be examined. Limitations in the study included the retrospective design, short-term follow-up, lack of randomization, which could have led to confounding by indication or other forms of biases, no postoperative management protocol, efficacy measurement of IOP, and author conflict of interest with manufacturer.

An ECRI clinical evidence assessment (2018, updated 2023) on the KDB Glide for treating glaucoma identified four nonrandomized comparative studies and two case series that reported on clinical outcomes of standalone KDB trabeculectomy. The evidence demonstrated large gaps with limited conclusions on the safety and effectiveness of the standalone trabeculectomy. These publications consistently reported favorable outcomes with KDB, however the findings indicated high risk of bias because the studies were retrospective or without controls and involved small samples or a single center. In addition, the findings may not fully generalize to specific patient groups because of the variability in glaucoma etiologies and patient characteristics. The studies lacked outcomes beyond three years and independent validation, therefore comparative effectiveness was not achievable. The report concluded large, prospective studies that compare KDB with microstenting, laser surgery, other ab interno surgical approaches, and long-term outcomes are needed to support stronger conclusions to guide patient/clinician decisions.

Grover et al. (2018, included in the systematic review by Guo et al. 2020 discussed above) conducted a retrospective chart review case series of patients with various types of OAG who underwent a GATT. The purpose of the study was to provide 24-month follow-up on surgical success and safety. A total of 198 patients (198 eyes) between 24 to 89 years of age with IOP of ≥ 18 mmHg underwent GATT. Patients were stratified into 6 groups: (1) POAG with no prior CE, receiving only GATT; (2) POAG with no prior CE, receiving combined GATT and CE; (3) POAG with prior CE, receiving only GATT; (4) Other glaucoma with no prior CE, receiving only GATT; (5) Other glaucoma with no prior CE, receiving combined GATT and CE; and (6) Other glaucoma with prior CE, receiving only GATT. At 24 months, patients with primary OAG (groups 1-3, n = 72) had an average IOP decrease of 9.2 mmHg and an average decrease of 1.43 glaucoma medications. The mean percentage of IOP decrease in these POAG groups at 24 months was 37.3%. In patients with SOAG (groups 4-6, n = 49), there was an average decrease in IOP of 14.1 mmHg and an average of 2.0 fewer medications. The mean percentage of IOP decrease in the SOAG groups at 24 months was 49.8%. The cumulative proportion of failure at 24 months ranged from 0.18 to 0.48, depending on the group. In all 6 study groups, at all 5 postoperative time points (3, 6, 12, 18, and 24 months) the mean IOP and reduction in glaucoma medications was significantly reduced from baseline ($p < 0.001$) with the exception of one time point (i.e., the POAG Prior CE group, at 24 months, reduction in glaucoma medication, $p = 0.059$). The authors concluded that the 24-month results demonstrate that GATT is relatively safe and effective in treating various forms of OAG. They noted that long-term results for GATT are relatively equivalent to those previously reported for GATT and ab externo trabeculotomy studies. However, limitations of this study should be noted. For example, all cases are from a single glaucoma center, the decision for this particular surgical intervention was based on the individual surgeon's discretion rather than a randomization scheme, the number of patients who were lost to follow-up or censored after reoperation, and the study design, which is prone to selection bias, missing data, inaccuracies and lacks a control. Multicenter RCTs with longer follow-up are still needed to ensure the safety and efficacy of GATT.

Sieck et al. (2018) conducted a retrospective chart review to determine the effectiveness and safety of the KDB goniotomy in reducing IOP and medication use in patients with glaucoma with combined with phacoemulsification or as a standalone procedure. A total of 197 eyes were included in the analysis with a wide range of glaucoma types. At twelve months only 140 eyes remained due to attrition, KDB goniotomy (n = 16) and KDB goniotomy with phacoemulsification (n = 124). The most common complications included postoperative IOP spike and transient hyphema. At twelve months the KDB

goniotomy combined with phacoemulsification cataract surgery (phaco-KDB) group mean IOP was reduced from 16.7 mmHg on 1.9 medications to 13.8 mmHg on 1.5 medications. In the KDB goniotomy alone (KDB-alone) group mean IOP reduced from 20.4 mmHg on 3.1 medications to 14.1 mmHg on 2.3 medications. The success rate was 71.8% for the phaco-KDB group and 68.8% for the KDB-alone group. The authors concluded that goniotomy with KDB has a favorable safety profile and is effective at reducing IOP and medication burden. However, future prospective, controlled and randomized studies will be crucial to validate the clinical results demonstrated here. Study limitations included the study design (lack of comparison group undergoing interventions and other and KDB), the lack of long-term follow-up, small sample size and possible conflict of interest.

Bussel et al. (2015) conducted a prospective interventional cohort study evaluating the outcomes of AIT and phaco-AIT with trabectome following failed trabeculectomy. The study included participants with a diagnosis of glaucoma (with or without visually significant cataract) who failed trabeculectomy at least three months prior and had at least 1 year of follow-up. A total of seventy-three eyes of 73 patients were assessed for IOP, medications, complications, secondary procedures and success. Success was defined as IOP less than 21 mmHg and greater than 20% reduction from baseline without further surgery. The results showed AIT performed alone showed a statistically significant decrease in IOP and in the number of glaucoma medications, while phaco-AIT resulted in a similar trend but did not reach statistical significance for medications. AEs included transient hypotony occurred (7%) and further glaucoma surgery (18%) was necessary within 1 year. The authors concluded AIT can be considered a viable therapeutic option for patients with a history of previously failed trabeculectomy who require further IOP lowering and are unable to tolerate conventional glaucoma surgery. Limitations of the study include potential selection bias, limited sample size, relatively short follow-up, and lack of comparison group undergoing interventions other than AIT.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The 2020 AAO Preferred Practice Patterns on POAG state. that although less effective in lowering IOP than trabeculectomy and aqueous shunt surgery, MIGS appears to have a more favorable safety profile in the short term. Limited long-term data is currently available for MIGS, given its relatively recent introduction. Modest IOP reduction has been reported following MIGS, and postoperative pressures are typically in the middle to upper teens. Currently available MIGS includes procedures targeting the trabecular meshwork/Schlemm's canal and the subconjunctival space. They are commonly combined with phacoemulsification; some are only FDA approved to be performed concurrently with phacoemulsification.

The guideline states that modest reductions in IOP and glaucoma medical therapy have been observed in patients undergoing concomitant iStent or iStent inject and cataract surgery compared with those receiving cataract surgery alone. Studies have found very low-quality evidence that iStent may achieve better IOP control or reduction in medications, and that future research should include more quality-of-life outcomes. The XEN gel stent studies were of insufficient quality, no RCTs assessing the safety and efficacy of the device exist. Therefore, the use of these devices should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient. The guideline also states that Hydrus microstent is approved for use in patients with mild to moderate POAG who are undergoing concurrent phacoemulsification. Studies have demonstrated IOP reductions to midteens, with a decreased need for glaucoma medications after Hydrus microstent implantation combined with cataract surgery compared with cataract surgery alone. 3 The Hydrus microstent appears to have excellent safety, with complications largely limited to focal peripheral anterior synechiae.

On the topic of combining glaucoma and cataract surgery, the guideline state:

- 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 (Prum et al., 2016).

An AAO Ophthalmic Technology Assessment by Chopra et al. (2024) provided an evidence-based summary of aqueous shunts (e.g., Ahmed, Baerveldt, Krupin, and Molteno) that are used to control IOP in various glaucomas. Success rates for aqueous shunts were found to be better than for trabeculectomies in eyes with prior incisional surgery. Conversely, in eyes without prior incisional surgery, implantation of aqueous shunts was found to have an overall lower success rate as the primary glaucoma procedure compared with trabeculectomy. Although both valved and nonvalved aqueous shunts

with extraocular reservoir were effective, the nonvalved device generally achieved slightly lower long-term IOPs with fewer glaucoma medications and less need for additional glaucoma surgery. Both devices slow the rates of visual field progression with efficacy comparable with that of trabeculectomy. Implantation of aqueous shunts with extraocular reservoir, including valved or nonvalved devices, has been shown to be an effective strategy to lower IOP. Strong level I evidence supports the use of aqueous shunts with extraocular reservoir by clinicians for the management of adult OAG.

National Institute for Health and Care Excellence (NICE)

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 demonstrates that trabecular stent bypass microsurgery for OAG is safe and effective (2017).

Other Laser Procedures for Glaucoma

There is insufficient quality evidence in the published clinical literature to determine the safety and efficacy of other laser procedures for glaucoma [e.g., excimer laser trabeculostomy/trabeculotomy (ELT), femtosecond laser trabeculotomy (FLT) and optical coherence tomography (OCT) guided laser trabeculotomy]. While these laser treatments are approved for multiple types of surgery such as refractive surgeries (e.g., LASIK, myopia, presbyopia), they are not currently FDA approved for glaucoma treatment in the US.

A Hayes report (2024) evaluated evidence related to OCT guided laser trabeculotomy for the treatment of glaucoma. A review of abstracts suggests there are currently not enough published peer-reviewed literature to evaluate the evidence for a full assessment. Therefore, based on the review guidance appears to confer no/unclear support for OCT-guided laser trabeculotomy for the treatment of glaucoma.

Nagy et al. (2023) conducted a prospective, nonrandomized, single-center, interventional, single-arm clinical trial to evaluate possible adverse events and IOP changes in noninvasive glaucoma surgery utilizing femtosecond laser, image-guided, high-precision trabeculotomy (FLIGHT). Eighteen eyes from 12 individuals were enrolled in the study; 11 individuals (17 eyes) returned at 24 months. The results demonstrated anticipated adverse events such as blood reflux and conjunctival hemorrhage. These events were visible only under gonioscopy, and all cases were resolved by postoperative day 1. There were also instances of transient conjunctival hemorrhage in 3 eyes (n = 3 of 18; 16.7%), which were related to the coupling lens suction ring. At 24 months, the mean IOP was reduced by 34.6% from 22.3 ±5.5 to 14.5 ±2.6 mmHg ($p < 5e-5$), with an average of 2.0 ±1.2 hypotensive medications compared with 2.2 ±1.1 at baseline ($p = 0.22$). Fourteen out of the 17 study eyes (82.3%) achieved a ≥ 20% reduction in IOP at 24 months when compared with baseline. The authors concluded that the initial safety profile of FLIGHT is favorable. Further multi-center randomized clinical studies to evaluate safety and efficacy in a washed-out population of greater diversity is necessary to understand the effects of femtosecond laser trabeculotomy. The limitations of this study are small sample size, single-arm study design, lack of randomization, and risk of bias.

Deubel et al. (2021) performed a cohort study analyzing 512 patients who underwent ELT or combined ELT with cataract surgery at a German Institution from November 2000 until March 2011. Only participants with POAG, pseudoexfoliation glaucoma (PEX) and ocular hypertension (OHT) were included. The usage of IOP-lowering medications and the IOP were recorded at follow-up examinations. Criteria for failure were defined as the need for another surgical glaucoma procedure, when IOP was not 21 mmHg or less and a reduction of 20% from the baseline was not achieved. The results showed after 656 days 87% (combined surgery) and 66% (ELT) patients did not have to undergo another IOP-lowering intervention; 47/31% were classified as a qualified success and 31/11% as a complete success. However, the IOP-lowering medications could not be significantly reduced within that time-period. The authors concluded ELT compared to other trabecular meshwork laser procedures may confer better long-term outcomes. Nevertheless, ELT is still a limited procedure, especially in the long-term and does not deliver sustainable IOP-lowering as more invasive procedures. Limitations in the study include study design, and possible exclusion of uncomplicated cases of ELT interventions done by ophthalmologists in private practice.

Durr et al. (2020) conducted a systematic review to evaluate the current evidence surrounding the efficacy and safety of the ELT. Eight studies met the inclusion criteria which included: 1 randomized control trial, 4 prospective case series and 5 retrospective studies. The authors concluded the evidence showed an IOP-lowering effect from ELT alone or in combination with cataract surgery with encouraging results. The procedure appears to have a favorable safety profile with few intraoperative or postoperative risks. However, more studies are needed to better characterize ELT and further substantiate these promising effects. Limitations of the studies include lack of controls, small sample sizes, washout IOP, variable loss to follow-up, and have not shown long-lasting response after initial surgery.

A systematic review and meta-analysis by Lavia et al. (2017) analyzed the change in IOP and glaucoma medications using different MIG devices as a solo procedure or in association with phacoemulsification. The review included a total of 3,069 studies, nine RCTs and 21 case series with a total of 2928 eyes with at least one year follow-up in patients affected by OAG, pseudoexfoliative glaucoma or pigmentary glaucoma. The studies for ELT included one RCT and two observational studies. The RCT compared ELT surgery with SLT on 30 patients. Medicated IOP data were reported and showed at 1 year a mean change of 9.0 ±2.4 mmHg and 4.9 ±1.8 mmHg in the MIGS and control groups. The change in the number of glaucoma medications was not reported at one year. Two years after surgery the IOP change in the ELT group was slightly inferior then it was at 12 months. The observational studies showed significant difference in IOP and medication reduction comparing ELT with medical therapy, yet sample sizes remained small. The authors concluded that the evidence on the efficacy of MIGS compared to other therapies is still limited and is based on few RCTs of acceptable quality and larger number of (NRS) nonrandomized studies. Limitations include lack of reporting on complications, randomization, risk of bias, small sample size and possible conflict of interest.

One prospective, multicenter, RCT is actively recruiting to compare the effectiveness and safety of ELIOS or competitor device in patients with OAG undergoing cataract surgery available at: http://clinicaltrials.gov/ct2/show/NCT06246136. (Accessed April 21, 2025)

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

ELT as an invasive surgical procedure has shown favorable outcomes when compared to other MIGS procedures. Several limitations have been identified within the current ELT technique; therefore, the next generation of devices is currently under development. Although ELT is not comparable in laser/tissue interaction effects, as a laser treatment for glaucoma, it is likely to be considered with other glaucoma laser treatments. ELT has been approved for use in the European Union and Switzerland, clinical studies are pending in both Canada and the United States (Berlin, 2013).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Specialized devices used for viscocanalostomy and canaloplasty are regulated by the FDA as Class II devices. Additional information under product codes HMX (cannula, ophthalmic), MPA (endoilluminator), or MRH (pump, infusion, ophthalmic) is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

The Canaloplasty Ophthalmic Microcannula, or iTRACK (K062259), is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye such as the AC and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The FDA approved the Ophthalmic Microcannula in August 2006. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

The OMNI Surgical System is a handheld, manually operated device used by ophthalmologists to access, microcatheterize, and viscodilate SC ("canaloplasty") and to re-access SC and cut trabecular meshwork tissue ("trabeculotomy"). Additional information under product codes MRH (pump, infusion, ophthalmic) and HMZ (trabeculotomy) is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

The Streamline Surgical System (K211680) also known as the Streamline Viscoelastic Injector is a single-use disposable cannula for use during ophthalmic surgical procedures to deliver small amounts of viscoelastic fluid. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

Glaucoma Drainage DevicesThe ExPRESS™ Mini Glaucoma Shunt (K030350), 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 26, 2002. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

Predicate Devices include the Molteno Implant (K890598 and K902489), the Baerveldt Glaucoma Implant (K905129 and K955455), the Krupin Eye Valve (K885125 and K905703), and the Ahmed Glaucoma Valve Implant (K925636). Additional information under product code KYF (Implant, Eye Valve) is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

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 OAG and a cataract who are currently being treated with medication to reduce IOP. The iStent Inject® Trabecular Micro-Bypass System (Model G2-M-IS) received FDA approval through the Premarket Approval (PMA) process (P170043) on June 21, 2018. The device is approved only for use in conjunction with cataract surgery; use in a standalone procedure would be considered "off-label." Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

Hydrus® Microstent (P170034) was approved by the FDA on August 10, 2018. This device is approved for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate POAG. Additional information is available at:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

The XEN Glaucoma Treatment System (K161457) was approved by the FDA on November 21, 2016. This device is used to reduce intraocular pressure for the management of glaucoma. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 1, 2025)

The Eagle device (K230722) was approved by the FDA on December 12, 2023. This device is approved for use in laser glaucoma treatment. A Q-switched, 532 nm-wavelength, frequency-doubled Nd: YAG laser, the Eagle is intended for use in performing selective laser trabeculoplasty (SLT). Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Assessed May 8, 2025)

The Family of OPTIMIS FUSION Ophthalmic Laser Systems, Delivery Device and Accessories [OPTIMIS FUSION SLT/YAG, OPTIMIS FUSION YAG, OPTIMIS FUSION SLT (K140336)] was approved by the FDA on June 25, 2014. This device is approved for photodisruption of ocular tissue using light energy emitted by a Nd: YAG Laser, including discission of posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy; and Selective Laser Trabeculoplasty. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Assessed May 8, 2025)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Applicable Codes** • Added CPT code 1012T • Added notation to indicate CPT codes 0253T, 0449T, 0450T, 0474T, 0621T, 0622T, 0671T, 0730T, and 1012T are not on the State of Idaho Medicaid Fee Schedule and therefore may not be covered by the State of Idaho Medicaid Program; for additional information on non-covered and excluded services, refer to the *Idaho Medicaid Provider Handbook, General Information, General Information and Requirements for Providers: Non-Covered and Excluded Services* **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CS050ID.B

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.