Glaucoma Surgical Treatments

Policy Number: 2026T0443MM
Effective Date: September 1, 2026

➲ Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Applicable Codes 1
Description of Services 3
Clinical Evidence 4
U.S. Food and Drug Administration 33
References 34
Policy History/Revision Information 40
Instructions for Use 40

Related Commercial/Individual Exchange Policy
- Outpatient Surgical Procedures – Site of Service

Community Plan Policy
- Glaucoma Surgical Treatments

Medicare Advantage Policy
- Surgical Procedures

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

The following are proven and medically necessary:

- Goniotomy or trabeculotomy for pediatric glaucoma (age 18 years or less)
- Goniotomy, trabeculotomy, canaloplasty (ab interno), or combined canaloplasty (ab interno) and trabeculotomy (e.g., OMNI® Surgical System, Streamline Surgical System) for adults (age 19 years or more) when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma and cataract in adults who are 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 and cataract in adults currently being treated with ocular hypotensive medication
- Glaucoma 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 U.S. Food and Drug Administration–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 the member specific benefit plan document and

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

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

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
L8612	Aqueous shunt

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Description of Services

Glaucoma refers to a group of eye diseases that are 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 define 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. Primary open-angle glaucoma 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° 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° 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 that 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 the Schlemm 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 inward while permanently opening the SC. With an ab interno approach, the microcatheter is inserted through either a clear corneal or limbal incision, through the trabecular meshwork, and then into the SC. Once in the canal, a viscoelastic gel is used to dilate it (National Institute for Health and Care Excellence, 2017, 2022).

Laser ciliary body destruction, also known as cyclophotocoagulation, is a surgical procedure that is used to treat glaucoma. Cyclophotocoagulation 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 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, 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 and selective laser trabeculoplasty types, is used to increase aqueous outflow facility through the trabecular meshwork to lower 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 individuals with glaucoma to reduce the IOP by reducing the resistance to aqueous flow by incising the trabecular meshwork and the inner wall of the SC (Miura and Fukuda, 2022).

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

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

(AC) via an internal approach through the AC (AAO, 2023a). Examples of devices that may be used during the goniotomy (also known as ab interno trabeculotomy) may include the Kahook Dual Blade 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 the 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 is used to create a 360° trabeculotomy (Baykara et al., 2019; SooHoo et al., 2015).

Canaloplasty (ab interno) and trabeculotomy involve 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 et al., 2021).

Glaucoma drainage devices, also known as aqueous shunts, include the EX-PRESS mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Ahmed Glaucoma Valve implant, and 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 the anterior or posterior chamber and connect to a plastic or silicone plate with a large surface area that is secured to the posterior sclera between two of the extraocular muscles and covered by conjunctiva. The plate acts as a physical barrier to scarring the conjunctiva to the sclera, providing a large surface area bleb posterior to the limbus. The Krupin-Denver valve implant has a pressure-sensitive, unidirectional valve to provide filtration restriction, and the implant is designed to open when the IOP is > 11 mm Hg (Krupin et al.,1988).

Glaucoma drainage devices such as the iStent and iStent *inject* trabecular microbypass systems divert aqueous fluid from the AC directly into the SC (Samuelson, 2008). The XEN Gel Stent is available for individuals with refractory glaucomas, including failure of previous surgical management of primary open-angle glaucoma cases. A small tube about the length of an eyelash placed under the conjunctiva, it creates a channel in the eye to drain fluid and help lower eye pressure (XEN gel stent, 2023). 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 that is usually combined with phacoemulsification surgery, which allows for minimal disruption of normal ocular anatomy. Compared with traditional incisional surgeries, MIGS carries a lower risk of complications; however, the level of IOP reduction is often inferior to that with traditional filtering surgery. These procedures should offer at least a 20% IOP reduction or, alternatively, an IOP reduction of at least one medication. MIGS is often conducted in 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., Kahook Dual Blade goniotomy, Trabectome, GATT, TRAB 360/OMNI); enhancing aqueous outflow through the SC (e.g., Visco 360/OMNI, ab interno canaloplasty, Streamline Surgical System); enhancing aqueous outflow through the suprachoroidal space (e.g., CyPass Micro-Stent); shunting aqueous outflow into the subconjunctival space (e.g., XEN Gel Stent); and reducing aqueous production by ciliary body ablation (e.g., endocyclophotocoagulation). The Cypass Micro-Stent was withdrawn from the market in August 2018 (AAO, 2023d).

Clinical Evidence

Goniotomy or Trabeculotomy for Pediatric Glaucoma (Age 18 Years or Less)

Abbas et al. (2026) conducted a systematic review and meta-analysis that compared 360° trabeculotomy with traditional angle surgery (goniotomy and rigid probe trabeculotomy) in children aged under 18 years with primary congenital glaucoma (PCG). Twelve studies, including three randomized controlled trials (RCTs) and nine observational studies that encompassed 778 eyes, met the inclusion criteria. Complete success was defined as an intraocular pressure (IOP) of less than 18 to 21 mm Hg without medication and qualified success required medication; failure was defined as not achieving the target IOP or requiring systemic medication or surgery. The primary outcomes were reduction in IOP and number of antiglaucoma medications at 12 months post operation, analyzed using mean differences (MDs) and odds ratios (ORs) with 95% CIs in RevMan 5.4. A pooled analysis showed that 360° trabeculotomy reduced IOP by -2.10 mm Hg (95% CI, -3.26 to -0.94 mm Hg; p = 0.0004) and medication use by -0.47 drops (95% CI, -0.69 to -0.25; p < 0.0001) compared with traditional angle surgery, with higher complete success (OR, 5.07; 95% CI, 3.43-7.50; p < 0.0001) and qualified success

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

(OR, 3.00; 95% CI, 1.47-6.12; p = 0.003) rates and lower failure rate (OR, 0.18; 95% CI, 0.11-0.31; p < 0.0001). The prespecified secondary end points included postoperative axial length, cup/disc ratio, and horizontal corneal diameter. The authors concluded that 360° trabeculotomy resulted in greater IOP reduction (IOPR), fewer glaucoma medications, and higher surgical success rates than traditional angle surgery in PCG, with both procedures showing similar safety profiles. Key limitations include a mix of observational studies and RCTs and unclear allocation concealment and significant baseline age differences between study groups. There are limitations related to the study design, including small sample sizes, retrospective methodologies, and potential small study effects that may weaken the overall strength of evidence. Measurement limitations include difficulty in evaluating visual acuity in children due to confounding factors such as amblyopia, corneal clarity, refractive error, and neurological development. Additional limitations involved the time required for circumferential surgery, technical challenges in fully traversing the Schlemm canal, and the broader context that achieving lifelong functional vision extends beyond IOP control. (Gupta et al. 2025, cited in this policy is included in this review)

Gupta et al. (2025) conducted a prospective RCT that compared circumferential gonioscopy-assisted transluminal trabeculotomy (GATT; 360°) vs hemi-GATT (180°) in children with PCG. Eligible participants had corneal diameters of less than 14 mm and relatively clear cornea, with exclusions for syndromic associations, secondary glaucoma, prior ocular surgery, lack of consent, or inability to complete the 12-month follow-up. Overall, 52 eyes in 37 children were randomized, with 22 eyes undergoing 360° GATT and 30 eyes undergoing 180° GATT. Participants were followed up for a median of approximately 22 months. Surgical success was defined by IOP thresholds of ≤ 18 mm Hg (criterion A) or ≤ 15 mm Hg (criterion B), classified as absolute if achieved without medications and qualified if achieved with medications. Statistical analysis used SPSS with t tests, chi-square, or Fisher exact tests and Kaplan-Meier curves with log-rank tests for success criteria. The primary outcome showed a 48.9% IOPR in the 360° GATT group vs 20.5% in the 180° GATT group, with postoperative IOP significantly lower with 360° GATT (p = 0.0003) and higher absolute success at 1 year (91% vs 67%; p = 0.009). The prespecified secondary end points included cup-to-disc ratio, corneal diameter, and axial length reversal. The authors concluded that circumferential GATT demonstrated superior efficacy for IOP control in eyes with congenital glaucoma, and circumferential angle treatment is favored in children to recruit distal aqueous humor outflow channels early and reduce the risk of surgical failure. There are limitations, including the relatively small sample size, short follow-up duration, and possible selection bias toward less severe cases with smaller corneal diameters. Another limitation was the difficulty in detecting immediate postoperative IOP spikes, as assessments were performed only at 1 and 4 weeks. The single-center design further limits the generalizability of these findings to other clinical settings.

Lee et al. (2023) conducted a systematic review and network meta-analysis that compared the efficacies of surgical interventions for PCG in children. The study included 16 eligible RCTs, which included 710 eyes in 484 individuals and 13 surgical interventions. The surgical interventions included conventional partial trabeculotomy (CPT; control), 240° trabeculotomy, illuminated microcatheter-assisted circumferential trabeculotomy (IMCT), viscocanalostomy, visco-circumferential-suture-trabeculotomy, goniotomy, laser goniotomy, Kahook Dual Blade (KDB) ab interno trabeculectomy, trabeculectomy with mitomycin C, trabeculectomy with modified scleral bed, deep sclerectomy, combined trabeculectomy-trabeculotomy with mitomycin C, and Baerveldt implant. The main outcomes were mean IOPR and surgical success rate at postoperative 6 months. The MDs or ORs were analyzed by a random-effects model, and the efficacies were ranked by p score. The results demonstrated that IMCT was superior to CPT in both IOPR (MD, -3.10; 95% CI, -5.50 to -0.69) and surgical success rate (OR, 4.38; 1.61-11.96). The MD and OR comparing the other surgical interventions and combinations with CPT were not statistically significant. The p scores ranked IMCT as the most efficacious surgical intervention in terms of success rate (p score = 0.777). The results for goniotomy were similar to those for the refence method (CPT) and similar interventions. The authors concluded further long-term follow-ups from multicountry RCTs are required to accumulate evidence on the efficacy of surgical interventions for PCG. In addition, use of a standardized reporting system for surgical outcomes is needed to improve comparability between studies. Lastly, studies that compare the complications of surgical interventions would provide valuable information for practitioners. Limitations include a small sample size from each trial, a small-study effect, inconsistent definitions of surgical success rates, and inaccessibility of patient data; additionally, small study subgroups made analysis difficult, and individuals were not adherent to the current study's eligibility criteria. Furthermore, the findings are limited by the indirect comparison of network meta-analyses.

Qiao et al. (2021) compared the efficacy and safety of GATT and KDB excisional goniotomy in patients with uncontrolled juvenile open-angle glaucoma (JOAG). Overall, 33 patients (ages 4-40 years) were included in this single-center, retrospective comparative study and treated with GATT (36 eyes) or KDB goniotomy (13 eyes). During pre- and postoperative visits, IOP, glaucoma medication usage, adverse events (AEs), and additional antiglaucoma procedures were collected. The cumulative proportion of partial and complete success was 65.6% and 44.7% in the GATT group, respectively, and 30.8% and 15.4% in the KDB group at 6 months. Additional procedures were required in 13.9% of cases after GATT and in 61.5% after KDB (p = 0.001). Patients in the GATT group with prior antiglaucoma procedures and postoperative IOP spike were more likely to experience failure, while those with complete trabeculotomy had a better prognosis. The authors concluded that reduction of IOP and medications were greater after GATT in uncontrolled JOAG

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

eyes, whereas more additional IOP-lowering procedures were required after KDB goniotomy. The authors recommended that future studies are needed to confirm the discrepancy in efficacy and safety between the two surgical approaches using larger sample sizes and prospective randomized designs. Limitations of this study include a small sample size, limited follow-up evaluation, and the retrospective nature of the study.

Gagrani et al. (2020) updated a previously conducted systematic review (Ghate, 2015) that aimed to compare the effectiveness and safety of various surgical techniques for PCG. A search was conducted using CENTRAL (Cochrane Central Register of Controlled Trials), Ovid MEDLINE, Embase, PubMed, mRCT (metaRegister of Controlled Trials), ClinicalTrials.gov, and the World Health Organization ICTRP (International Clinical Trials Registry Platform). Overall, 16 trials (13 RCTs and three quasi-RCTs), with 587 eyes in 446 children, were included in the review. Three trials (in 68 children) compared combined trabeculotomy and trabeculectomy (CTT) with trabeculotomy; two trials (in 39 children) compared viscotrabeculotomy with conventional trabeculotomy; two trials (in 95 children) compared microcatheter-assisted 360° circumferential trabeculotomy with conventional trabeculotomy; one trial compared CTT vs CTT with sclerectomy; three trials compared various suturing techniques and adjuvant use, including mitomycin C and collagen implant in CTT; one trial compared CTT vs the Ahmed valve implant in previously failed surgeries; one trial compared CTT with trabeculectomy; one trial compared trabeculotomy with goniotomy; and two trials compared different types of goniotomy. The authors concluded that evidence of the comparative benefits and risks of different surgical procedures for PCG is limited; however, microcatheter-assisted 360° trabeculotomy is probably more beneficial than standard trabeculotomy but probably causes more unwanted effects. The authors also stated that with the rarity of the disease in consideration, future research would benefit from a multicenter, possibly international trial that involves parents of children with PCG and with a follow-up of at least 1 year. Key limitations include the small sample sizes and relatively short follow-up durations across the studies. There are limitations related to study design, as each trial compared different surgical techniques or exposure durations, which may reduce comparability. Another limitation is that the results were summarized in a secondary table rather than fully detailed in the main analysis.

Huang et al. (2018) conducted a single-center cohort study to investigate the long-term postoperative outcome of three surgical procedures for childhood glaucoma. The investigators retrospectively reviewed the medical records of patients with several types of childhood glaucoma and based on the initial surgery, categorized patients into goniotomy, trabeculotomy, or filtering surgery groups. The main outcome measure was the probability of success of surgery based on a Kaplan-Meier analysis. Surgical failure was defined as one of the following: (1) when additional glaucoma filtering surgery was performed; (2) visual acuity deteriorated to an absence of light perception; and (3) an IOP of greater than or equal to 21 mm Hg was observed with ocular hypotensive medications, verified during two consecutive visits. Overall, 73 eyes in 43 patients were analyzed. The age at the initial surgery was 4.1 ±6.4 years (mean ±SD; range, 1 month to 17.7 years). The follow-up period was 9.6 ±6.7 years (range, 2-20 years). Overall, 40 eyes in 25 patients, 21 eyes in 15 patients, and 12 eyes in seven patients underwent initial surgery with goniotomy, trabeculotomy, and filtering surgery, respectively. The probability of success was 65.2% ±7.8% and 65.2% ±7.8% (estimated probability ±SE) 10 and 20 years after the initial surgery, respectively, in the goniotomy group. It was 42.2% ±13.6% at 10 years in the trabeculotomy group (no data for 20 years) and 91.7% ±8.0% and 80.2% ±12.8% at 10 and 20 years after the initial surgery in the filtering surgery group. The authors concluded that all three procedures maintained an IOP of less than 21 mm Hg for up to 10 years and provide valuable options for the treatment of childhood glaucoma. There are limitations, including the retrospective study design and relatively small number of patients. The varied surgical indications could have introduced selection bias among the treatment groups.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The AAO's report (Chen et al., 2014; updated 2020) on pediatric glaucoma surgery states that there are many surgical options for the treatment of pediatric glaucoma (e.g., PCG, aphakic glaucoma, and glaucoma associated with other ocular or systemic anomalies), including goniotomy, trabeculotomy, trabeculectomy, CTT, tube shunt surgery, cyclodestruction, and deep sclerectomy. The relative efficacy of these various procedures for specific diagnoses and clinical situations should be weighed against the specific risks associated with the procedures for individual patients.

iStent and iStent *inject*

Fan et al. (2024) conducted a prospective, randomized, assessor-masked controlled trial at a single center that compared combined cataract surgery with iStent *inject* vs cataract surgery alone in participants with mild to moderate open-angle glaucoma (OAG) and visually significant cataract. Eligible eyes had a preoperative IOP of 12 to 30 mm Hg on zero to three ocular hypotensive medications, normal open-angle anatomy, and reliable visual fields. Overall, 111 eyes in 93 participants were randomized, and 101 eyes (55 iStent; 46 control) were included in the primary analysis set, with 42 eyes per group completing the 24-month follow-up. The coprimary end points were the number of ocular hypotensive medications and IOP at 24 months, measured by Goldmann applanation tonometry. At 24 months, the iStent group used

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

0.7 ±0.9 medications vs 1.5 ±1.9 in controls, which is an adjusted difference of 0.6 fewer medications per eye (95% CI, 0.2-1.1; p = 0.008), while IOP did not differ significantly between groups (adjusted difference, 0.8 mm Hg; 95% CI, -1.1 to 2.8 mm Hg; p = 0.405). The prespecified secondary end points were ocular comfort (Ocular Surface Disease Index) and vision-related quality of life (Glaucoma Activity Limitation Questionnaire). The authors concluded that combined cataract surgery with iStent *inject* achieved a clinically and statistically significant greater reduction in ocular hypotensive medication use at 24 months compared with cataract surgery alone, with no significant difference in IOP, demonstrating efficacy and safety in reducing medication burden in mild to moderate OAG. Key limitations include the reliance on secondary effectiveness end points such as ocular comfort, as measured by the Ocular Surface Disease Index; vision-related quality of life, as measured by the Glaucoma Activity Limitation Questionnaire at 24 months; and incomplete scores, as measured by the Glaucoma Activity Limitation Questionnaire, across baseline, 22 weeks, and 24 months. There are limitations, including possible participant awareness of their treatment allocation under local anesthesia, which could have introduced a placebo effect that influenced subjective outcomes and postoperative medication adherence. The study has limitations in measurement, as medication washout was not performed before or after surgery, preventing evaluation of IOP changes that are attributable solely to the device. Generalizability may be limited because the trial design sought to emulate routine clinical practice rather than a strictly controlled research environment, and early IOP results showed no meaningful group differences.

Kahale et al. (2023) performed a systematic review and meta-analysis that compared the effect of iStent insertion at the time of phacoemulsification with phacoemulsification alone in individuals with OAG. The results included 10 comparative studies, reporting on 1,453 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 that IOPR was higher with the combined surgery at 4.7 ±2 mm Hg compared with 2.8 ±1.9 mm Hg with 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 vs 0.6 ±0.6 drops in isolated phacoemulsification. The quality effect model showed an IOPR weighted MD of 1.22 mm Hg (CI, -0.43 to 2.87 mm Hg; Q = 315.64; p < 0.01; I^2 = 97%) and decreased eye drops weighted MD 0.42 drops (CI, 0.22-0.62; Q = 42.6; p < 0.01; I^2 = 84%) between both surgical groups. The authors concluded that the findings support the use of iStent in combination with cataract surgery when further IOPR is desired in OAG. The iStent second-generation seems more effective in lowering IOP. Although the results were statistically significant, with iStent showing a good safety protocol and offering the benefit of decreasing the dependence on 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 a 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 used independently of cataract surgery in individuals 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 nonrandomized studies that included at least 6 months of follow-up or more than 10 eyes. Efficacy analyses included postoperative IOP and medication use and the proportion of eyes free of ocular medication. Postoperative AEs were descriptively summarized. The literature search yielded a total of 760 citations, and after further review, 13 studies were included in the analysis. Those included four RCTs and nine nonrandomized or single-arm studies that provided data for 778 eyes. In eyes that were implanted with iStent devices, a weighted mean IOPR of 31.1% was observed at 6 to 12 months. In studies reporting longer-term outcomes (36 to 48 months or 60 months), the weighted mean IOPR was 30.4% and 32.9%, respectively. The pooled weighted mean reduction in IOP from baseline across all studies at 6 to 12 months and 36 to 60 months post stent implantation was 7.01 mm Hg (95% CI, 5.91-8.11 mm Hg) and 6.59 mm Hg (95% CI, 5.55-7.63 mm Hg), respectively. Medication burden was reduced by approximately 1.0 medication at 6 to 18 months and 1.2 medications at 36 to 60 months. AEs that were reported in more than 5% of individuals included progression of preexisting cataract/cataract surgery and loss of best-corrected visual acuity (BCVA), but these rates were no different than 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 5 years after treatment, without the potential for confounding from cataract surgery. Key limitations include the exclusion of control groups from the primary efficacy analysis and use of preoperative baseline measurements as a proxy for a control arm. There are limitations, including inconsistent reporting of medication use at the end point, which restricted the robustness of statistical meta-analyses. The study has limitations, as bias was not formally assessed, and studies were excluded only for small sample size or short follow-up to allow inclusion of nonrandomized studies, which may have affected the comprehensiveness of the review. Another limitation is that the comparative efficacy of several trabecular microbypass glaucoma surgery RCTs has already been reported, which may reduce the novelty of the present analysis.

An ECRI review on the iStent *inject* trabecular microbypass system for treating OAG during cataract surgery (2019) evaluated seven studies (five full text and two abstracts) that included a total of 1,112 eyes. Those included one multicenter RCT, one single-center RCT, and five nonrandomized comparison studies. Evidence from those studies

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

showed that iStent *inject* implantation during cataract surgery reduced IOP (> 20%) and use of glaucoma medication in individuals with mild to moderate primary OAG (POAG) through 2 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 microbypass system (Glaukos Corporation, San Clemente, CA, USA) in combination with cataract surgery in participants 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). Participants were followed up for 2 years post implant. At 24 months, 75.8% of treatment eyes vs 61.9% of control eyes experienced a ≥ 20% reduction from baseline in unmedicated diurnal IOP (DIOP), and the mean reduction in unmedicated DIOP from baseline was greater in treatment eyes (7.0 ±4.0 mm Hg) than in control eyes (5.4 ±3.7 mm Hg). Of the participants 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 of ≤ 18 mm Hg 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 vs cataract surgery alone. Additionally, the pivotal study's findings support the consideration of this second-generation trabecular microbypass stent system as a safe, durable, and less adherence-dependent treatment modality for additional unmedicated IOPR in POAG eyes that are undergoing cataract surgery. This study was included in the ECRI review. Key limitations include the lack of surgeon masking to treatment groups and the influence of the surgeons' learning curve with the technology.

Guedes et al. (2019) conducted a single-center, longitudinal, retrospective, side-by-side comparison of the iStent and iStent *inject* trabecular microbypass stent systems. The study evaluated performance and safety in consecutive eyes following implantation of either device with concomitant cataract surgery. The performance outcomes included IOPR; glaucoma medication reduction; proportions of eyes achieving an IOP of < 18, < 16, < 14, or < 12 mm Hg; and proportions of eyes on zero, one, two, or three or more medications. The safety outcomes included AEs, secondary surgeries, and BCVA. The follow-up period was 6 months. Overall, 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, the mean IOP had fallen in both groups; however, the reduction was significantly greater in the iStent *inject* eyes vs the iStent eyes (26.6% vs 15.8%). All who received the iStent *inject* device achieved an IOP of < 18 mm Hg at 6 months compared with 86.8% of the iStent recipients, and > 70% of eyes in both groups became medication free by 6 months post implantation. AEs occurred in two iStent eyes, which resulted in no sequelae, and two iStent eyes underwent nonpenetrating 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 vs 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 patient with the iStent *inject* stent had four lateral outflow lumens and used two stents vs 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 that includes a larger population and longer follow-up is necessary to validate these findings. This study was included in the ECRI review.

Hengerer et al. (2018) performed a prospective, nonrandomized, consecutive case series to assess 36-month outcomes after cataract surgery and implantation of two second-generation trabecular microbypass stents (iStent *inject*). Participants (81 eyes in 55 consecutive participants) 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. The effective end points included the IOP, number of medications, and proportion of eyes with ≥ 20% IOPR, IOP of ≤ 18 mm Hg, and IOP of ≤ 15 mm Hg. Safety measures included corrected distance visual acuity, AEs, and secondary surgeries. The 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 post operation. With regard to the POAG and PEX subgroups, the outcomes in PEX eyes were similarly favorable to those in POAG eyes, thereby corroborating prior studies that showed iStent technology to be a highly suitable and effective treatment option in individuals 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 are several limitations in this unmasked single-arm study, these outcomes were interpreted as significant, and future studies are encouraged.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Popovic et al. (2018) conducted a systematic review and meta-analysis on the efficacy and AE profile of the iStent in the treatment of OAG. Using predetermined search terms, the authors performed a systematic review using Ovid MEDLINE and Ovid Embase. Overall, 28 studies were included in the meta-analysis. The main analysis was performed based on whether individuals had one, two, or three 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 individuals were male. There was a significantly greater IOPR after the use of two first-generation stents compared with one, irrespective of phacoemulsification status ($p < 0.001$). Additionally, there was a significantly greater IOPR 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 IOPR ($p < 0.001$) 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 with the iStent due to varying parameters, including the number of iStents and phaco-iStent compared with either iStent alone or phacoemulsification alone. In their analysis, two stents delivered a greater response in terms of IOPR relative to one, and iStent alone had a significantly greater IOPR than phaco-iStent. Combined phaco-iStent was statistically superior relative to phacoemulsification alone in the reduction of IOP and medication classes prior to and post operation. Key limitations include differential reporting across studies, which resulted in each end point being derived from a distinct set of studies, and the small sample size in the three-stent group, which comprised only 63 eyes. There are limitations related to study design and comparability, including unbalanced baseline characteristics, lack of subgroup analysis between the phaco-iStent and iStent-alone groups, and uncertainty regarding the balance of surgeon experience between the comparator arms. Measurement limitations include variable reporting of surgeon learning curves and inconsistent handling of medication washout before stent implantation, which limited the assessment of preoperative medication effects on baseline IOP. Analytical limitations include potential selection bias from differing disease severity, high heterogeneity among studies, and insufficient data to perform robust meta-analyses for some end points

Hydrus Microstent

Salimi et al. (2026) conducted a retrospective consecutive case series that evaluated 64 eyes in 41 patients who had OAG and underwent Hydrus Microstent implantation combined with cataract surgery; patients were followed up for 5 years. Inclusion required at least 5 years of follow-up, while eyes with prior incisional glaucoma surgery or other ocular comorbidities were excluded. The cohort had a mean age of 71.6 years, had a baseline IOP of 17.8 ±4.6 mm Hg on 2.8 ±1.1 medications, and included mild to severe glaucoma cases. The primary outcome was surgical success, defined by IOP thresholds (≤ 21, ≤ 18, and ≤ 15 mm Hg), stable or reduced medication use, and absence of secondary glaucoma surgery, which was analyzed using Kaplan-Meier survival curves and Cox proportional hazard models. At 5 years, the mean IOP decreased from 17.8 mm Hg (95% CI, 16.6-18.9 mm Hg) to 13.2 mm Hg (95% CI, 12.5-14.0 mm Hg), and medications declined from 2.8 (95% CI, 2.6-3.1) to 2.2 (95% CI, 1.9-2.5), both with a p value of < 0.001. Success rates of 75%, 70%, and 58% were observed for the respective thresholds. A higher preoperative IOP (hazard ratio, 1.145; $p < 0.001$) and postoperative IOP spikes (hazard ratio, 3.382; $p = 0.003$) predicted failure. The prespecified secondary end points included changes in IOP, antiglaucoma medication use, BCVA, and optic nerve structural measures. The authors concluded that the study provides the longest real-world follow-up on the Hydrus Microstent with cataract surgery, confirming its safety and efficacy in reducing IOP and antiglaucoma medication use, with structural parameters remaining stable and no significant change over 5 years. Key limitations include the absence of a phacoemulsification-only control group, which makes it difficult to isolate the effects of the Hydrus Microstent from those of cataract surgery. There are limitations in measurement quality, as averaging the last two preoperative IOP readings was feasible for only 70% of eyes due to missing data. Although heterogeneity in disease type and severity may be viewed as a limitation, it also enhances the study's external validity and real-world relevance. Generalizability is limited because all procedures were performed by a single surgeon, which may restrict applicability to other operators and surgical techniques.

Hu et al. (2022) conducted a systematic review and network meta-analysis to compare the efficacy and safety of two Schlemm canal–based MIGS devices: the Hydrus Microstent and the iStent trabecular bypass combined with phacoemulsification for the treatment of OAG. Literature searches were conducted on PubMed, Web of Science, Cochrane Library, and ClinicalTrials.gov to identify RCTs that assessed the Hydrus or the iStent implantation combined with phacoemulsification for the treatment of OAG. Risk of bias was assessed using a six-item modified Jadad scale. Effects were estimated using the IOPR, percentage of IOPR, and proportion of medication-free individuals at the follow-up end. Safety was estimated using the proportions of AEs. The network meta-analysis was conducted in a Bayesian framework using the Markov chain Monte Carlo method in ADDIS software. Six prospective RCTs that comprised 1,397 individuals 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. A rank probability analysis suggested that Hydrus might be the best choice to lower IOP. There was no difference in the proportion of medication-free individuals among groups. The Hydrus and 2-iStent implantation had a higher probability of achieving medication-free status vs the 1-iStent implantation and phacoemulsification alone. The overall safety profiles were good

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

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 in 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 AEs were not always reported in each study, and due to the limited data, the authors did not perform a statistical analysis to compare the difference in treatment safety among groups. It is unclear whether there is a 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, and to directly compare these MIGS devices. Key limitations include the relatively small number of studies and variable sample sizes, which may have introduced bias and limited the precision of the findings. There are limitations related to study duration and scope, with relatively small populations and short follow-up affecting confirmation of comparative efficacy between single first-generation and second-generation iStent devices. The evidence base is also limited by the scarcity of studies that directly compared two first-generation stents with double iStent inject, which restricts conclusions about relative efficacy.

Ahmed et al. (2021) reported the 3-year outcomes of the HORIZON study (Samuelson et al., 2019b), which compared cataract surgery performed with Hydrus Microstent implantation (n = 369) vs cataract surgery alone (n = 187). The authors found that the results suggested that combining the Hydrus Microstent implantation at the time of the cataract surgery improved the participant'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 participants with secondary OAG (SOAG) and limitation of only one comorbidity (POAG) in participants, the authors felt that the study sufficiently demonstrated the difference in long-term IOP and medication reduction. In a 2022 update by Ahmed et al. after a 5-year follow-up, the outcomes measured IOP, glaucoma medication usage, repeat glaucoma surgery, visual acuity, visual field, AEs, and corneal endothelial cell counts. The outcomes showed that the Hydrus Microstent group included a higher proportion of eyes with an IOP of 18 mm Hg or less without medications vs the cataract surgery group; additionally, there was a greater likelihood of IOPR of 20% or more without mediations vs the cataract surgery group, and 66% of eyes in the Hydrus Microstent group were medication free compared with 46% in the cataract surgery group. The authors concluded that compared with cataract surgery, the microstent in conjunction with cataract surgery was safe; resulted in lowered IOP and medication use; and reduced the need for postoperative incisional glaucoma filtration surgery after 5 years. Study limitations include the inability to mask the surgeon to treatment group during examinations, limited experience of the surgeons with the Hydrus Microstent implantation technique, exclusion of participants with SOAG, inclusion of 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 individuals with OAG. A search was conducted using CENTRAL, Ovid MEDLINE, Ovid Embase, ISRCTN (International Standard Research Clinical Trial Number) registry, the U.S. National Institutes of Health Ongoing Trials Register, and the World Health Organization International Clinical Trials Registry Platform. Overall, 209 publications were screened, and 3 studies (4 publications, Ahmed 2020, Jones 2019, Samuelson 2019b, Pfeiffer 2015), with 808 randomized individuals, were included in the review. Two studies compared the Hydrus Microstent combined with cataract surgery with cataract surgery alone in individuals with visually significant cataracts and OAG; the other study reported short-term data for the Hydrus Microstent compared with the iStent trabecular microbypass stent. The authors concluded that in individuals with cataracts and mild to moderate OAG, there is moderate-certainty evidence that the Hydrus Microstent with cataract surgery compared with cataract surgery alone likely increases the proportion of individuals who do not require IOP-lowering medication and may further reduce IOP at the short- and medium-term follow-up. The authors also stated that (1) there is moderate-certainty evidence that the Hydrus Microstent is probably more effective than the iStent in lowering IOP in individuals with OAG in the short term and that (2) complications may be rare using the Hydrus Microstent as well as the iStent. They stated that because only a few Hydrus Microstent studies exist, additional larger studies are needed to fully investigate its safety. Key limitations include the incomplete methodological detail that prevents the assessment of study design, selection of individuals, and analytic procedures, reducing reproducibility and internal validity. There are limitations that are related to the unreported study identification and inclusion process, which introduces uncertainty about screening criteria and potential selection bias in the synthesized evidence. Another limitation is the absence of a described risk-of-bias assessment, which restricts evaluation of the included studies' quality and weakens confidence in the review's conclusions.

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 was considered to be favorable and showed that Hydrus implantation is safe

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

and effective in normalizing IOP in individuals with OAG up to the 5-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 (SLT), 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 that compare Hydrus with other OAG microstents and glaucoma surgery would be useful.

Glaucoma Drainage Devices

EX-PRESS

Inatani et al. (2026) conducted a 3-year prospective, observational surveillance study in daily clinical settings across Japan to evaluate the safety and efficacy of the EX-PRESS Glaucoma Filtration Device. Participants with glaucoma who had insufficient IOPR despite medication, laser therapy, or prior glaucoma surgery were included, while those with uveitis, ocular infections, severe dry eye, blepharitis, angle-closure glaucoma, or metal allergy were excluded. Overall, 890 eyes in 835 participants were enrolled from 52 institutions, with 824 eyes analyzed for safety and 821 eyes analyzed for efficacy; the mean age was 68.4 years, and 58.0% of participants were male. EX-PRESS filtration surgery was performed using either fornix-based or limbus-based conjunctival incisions, and IOP, medication use, and endothelial cell density were measured up to 36 months. The primary end point was IOP change, which decreased from 25.0 ±9.1 mm Hg at baseline to 14.5 ±5.8 mm Hg at 36 months ($p < 0.001$), with at least a 20% reduction achieved in 78% or more of eyes and success rates of 31.2% without medication and 64.6% with medication by Kaplan-Meier analysis. The mean number of glaucoma medications decreased from 3.5 ±1.4 to 1.7 ±1.7 at 36 months ($p < 0.001$) and mean endothelial cell density declined by -8.2% ±22.5% but remained above 2,000 cells/mm². The prespecified secondary end points included endothelial cell density and AE incidence. The authors concluded that the study demonstrated a significant reduction in postoperative IOP and glaucoma medications, with an acceptable safety profile, which confirmed the clinical benefits and safety of EX-PRESS in Japanese participants with glaucoma. There were downsides to the intervention, including adverse events and device malfunction, relatively lower success rates in exfoliative glaucoma and a high incidence of device-iris touch, which may affect long-term outcomes and indicate anatomical influences on surgical performance. Limitations include the absence of a control group, which restricts causal interpretation of safety and efficacy results. Data quality was limited because visual field and fundus photograph data were not analyzed due to inconsistent testing equipment, lack of standardized methods, and poor image quality. Further limitations include failure to assess whether EX-PRESS filtration surgery reduced visual field loss progression and failure to analyze the relationship between implantation site and AEs.

Otsuka et al. (2024) conducted a retrospective single-facility study that analyzed consecutive patients who had POAG, had a preoperative IOP of ≤ 21 mm Hg, underwent trabeculectomy or EX-PRESS surgery, and were followed up for more than 3 years. Patients with other glaucoma types, prior conventional trabeculectomy, or a preoperative IOP of > 22 mm Hg were excluded, while those with prior cataract surgery, trabeculotomy, SLT, or vitrectomy were included. Overall, 75 eyes were analyzed, with 39 eyes in the trabeculectomy group and 36 eyes in the EX-PRESS group; the mean age was 65.8 ±9.8 and 64.2 ±11.4 years, respectively. Corneal endothelial cell density was measured using an EM-3000 specular microscope prior to the operation and every 12 months post operation, and the survival ratio was defined as postoperative divided by preoperative cell density. A statistical analysis used paired t tests with significance set at a p value of < 0.05. At 36 months, the survival ratio of corneal endothelial cells was 88.5% ±14.2% in the trabeculectomy group and 95.6% ±11.1% in the EX-PRESS group ($p = 0.037$), indicating significantly less endothelial cell loss with EX-PRESS surgery. The prespecified secondary end points included IOP and number of glaucoma medications. The authors concluded that compared with trabeculectomy, EX-PRESS surgery appears to be a safer surgical method regarding the risk of endothelial cell loss and that both procedures significantly decreased IOP, with equivalent postoperative results. There are limitations, including a small sample size that may have reduced the ability to evaluate corneal endothelial cell density loss and lack of randomization. Measurement limitations include variation in the exact central corneal site used for assessment and the reliance on a single measurement rather than repeated averaging, both of which may have introduced error. An additional limitation is the lack of consideration of potential confounding factors that could have influenced the findings.

Tokumo et al. (2023) conducted an open-label, randomized, single-center clinical trial at Hiroshima University Hospital that compared EX-PRESS implantation and trabeculectomy with mitomycin C in Japanese participants with OAG. Eligible participants were aged over 20 years, had an IOP of ≥ 15 mm Hg, and had no prior glaucoma surgery; 73 eyes (30 EX-PRESS; 43 trabeculectomy) were analyzed after exclusions. The primary end point, surgical success, was defined as achievement of target IOP ranges of 5 to 18, 5 to 15, or 5 to 12 mm Hg, with at least a 20% reduction from baseline at two consecutive visits, with or without medication and without further glaucoma surgery. The mean IOP decreased significantly in both groups at 3 years (EX-PRESS: 20.4 ±4.9 to 13.2 ±1.9 mm Hg, $p = 0.001$; trabeculectomy: 21.9 ±7.9 to 13.5 ±5.0 mm Hg, $p = 0.0012$), with no significant between-group differences ($p = 0.93$, 0.53, and 0.58 for criteria A to C). Three-year success rates were 60.0% vs 60.2% (criterion A), 45.7% vs 58.1% (criterion B), and 31.5% vs 40.5% (criterion

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

C) with EX-PRESS and trabeculectomy, respectively. The number of preoperative glaucoma medications was identified as a risk factor for trabeculectomy failure. The secondary end points included visual acuity and postoperative complications. The authors concluded that both EX-PRESS and trabeculectomy achieved similar IOPRs and surgical success rates, with no significant differences in visual acuity or failure rates, while the number of glaucoma medications was a risk factor for trabeculectomy failure. Key limitations include group imbalance and a relatively small sample size due to the exclusion of participants with a preoperative IOP below 15 mm Hg after randomization. There are limitations related to follow-up, as the 3-year duration led to an increased number of dropouts and may not capture the lifelong course of glaucoma requiring extended observation.

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 were published up to November 2018 were included. IOPR and antiglaucoma medication reduction were considered continuous variables, with the MD measured. Complications, postoperative success, and intervention were considered dichotomous variables measured as the OR. Complete success was defined as target end point IOP without antiglaucoma medication, while qualified success was defined as target end point IOP with or without antiglaucoma medication. All outcomes were reported with a 95% CI. Data were pooled using a random-effects model. Overall, eight 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 percentage at 12 months post operation compared with trabeculectomy. There was no difference in the antiglaucoma medication reduction and qualified success between the groups. Complete success at 1 year post operation 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 in individuals with OAG, EX-PRESS implantation provided better efficacy in IOP control and complete success at 1 year post operation, with fewer individuals with increased IOP and hyphema as well as fewer individuals requiring postoperative interventions. The EX-PRESS device and trabeculectomy were similar in the qualified success and antiglaucoma medication reduction. Key limitations include the heterogeneity arising from differences in follow-up duration, mitomycin C concentration, and exposure time as well as ununified definitions of success rate and variable study quality. There are limitations related to measurement and operator factors, as surgeons' experience was difficult to assess and may have contributed to variability among studies. Statistical limitations include unstable sensitivity analyses and incomplete evaluation at certain time points because only one trial provided data, leaving long-term efficacy beyond 3 years uncertain. Publication bias could not be excluded, as few studies were registered and trials with negative results may have been underrepresented; the inclusion of mixed OAG types further limited generalizability.

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 < or = 18 mmHg without the use of antiglaucoma medications. A more stringent target of IOP > 4 mmHg and < or = 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 < or = 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 the 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.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

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

Myers et al. (2023) conducted a retrospective cohort study at a tertiary eye hospital that included eyes that were undergoing first tube shunt surgery between 2005 and 2011, with at least 10 years of follow-up. Eligible adults without prior tube shunt surgery and with complete preoperative data contributed 85 eyes (in 78 patients) in the study group and 26 eyes in a comparison group, with a mean age of 60.6 years; 59% of patients were female, and the baseline IOP was 29.2 ±10.4 mm Hg on 3.1 ±1.2 medications. The primary end point was 10-year Snellen visual acuity change from baseline, with a mean BCVA worsening from 0.8 ±0.7 logMAR (20/125) to 1.3 ±0.9 logMAR (20/400) at 10 years ($p \leq 0.001$). The mean IOP decreased to 12.6 ±5.8 mm Hg on 2.2 ±1.4 medications ($p < 0.001$), and 56% of eyes met failure criteria, including 34% that required reoperation and 10% that progressed to no light perception. Statistical analyses used t tests, Wilcoxon rank sum or signed rank tests, chi-square or Fisher exact tests, and regression models to identify predictors of 10-year failure. The prespecified secondary end points included visual field mean deviation and IOP-lowering medication use. The authors concluded that 10 years after tube shunt surgery, approximately half of all eyes maintained control of IOP; however, approximately one in three required additional glaucoma surgery, and nearly 40% lost five or more lines of visual acuity, which indicates that tube shunt surgery is effective in long-term IOP control but that subsequent vision loss and need for additional surgeries are common. Key limitations include the retrospective design with a 10-year follow-up, which may have selected for eyes that required additional surgery, and the conduct of the study in a tertiary care center, which likely involved more severe disease and reduced generalizability to other clinical settings. There are limitations in data quality, including the influence of cataract surgery on visual outcomes, incomplete baseline visual field data, and exclusion of eyes with severe vision loss that could bias results toward better outcomes. Additional limitations involve incomplete follow-up in approximately half of the comparison group and the inherent challenges of maintaining long-term retention, as seen even in prospective studies that have substantial loss to follow-up over time. Differences in revision rates may reflect variations in prior surgical history and ocular complexity between cohorts, the predominance of tube shunt erosions in eyes with conjunctival scarring, and the longer follow-up period that could influence reported revision frequencies.

Luo et al. (2023) conducted a systematic review and meta-analysis to compare the efficacy and safety of tube shunt implantation with those of trabeculectomy in the treatment of individuals with glaucoma. A systematic literature search was performed for studies that compared tube with trabeculectomy in individuals with glaucoma. Comparisons between tube and trabeculectomy were grouped by the type of tube (Ahmed, Baerveldt, EX-PRESS, and XEN). The primary end points included IOP, IOPR, IOPR percentage, complete success rate, qualified success rate, and AEs. Overall, 49 studies were included in this meta-analysis, and data were presented for 3,795 eyes (Ahmed: 670; Baerveldt: 561; EX-PRESS: 473; XEN: 199; trabeculectomy: 1,892). Ahmed and EX-PRESS were comparable to trabeculectomy in terms of IOP outcomes and success rate [Ahmed vs trabeculectomy IOPR percentage: MD, 1.34 (-5.35, 8.02), $p = 0.69$; EX-PRESS vs trabeculectomy IOPR percentage: MD, 0.12 (-3.07, 3.31), $p = 0.94$]. The IOP outcomes with Baerveldt were worse than those with trabeculectomy [IOPR percentage: MD, -7.51 (-10.68, -4.35); $p < 0.00001$], but the qualified success rate was higher. No difference was shown for the complete success rate. XEN was worse than trabeculectomy in terms of IOP outcomes [IOPR percentage: 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 with 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 that were similar to those with trabeculectomy. This systematic review and meta-analysis had limitations. Most of the studies were not RCTs. Instead, they were nonrandomized, 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 that includes RCTs is needed to validate these findings. (De Jong et al. 2011, and Islamaj et al. 2020, cited in this policy is included in this review)

Raja et al. (2023) conducted a meta-analysis that compared the Molteno glaucoma implant (MGI) and the Ahmed Glaucoma Valve (AGV) in individuals with refractory, neovascular, or advanced uncontrolled glaucoma. Four studies were included, including two retrospective cohorts, one case control, and one RCT, comprising 257 individuals (130 MGI; 127 AGV), with mean ages of 63.2 and 62 years, respectively; follow-up ranged from 20 to 41.9 months. Studies were eligible if they compared AGV with MGI and reported IOPR, implant success rate, hypertensive phase, or antiglaucoma medication reduction. The primary outcome was postoperative IOP measured at 3 months, 6 months, 1 year, 2 years, and 3 years, analyzed using random-effects models with MD and 95% CIs. The pooled MD in IOP across all intervals was

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

-1.34 mm Hg (95% CI, -2.78 to 0.09 mm Hg; p = 0.07), showing no significant difference overall, although at 2 years, MGI achieved significantly lower IOP (MD, -2.12; 95% CI, -4.23 to -0.01; p = 0.05). The prespecified secondary end points included surgical success rate, hypertensive phase, antiglaucoma medication use, and total complications. The authors concluded that no significant difference was seen in IOP between the Molteno and Ahmed implants overall; however, at the 2-year interval, the Molteno implant was more effective at controlling IOP, both implants successfully lowered IOP, AGV was associated with fewer postoperative complications and a lower need for antiglaucoma medications, and overall success rates were comparable. There are limitations, including the inclusion of only one RCT, which reflects the scarcity of relevant trials and may introduce selection bias. Key limitations also involve incomplete reporting of baseline characteristics such as glaucoma severity and the lack of consideration of individuals' comorbidities that could influence surgical outcomes. Additional limitations include the short follow-up duration that restricts long-term insight, and failure to account for individual patient characteristics, all of which affect generalizability.

Islamaj et al. (2020) conducted an RCT to compare Baerveldt glaucoma implant (BGI) surgery and trabeculectomy in participants without previous ocular surgery. The inclusion criteria were age 18 to 75 years, POAG, normal-tension glaucoma, PEX glaucoma or pigmentary glaucoma, and the need for IOP-lowering surgery. Participants with a history of any ocular surgery, such as trabeculectomy, 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 (e.g., cataract surgery), narrow anterior chamber angle interfering with tube implantation, BCVA of < 0.1 in the study eye or fellow eye, and history of ocular motility disturbances. The primary outcomes were IOP and failure rate. The secondary outcomes were medication, anterior chamber laser flare value, and complications. Overall, 119 participants with glaucoma were included in the trial (60 participants received trabeculectomy surgery, and 59 received BGI). After 5 years, an IOP of 12.7 ±3.9 mm Hg (mean ±SD) was achieved in the trabeculectomy group and 12.9 ±3.9 mm Hg in the BGI group. There was no difference in the failure rate between the groups (p = 0.72). More BGI participants needed additional medication to control their IOP (85%; 1.9 ±1.2 types of glaucoma medication) compared with the trabeculectomy participants (57%; 0.5 ±0.9 types of glaucoma medication). Diplopia was significantly more present in the BGI group than in the trabeculectomy group (27% vs 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 trabeculectomy and BGI surgery and that the need for additional medication after BGI surgery is higher than that after trabeculectomy. They also stated that the increased risk of developing diplopia after BGI surgery must be taken into consideration. There are limitations, including the single-center and single-surgeon design, which may limit generalizability and result in relatively uniform surgical procedures.

XEN Glaucoma Treatment System

Hubayni et al. (2026) conducted a systematic review and meta-analysis that compared the efficacy and safety of ab externo vs ab interno XEN45 Gel Stent implantation for glaucoma management. Studies were included if they enrolled adults with POAG or SOAG and reported baseline and postoperative IOP and medication use, while those with incomplete data or prior filtering surgery were excluded. Six retrospective studies that comprised 596 individuals (614 eyes) were analyzed, with 318 treated using the ab externo approach and 278 using the ab interno approach. Meta-analyses were conducted using a random-effects REML model in Stata, pooling standardized MDs for IOP and medication outcomes at 12 months. The pooled standardized MD for IOP was -12.8 (95% CI, -19.4 to -6.2) for ab externo and -10.1 (95% CI, -16.3 to -3.8) for ab interno, with no significant difference between groups (p = 0.56). Reduction in IOP-lowering medications was also significant and similar between groups, with a standardized MD of -2.2 (95% CI, -2.6 to -1.9) for ab externo and -2.1 (95% CI, -2.5 to -1.7) for ab interno (p = 0.56). The prespecified secondary end points included AEs such as needling rate, corneal edema, hypotony, hyphema, and choroidal effusion. The authors concluded that both ab externo and ab interno XEN45 Gel Stent implantation techniques demonstrated comparable efficacy and safety in lowering IOP and reducing dependence on IOP-lowering medications, with the ab externo approach associated with a lower needling rate and fewer bleb-related complications. Key limitations include the retrospective design of all included studies, which restricts the ability to infer causality. There are limitations related to measurement consistency, as variability and deficiencies in follow-up duration reduced comparability of IOP outcomes across time points. (Tan et al. 2021, cited in this policy is included in this review)

Martínez-de-la-Casa et al. (2026) conducted a prospective, multicenter, open-label study that evaluated the XEN63 Gel Stent implanted alone or combined with phacoemulsification in 85 eyes with medically uncontrolled POAG over 36 months. Eligible adults had early to moderate disease with IOP of up to 33 mm Hg on one to four medications and met specific anatomical and ocular health criteria. Participants were divided into XEN63 stand-alone (n = 46) and XEN63 plus phacoemulsification (n = 39) groups, with procedures performed ab interno under local anesthesia and mitomycin C injection. The primary end point was the cumulative probability of complete surgical success at 36 months, which was defined as IOP between 6 and 18 mm Hg, with at least a 20% reduction from baseline without ocular hypotensive medications, analyzed using Kaplan-Meier survival methods. At 36 months, the overall surgical success was 67.1% (95% CI, 50.8%-86.9%), complete success was 45.9% (95% CI, 32.6%-62.7%), and the difference between the stand-alone

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

and combined groups was not significant for complete success (p = 0.7739). The mean IOP decreased from 21.3 ±4.7 mm Hg to 14.3 ±4.3 mm Hg (p < 0.0001), and the mean number of medications declined from 2.3 ±0.8 to 0.7 ±1.0 (p < 0.0001). The prespecified secondary end points included overall surgical success rate, mean change in IOP, reduction in ocular hypotensive medications, predictive factors for success, and incidence of AEs. The authors concluded that XEN63 implantation provided sustained IOPR and significant medication sparing over 36 months, with similar long-term outcomes between stand-alone and combined procedures and an acceptable safety profile; this supports XEN63 as an effective and durable surgical option for long-term IOP control in appropriately selected participants. There are limitations, including the nonrandomized open-label design and the absence of a control group, although outcome assessment was masked. Key limitations include baseline IOP differences between treatment groups, even though statistical adjustment using analysis of covariance was applied to reduce potential bias. The study has limitations related to a 30% attrition rate at 3 years and the reduced sample size at 36 months, which constrain interpretation of per-protocol outcomes. Generalizability is limited because the cohort consisted exclusively of Caucasian participants with POAG.

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 indicates favorable results that suggest that XEN Gel Stent implants successfully lower IOP to clinically normal levels in most individuals. The effect may last for up to 5 years, but most studies reported only to 12 or 24 months. These studies had a high risk of bias because most were retrospective. In studies that compare XEN with trabeculectomy (one systematic review, one RCT, and four retrospective comparison studies), both treatments were effective, with trabeculectomy 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 trabeculectomy 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 comparison studies compared XEN and trabeculectomy. The remaining six studies were single-arm (five retrospective and one prospective) pre-post studies, with more than 100 individuals, and published between 2024 and 2025. No studies compared XEN with other tube stent devices.

Gan et al. (2024) conducted a systematic review to summarize the complications and their management associated with XEN45 gel stent implantation. The review followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and MOOSE (Meta-Analysis of Observational Studies in Epidemiology) guidelines and searched MEDLINE, Embase, the Cochrane Library, and China National Knowledge Infrastructure from inception to February 1, 2024. The eligible studies included prospective or retrospective cohort studies, case reports, case series, or letters to the editor that reported postoperative complications of XEN45 implantation, excluding animal studies, incomplete reports, and studies that involved XEN63 or XEN140 devices. Overall, 48 studies that were published between 2017 and 2024 were included, comprising 16 original studies, 28 case reports, and four case series, with follow-up up to 5 years. The primary outcomes were the incidence and types of postoperative complications, with early complications that included hypotony maculopathy (1.9%-4.6%), occlusion (3.9%-8.8%), choroidal detachment (0%-15%), conjunctival erosion and exposure (1.1%-2.3%), wound and bleb leaks (2.1%), and malignant glaucoma (2.2%). Mid-postoperative complications included migration (1.5%), ptosis (1.2%), endophthalmitis (0.4%-3%), macular edema (1.5%-4.3%), hypertrophic bleb (8.8%), and subconjunctival stent fragmentation; late complications included spontaneous dislocation and intraocular degradation. The authors concluded that XEN Gel Stent implantation is a minimally invasive glaucoma surgery that can minimize tissue damage and reduce surgical duration but carries risks of severe complications such as endophthalmitis, suprachoroidal hemorrhage, and malignant glaucoma, emphasizing the importance of postoperative follow-up and early recognition of severe complications for surgical management. Key limitations include the absence of a formal quality or risk-of-bias assessment, which prevents evaluation of internal validity and allows low-quality evidence to influence pooled conclusions. There are limitations in data handling, as no standardized synthesis or meta-analytic pooling was described, leaving complication rates unstandardized and summary estimates potentially misleading. The study has limitations related to design heterogeneity, including the inclusion of case reports and series alongside clinical studies, which introduces selection bias and reduces generalizability. Combining prospective and retrospective cohorts with case reports and series without stratified analysis further undermines comparability and inflates bias in complication rate estimates.

Chen et al. (2022) conducted a systematic review on XEN Gel Stents used in the treatment of OAG. Overall, 56 studies that were published between September 2015 and December 2021 were included in the analysis, and none of them were RCTs. The authors found that the XEN Gel Stent lowered IOP by approximately 35% to a final average of 15 mm Hg. In addition, the number of antiglaucoma medications also showed a significant decrease. The authors concluded that 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 individuals in the analysis were Caucasian. The publication is limited by only reporting findings based on before-after measurements, without comparison to groups that received different treatments. This systematic review included the following studies, which are summarized below: Tan et al. (2021), Rauchegger et al. (2021), and De Gregorio et al. (2018).

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

A Hayes Technology Assessment (2019; updated April 2023) on the XEN Glaucoma Treatment System for the treatment of OAG identified seven 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 in individuals with POAG and individuals with PEX glaucoma; and one study assessed the use of medication between individuals with prior glaucoma surgery and individuals 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 in participants with POAG; 23 of these participants had PEX glaucoma. The primary outcome of the study was mean reduction in IOP, along with a decrease in medication usage. Participants were evaluated prior to the operation and day 1 post operation, in addition to evaluations at 1 week and then every month up to 2 years. Overall, 28% of the participants completed postoperative visits through the 24-month follow-up. Needling was documented in 62% of the participants as an additional postoperative treatment to improve aqueous flow and lower IOP. In total, 13 eyes needed a glaucoma-related secondary surgical intervention and were considered complete surgical failures. The most common AE was hyphema, which occurred in five participants and self-resolved within 7 days. The authors saw a meaningful drop in IOP from 23.4 ±7.9 mm Hg prior to the operation to 14.6 ±3.6 mm Hg at month 12 and 14.8 ±4.4 mm Hg at month 24 post operation. The results suggest that the XEN Gel Stent significantly reduces the individual'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 participants being seen at 24 months; however, the authors contributed this to the number of participants who 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 50 eyes that underwent the ab interno placement and 30 eyes that underwent the ab externo placement. The cohort that received the ab interno procedure had a mean IOPR of 8.4 ±1.7 mm Hg by 12 months; the ab externo group underwent a mean reduction of 12.8 ±3.0 mm Hg. The average medication 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 that there were no differences in outcomes between the two procedures and the insertion of the XEN Gel Stent. Limitations include the retrospective review, lack of comparison group receiving treatments other than the XEN Gel Stent, small sample size, lack of long-term data beyond 1 year, and differences in technique proficiency among 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 individuals with chronic OAG. Using predetermined search terms, a systematic review was performed using PubMed. Overall, eight case series or cohort studies (six prospective and two retrospective) that were published between 2016 and 2018 were included. There were no RCTs included. Data were analyzed for 777 individuals or 958 eyes. The various studies showed a mean IOP at 12 months of between 13 and 16 mm Hg, which represented an IOPR of 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 with XEN implantation as a stand-alone procedure (44%) than with 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 anterior chamber (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 a cyclodestructive procedure. The authors concluded that the XEN Gel Stent appears effective for reducing IOP and the number of medications in individuals with OAG within 1 year post operation, 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. There are limitations, including that the analysis relied on comparisons of previously published studies rather than a randomized comparative trial between the two techniques. Key limitations include the heterogeneity in both individuals' characteristics and procedural approaches. The study is also limited by the absence of long-term efficacy data for the XEN stent due to its recent market introduction.

De Gregorio et al. (2018) conducted a nonrandomized, prospective clinical study to assess the safety and efficacy of the XEN45 Gel Stent when combined with microincisional cataract surgery. Overall, 41 eyes in 33 participants with OAG underwent the combination surgery, and there were no major intra- or postoperative complications noted. Complete success was achieved in 80.4%, and a qualified success was reported in 97.5% after 12 months of follow-up. The authors concluded that the XEN45 gel implant is statistically effective in reducing IOP and medication use, with minimal complications in participants with glaucoma. The findings are limited by the lack of a comparison group. This study was included in the Buffault et al. (2019) study.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Laser Trabeculoplasty

So et al. (2026) conducted a systematic review and meta-analysis of RCTs that compared SLT and medication treatments in adult patients with OAG. Eligible studies enrolled adults with OAG who were receiving SLT-related therapy and excluded pediatric, normotensive, or angle-closure glaucoma populations. The review included 16 RCTs, with 2,412 individuals from multiple countries; mean ages ranged from approximately 52 to 70 years, with a baseline IOP of between 15.2 and 29.3 mm Hg. Interventions were categorized as SLT only and SLT plus medication, and random-effects DerSimonian-Laird meta-analyses were performed using standardized MDs with 95% CIs. The primary outcome was IOPR, which showed significant improvement with SLT at 52 weeks or longer (standardized MD, 1.91; 95% CI, 1.55-2.27; $p = 0.01$) and with combination therapy at 26 weeks (standardized MD, 0.78; 95% CI, 0.56-1.01; $p < 0.01$). The number of medications used was also significantly reduced in the combination group (standardized MD, 0.78; 95% CI, 0.56-1.01; $p < 0.01$), while no significant change occurred in the medication-only group (standardized MD, -0.01; 95% CI, -0.23 to 0.21; $p = 0.93$). The prespecified secondary end points included quality of life and adverse ocular events. The authors concluded that long-term IOPR was greater with SLT than medication; SLT significantly reduced the number of medications used; and quality of life was similar between SLT and medication treatments, with SLT offering the advantage of requiring minimal patient action beyond follow-up appointments. There are limitations, including high heterogeneity in the SLT and medication groups, which may introduce variability and reduce confidence in the pooled findings. The strength of evidence for the number of medications outcome was only moderate because few RCTs were available. Measurement limitations were present, as differing quality-of-life scales prevented a consistent meta-analysis.

Chen et al. (2025) conducted a systematic review and meta-analysis that evaluated the long-term efficacy and safety of SLT in adult individuals with POAG and followed PRISMA 2020 and MOOSE guidelines. Eligible studies included RCTs and observational cohorts that had at least 12 months of follow-up in adults who were diagnosed with POAG, excluding secondary glaucoma and non-SLT interventions. Overall, 60 clinical studies met the inclusion criteria, with 50 contributing to meta-analysis and a pooled sample of 8,934 eyes, analyzed using random-effects models and I^2 statistics to quantify heterogeneity. The primary outcomes were long-term IOPR and SLT failure rates, as measured by standard tonometry methods, with a pooled MD of 0.04 mm Hg (95% CI, -0.27 to 0.34 mm Hg) showing equivalence to medical therapy. SLT significantly reduced medication use by 0.87 medications (95% CI, -1.13 to -0.62) and improved the visual field mean deviation by 0.79 dB (95% CI, 0.76-0.82 dB). The prespecified secondary end points included medication use, visual field changes, and AEs. The authors concluded that SLT maintained IOP, reduced medication burden, preserved visual function, and demonstrated a favorable safety profile, all of which support its use as an effective primary treatment strategy for POAG. There are limitations, including heterogeneity in SLT protocols, treatment angles, and energy parameters, which introduced variability in outcome interpretation. Key limitations include differences in baseline IOP and disease severity as well as inconsistent re-treatment criteria and definitions of failure across studies. Some studies exhibited a moderate to high risk of bias in outcome measurement and reporting, and variability in reporting standards persisted despite generally high methodological quality. Although a random-effects model addressed statistical heterogeneity, clinical variability remained, and several trials had incomplete datasets or lacked long-term documentation of re-treatment and AEs.

Gazzard et al. (2025) conducted a prospective, multicenter, randomized controlled, evaluator-masked noninferiority trial that compared image-guided direct SLT (DSLT) with conventional SLT for IOPR in participants with OAG or ocular hypertension. Eligible participants were aged 40 years or older with an IOP between 22 and 35 mm Hg after medication washout, visual acuity of better than 6/60, and no secondary glaucoma other than exfoliative or pigmentary types. Of 276 screened, 201 were randomized (102 DSLT; 99 SLT), 192 were treated, and 156 (81.3%) were included in the 6-month modified per-protocol analysis. The primary end point was the between-group difference in mean washout IOP change from baseline to 6 months, which was analyzed by analysis of covariance adjusted for baseline IOP and β-blocker use, with a noninferiority margin of -1.95 mm Hg; the mean washout IOPR was 5.5 ±0.5 mm Hg with DSLT and 6.2 ±0.5 mm Hg with SLT, showing a difference of -0.7 mm Hg (95% CI, -2.2 to 0.8 mm Hg; $p = 0.09$), and did not meet noninferiority. At 12 months, the mean nonwashout IOPR was 3.2 ±0.4 mm Hg in both groups (difference, 0.01 mm Hg; 95% CI, -1.1 to 1.1 mm Hg; $p < 0.001$ for noninferiority). The prespecified secondary end points included the proportion of participants with more than 20% washout IOPR at 6 months and change in the number of topical hypotensive medications from screening to 6 months. The authors concluded that although DSLT did not meet noninferiority to SLT at 6 months, it achieved sustained IOPR for 12 months, with similar safety, except for mild punctate subconjunctival hemorrhage; this supports DSLT as a convenient and accessible alternative and potential first-line treatment option for glaucoma. Key limitations include the hierarchical testing strategy that restricted a formal claim of noninferiority for medication reduction at 6 months and the larger-than-anticipated variability in baseline IOP measurements that may have affected statistical power. There are limitations related to the study design, including the introduction of an updated DSLT device with a minor reduction in laser pulse duration, although image processing algorithms and laser performance specifications remained unchanged. Generalizability is limited because the trial was conducted at four European sites that enrolled predominantly White participants, which may not represent the broader glaucoma population. Follow-up was limited to 6 months for ocular safety events, which restricted assessment of longer-term outcomes.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Bengtsson et al. (2024) conducted a randomized controlled, open-label, two-center clinical trial that enrolled 242 participants who were aged 40 to 78 years and had newly detected, untreated, early or moderate OAG at two Swedish university hospitals. Eligible participants had primary open-angle or PEX glaucoma, with a visual field index (VFI) of ≥ 65%, and were randomized 1:1 to either initial intensive IOP-lowering therapy using three drug classes plus 360° laser trabeculoplasty or to conventional stepwise monotherapy escalation. Participants were followed up for 5 years, and analyses were conducted according to the intention-to-treat principle. The primary outcome was predicted remaining visual field that was measured by the VFI at projected end of life, with progression defined as at least three deteriorated test points in three consecutive visual field tests. The median end-of-life VFI was 79.3% in the monotreatment group and 87.1% in the multitreatment group (p = 0.15), and the median rate of visual field progression was -0.65% per year vs -0.25% per year (95% CI, -6.76 to 1.64 and -7.57 to 1.60; p = 0.09). Definite progression occurred in 21% of monotreatment and 11% of multitreatment participants (p = 0.03). The prespecified secondary outcomes included visual acuity, IOP and its reduction, adherence, adverse and serious AEs, number of glaucoma-related visits, vision-related quality of life, and ocular surface disease signs. The authors concluded that multitreatment had a clearly favorable effect, particularly in participants with higher pretreatment IOP, while escalating monotherapy was equally effective in those with a lower baseline IOP. Key limitations include the imposition of a minimum baseline VFI value for inclusion, which excluded participants with a baseline VFI of below 65%. There are limitations related to generalizability, as nearly all participants were European, and the findings may not extend to non-European populations. Another limitation is the projection of end-of-life visual field damage based only on 5 years of follow-up data.

Chavez et al. (2024) conducted a systematic review and meta-analysis of RCTs that compared SLT with medical therapy for OAG or ocular hypertension. Eligible studies enrolled individuals with OAG or ocular hypertension, whether treatment naive or previously treated, and reported at least one relevant outcome. Overall, 14 trials that included 1,706 individuals were analyzed, with 936 receiving SLT; the mean age ranged from 47.8 to 68.1 years, and the baseline IOP ranged from 13.3 to 29.3 mm Hg. The primary end point was IOP, which was analyzed using MDs or standardized MDs with 95% CIs under random-effects models. At 1 month, medical therapy showed significantly lower IOP than SLT (MD, 1.62 mm Hg; 95% CI, 0.23-3.01 mm Hg; p = 0.02), while no significant differences were observed at 2 to 12 months; after 5 years, SLT had a higher IOP (MD, 0.88 mm Hg; 95% CI, 0.42-1.35 mm Hg; p < 0.01). The prespecified secondary end points included ≥ 20% IOPR, proportion of eyes at target IOP, IOP fluctuation, visual field mean deviation, Assessment of Quality of Life-7D, Glaucoma Quality of Life-15, number of medications, adverse effects, and ocular adverse effects. The authors concluded that SLT demonstrated comparable efficacy to medical therapy in IOP control at most follow-ups and showed favorable impacts on treatment-related factors, which supports SLT as a safe and effective treatment for OAG or ocular hypertension. Key limitations include the substantial heterogeneity among the included trials, which reduces the reliability and interpretability of pooled effect estimates. There are limitations related to the study design, as randomization by eye rather than by individual in two trials introduced unit-of-analysis error and potential bias in treatment precision. A further limitation is the conversion of medians and ranges to means and SDs, which assumes normality and may distort skewed outcome distributions. Incomplete reporting of methodological details limited assessment of randomization and masking, which constrained evaluation of internal validity and reproducibility.

Gazzard et al. (2023) conducted the LIGHT trial on the clinical effectiveness of SLT compared with that of IOP-lowering eye drops after 6 years of treatment for OAG and ocular hypertension. Participants were allocated randomly to initial SLT or eye drops. The study included 629 participants who completed 3 years (91.5%) and 524 participants who completed 6 years in the trial extension (82.8%). The results demonstrated that at 6 years in 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 had disease progression (26.8% vs 19.6%, respectively; p = 0.006). The authors concluded that SLT is a safe treatment for OAG and ocular hypertension and provides better long-term disease control than drop therapy. The trial limitations were where no washout was performed, and a proportion of eyes was receiving IOP-lowering topical medical treatment. Success rates with SLT have been published using various definitions and success rates.

Laser Iridotomy/Iridectomy

Ji et al. (2025) conducted a systematic review and meta-analysis that evaluated progression of primary angle closure suspects (PACSs) to primary angle closure, acute angle closure (AAC), and primary angle closure glaucoma (PACG) and assessed the effect of prophylactic laser peripheral iridotomy (LPI) on disease progression. Studies were included if they investigated PACS progression to primary angle closure in at least five individuals, excluding nonoriginal and non-English reports; five studies, with 1,997 individuals from Southeast and East Asia, met the criteria. Primary angle closure was defined as the development of peripheral anterior synechiae and/or an IOP of greater than 21 mm Hg; PACS as normal IOP with at least 180° of appositional contact without synechiae or optic nerve abnormalities; PACG as glaucomatous optic neuropathy or visual field defects in eyes with primary angle closure; and AAC as acutely elevated IOP above 30 mm Hg with characteristic anterior segment findings. A random-effects meta-analysis that used the Mantel-Haenszel method estimated pooled risk ratios and 95% CIs comparing LPI vs no LPI. Overall, 14.2% of individuals experienced progression, and those without LPI had a 2.47-fold higher risk of progression to primary angle closure (risk ratio, 2.47;

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

95% CI, 1.50-4.07; p < 0.001; number needed to treat, 15), while effects on AAC (risk ratio, 3.33; 95% CI, 0.67-16.45; p = 0.14) and PACG (risk ratio, 2.20; 95% CI, 0.77-6.31; p = 0.89) were not statistically significant. The prespecified secondary outcomes included progression rates by LPI status, baseline characteristic comparisons in progressors, and LPI-associated AEs. The authors concluded that LPI appears to offer significant protection against the development of primary angle closure in individuals with PACSs, although its long-term clinical efficacy remains uncertain, and treatment decisions should balance potential benefits and risks. Key limitations include the lack of demonstrated clinical efficacy for the intervention and the wide variation in follow-up duration, which may have underestimated long-term disease progression and the effectiveness of LPI in shorter studies. There are limitations related to study design and sampling, including differing recruitment methods that may have led to overrepresentation of higher-risk individuals and small, underpowered subgroup samples with mixed ethnic data. Measurement and reporting limitations include stringent progression criteria that may have underestimated disease progression and insufficient documentation of AEs such as dysphotopsia and cataracts, limiting assessment of the safety profile. Generalizability is constrained by the geographic focus on Southeast and East Asia, the context-specific findings of the EAGLE trial, and its emphasis on more advanced disease stages rather than PACSs.

Sharif et al. (2024) conducted a systematic review and meta-analysis that compared phacoemulsification and LPI for treating PACG. RCTs that enrolled individuals with this condition were included, with phacoemulsification as the intervention and LPI as the comparator. Five trials that comprised 917 individuals (455 phacoemulsification; 462 LPI), with mean ages ranging from 65.1 to 72.3 years, were analyzed. Continuous outcomes such as IOP, visual acuity, visual field, corneal thickness, and endothelial cell density were analyzed using standardized MD, and dichotomous outcomes such as poor surgical response were analyzed using risk ratio under a random-effects model. Phacoemulsification showed significantly lower mean central corneal thickness (standardized MD, -1.10; 95% CI, -1.50 to -0.70; p < 0.001), lower central endothelial cell density (MD, -366.12; 95% CI, -652.59 to -79.65; p = 0.01), and lower risk of poor response to surgery (risk ratio, 0.35; 95% CI, 0.23-0.54; p < 0.001) than LPI, while no significant differences were found between the two procedures in IOP, number of medications, visual acuity, visual field, peripheral anterior synechiae, or Shaffer gonioscopy grading. The prespecified secondary end points included IOP, number of glaucoma medications, visual acuity, visual field progression, peripheral anterior synechiae, Shaffer gonioscopy grading, central corneal thickness, central endothelial cell density, and poor response to surgery. The authors concluded that phacoemulsification was associated with a significantly lower risk of poor surgical response and reductions in central corneal thickness and endothelial cell density compared with LPI, with no significant differences in other ocular parameters. There are limitations, including variation in follow-up periods among the RCTs and the limited availability of long-term follow-up data. Another limitation is the scarcity of evidence on cost-effectiveness, as only one RCT evaluated this outcome. The restriction to English-language RCTs further limits the comprehensiveness and generalizability of the review.

Baskaran et al. (2022) conducted a multicenter RCT to examine the efficacy of LPI in participants who received a diagnosis of PACS. The study enrolled 480 participants who were older than 50 years, had bilateral asymptomatic PACS, and were followed up yearly for 5 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 (defined as presence of peripheral anterior synechiae, IOP of > 21 mm Hg, or both or AAC) or PACG. The results demonstrated that eyes that were treated with LPI reached the end point less frequently after 5 years [n = 24 (5.0%); incidence rate, 11.65 per 1,000 eye-years] compared with control eyes [n = 45 (9.4%); incidence rate, 21.84 per 1,000 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, over 5 years compared with eyes that underwent prophylactic LPI. The study limitations include that baseline visual fields showed a low mean deviation and high pattern SD, increased participant dropout due to cataract surgery, and lack of masking for the intervention.

Laser Iridoplasty

Nguyen et al. (2023) conducted an RCT that compared combined laser iridoplasty followed by surgical iridectomy (LI-SI) vs trabeculectomy for medically unresponsive acute primary angle closure without significant cataract. Participants were recruited from three centers in Hanoi, Vietnam, between June 2017 and June 2019, with inclusion requiring uncontrolled IOP of ≥ 22 mm Hg despite maximal medical therapy for at least 3 days and Shaffer grade II for at least 180° on gonioscopy. Overall, 67 eyes in 67 participants (59 female; eight male; mean age, 57.67 years) were randomized to LI-SI (37 eyes) or trabeculectomy (30 eyes), and 35 and 27 eyes, respectively, completed 12 months of follow-up. The primary outcome was the rate of postoperative surgical complications within 3 months, analyzed using a Student t test and Fisher exact test; complications occurred in 45.9% of the LI-SI group and 33.3% of the trabeculectomy group (p = 0.23), and all resolved without sequelae. Complete success at 12 months (IOP < 21 mm Hg without drops) was achieved in 97.1% of LI-SI eyes and 92.6% of trabeculectomy eyes (p = 0.19). The prespecified secondary outcomes included IOPR, mean IOP, BCVA, and mean change in angle width at 1 year. The authors concluded that both LI-SI and trabeculectomy effectively treated medically unresponsive acute primary angle closure, without severe complications, although LI-SI was

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

associated with a higher rate of postoperative complications; comparable IOP results suggest that creating a filtration bleb may be unnecessary, with refractory cases managed effectively using less invasive procedures. Key limitations include the inability to mask the surgical treatment and a possible learning curve with surgical iridectomy that may have affected complication rates. There are measurement limitations, as corneal edema often made it difficult to accurately assess cataract severity, and the severity of complications could not be fully evaluated. Statistical limitations include a sample size that may have been insufficient to detect differences in IOP between groups. Generalizability is limited because all participants were Vietnamese, and adjunctive mitomycin C was not used in the trabeculectomy group due to its unavailability in Vietnam.

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, which was assessed by swept-source anterior segment optical coherence tomography (AS-OCT). Participants with primary angle closure disease following BCVA, IOP, anterior chamber gonioscopy, ultrasound biomicroscopy, optic disc optical coherence tomography (OCT), and visual field examinations were enrolled in this RCT. Overall, 32 participants (64 eyes), including two men and 30 women, with an average age of 61.80 ±9.79 years (range, 42-77 years), were enrolled and placed in one of four groups. The time of the last follow-up ranged from 6 months to 2 years. Each of the four study groups comprised eight participants (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 LPI. 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 2 years. The IOP in all enrolled participants decreased after surgery compared with 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 every two groups were compared, the high-energy/far-periphery group had 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 6 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 TIA. 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 participants 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.

Bayliss et al. (2021) conducted a Cochrane systematic review on the effectiveness of LPIp in the treatment of people with chronic angle closure, with comparison to LPI, medical therapy, or no further treatment. The study included four RCTs that involved 252 individuals (276 eyes) from various outpatient settings in the UK, Singapore, China, and Korea, with either PACS, primary angle closure, or PACG. The results that were 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 it is 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 the outcomes assessed. The authors stated that LPIp is currently used as a second-line treatment option in people with remaining appositional angle closure after LPI. All studies that were included in this assessment showed elements of a high risk of bias. Due to the nature of the intervention assessed, a lack of masking of both individuals and assessors was noted in all trials.

Laser Ciliary Destruction

Chen et al. (2019) conducted a Cochrane systematic review to assess the relative effectiveness and safety of cyclodestructive procedures compared with those of 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 quasirandomized trials with any laser type, route of administration, and laser settings were included. The primary comparison was any cyclodestructive procedure vs another glaucoma treatment, and the secondary comparisons were individual cyclodestructive procedures vs another cyclodestructive procedure. The study included five trials that reported

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

data for 330 eyes (326 individuals). The results demonstrated that 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, the median IOP was reported to be similar between the two groups at all time points. Two studies compared cyclophotocoagulation using a semiconductor diode vs an Nd:YAG laser. At 12 months post intervention, the mean deviation in IOP was 1.02 mm Hg (95% CI, -1.49 to 3.53 mm Hg) in one study. The second study did not report mean IOP beyond 3 months of follow-up. Lastly, one study compared different energy settings of the same Nd:YAG laser. At the 12-month follow-up, visual acuity was unchanged or improved in 21 of 33 individuals in the 8J group and 20 of 27 individuals in the 4J group (risk ratio, 0.86; 95% CI, 0.61-1.21). A 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 AEs across all five studies were hypotony and phthisis bulbi. Large, well-designed RCTs are needed. The studies that were 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 that compared cyclodestructive procedures with medical management were included.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

In the Preferred Practice Pattern guideline that addresses POAG (Gedde et al., 2026), the AAO states that 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. The current literature shows laser trabeculoplasty to be safe and efficacious.

The AAO's technical assessment (Takusagawa et al., 2024) on SLT states that SLT is an effective treatment option, with minimal safety concerns, for IOP control in patients with ocular hypertension, POAG, pigmentary glaucoma, PEX glaucoma, or JOAG. The assessment also states that SLT is equivalent to glaucoma medications for IOP control as firs-line treatment for POAG and ocular hypertension and that it may provide better long-term disease control than medications. In patients with POAG that is well controlled with medications, the AAO found that SLT can decrease or completely replace medications that are needed for IOP control; however, SLT does not seem to result in measurable quality-of-life improvement.

Cyclodestructive procedures have traditionally been used for refractory glaucoma, 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 primary angle closure. The literature demonstrated that 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 primary angle closure and acute primary angle closure eyes and most PACG eyes receive further treatment. Progression to PACG is uncommon in PACS and primary angle closure. There are limited data on the comparative efficacy of LPI vs that of other treatments for the various stages of angle closure.

Canaloplasty (Ab Interno)

Wong et al. (2026) conducted a systematic review and meta-analysis comparing the efficacy of standalone ab-interno canaloplasty (ABiC) versus ABiC combined with phacoemulsification (ABiC+Phaco) in adults aged 18 years or older with open-angle glaucoma. Eight observational studies comprising a pooled total of 663 eyes were included, with 239 eyes undergoing ABiC+Phaco and 344 eyes receiving standalone ABiC, and participants had baseline intraocular pressures ranging from 14.1 ±2.2 to 28.8 ±6.4 mm Hg while using 1.5 ±1.0 to 3.94 ±1.0 glaucoma medications. Random-effects meta-analyses using inverse variance methods pooled mean differences in intraocular pressure and glaucoma medications compared to baseline, showing no significant difference in intraocular pressure reduction between ABiC+Phaco and standalone ABiC at 6 months (0.36 mm Hg, 95% CI -2.83 to 3.56), 1 year (0.16 mm Hg, 95% CI -1.34 to 1.66), 2 years (-0.89 mm Hg, 95% CI -2.01 to 0.23), and 3 years (0.25 mm Hg, 95% CI -0.98 to 1.48), nor in glaucoma medication reduction at 3 years (0.03, 95% CI -0.18 to 0.23). No pre-specified secondary endpoints were reported. The authors concluded that adjunctive phacoemulsification may not enhance the intraocular pressure or glaucoma medication-lowering outcomes of standalone ABiC, and concurrent phacoemulsification should primarily be performed to address visually significant cataracts rather than to achieve additional intraocular pressure reduction. Key limitations included the restriction of analysis to eyes with open-angle glaucoma, which may show less pronounced intraocular pressure reduction

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

after phacoemulsification than angle-closure glaucoma. There are limitations in study design and evidence base, as no randomized controlled trials have compared outcomes between ABiC combined with phacoemulsification and standalone ABiC. Data reporting was limited because most studies did not provide mean differences in intraocular pressure or medication changes from baseline between the two treatment approaches. Reporting of complications and adverse event rates was incomplete, preventing detailed safety analysis in this review.

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

Ondrejka and Körber (2019) conducted a retrospective case series in 106 eyes in 71 patients who had mild to moderate POAG and underwent ab interno canal viscodilation with the VISCO360 device. Patients were divided into two groups; group 1 had 72 eyes with a baseline IOP of ≥ 18 mm Hg, and group 2 had 34 eyes with a baseline IOP of < 18 mm Hg. Overall, 12 eyes received stand-alone ab interno canal viscodilation (VISCO360 alone), and 94 eyes received ab interno canal viscodilation in conjunction with cataract extraction (VISCO360 plus cataract extraction). The primary outcomes that were measured were the change in mean IOP and mean number of IOP-lowering medications. Post operation, 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 BCVA, IOP, and medications. Follow-up visits occurred on postoperative day 1, at 1 month, at 3 months, and then every 3 months thereafter. At 12 months, the mean IOP in group 1 reduced from 24.6 ±7.1 mm Hg to 14.6 ±2.8 mm Hg; group 2 had a mean IOP of 14.9 ±1.8 mm Hg at baseline and at 12 months had no significant difference, with a mean IOP of 13.6 ±2.3 mm Hg. The authors found that microcatheterization and viscodilation of the Schlemm canal with the VISCO360 Viscosurgical System, with or without cataract extraction, can be safely and consistently performed in individuals with mild-moderate POAG. Limitations include the lack of a comparison group that was undergoing a different treatment approach, small sample size, and lack of long-term effectiveness beyond 1 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 of the OMNI Surgical System, performing ABiC only or in conjunction with cataract extraction. The authors concluded that 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 individuals with OAG. Key limitations include the small sample size and inclusion of both eyes in some patients, which reduced statistical independence and may have produced tighter CIs. There are limitations related to the study design, including the absence of a control or comparative arm and the retrospective, single-center nature of the case series, which may affect reliability and generalizability. The study has limitations in follow-up duration, as outcomes were assessed only between 9 and 15 months, leaving long-term effectiveness beyond 1 year uncertain. Including both eyes introduced additional variability, although this more closely reflects real-world performance.

Gallardo et al. (2018a) conducted a retrospective, single-center case series in patients with uncontrolled POAG who underwent ABiC as a stand-alone procedure or in conjunction with cataract extraction. The primary outcomes were mean IOP and mean number of glaucoma medications. The secondary outcomes included surgical and postsurgical complications and secondary interventions. A subset analysis was conducted that compared the outcomes in patients who underwent ABiC and phacoemulsification vs ABiC as a stand-alone procedure. Overall, 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 mm Hg, and mean medication use was 2.8 ±0.9. Twelve months post operation, the mean IOP reduced to 13.3 ±1.9 mm Hg (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 mm Hg on 2.6 ±1.0 medications prior to the operation to 13.0 ±1.8 mm Hg 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 mm Hg on 3.0 ±0.7 medications prior to the operation to 13.7 ±1.9 mm Hg 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 were from a single center; the study design, as a retrospective case series, was uncontrolled and subject to selection bias, and the combination cataract surgery results are confounded by the IOP-lowering effect of cataract surgery. Therefore, the precise mechanism of the ability of ABiC to reduce IOP is unclear, and only 12 months of follow-up were included. Longer-term, multicenter, prospective, randomized trials that include a larger sample size are still needed to assess the safety and efficacy of ABiC. There are limitations, including the retrospective design, with potential selection bias and variable follow-up, even though all eyes had 12-month data. Key limitations include the short-term follow-up and small sample size, which restrict the strength and generalizability of the findings. Another limitation is that the study's early results and minimally invasive ab interno approach may not fully represent long-term safety or effectiveness.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

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

Kailani et al. (2026) conducted a systematic review and meta-analysis that evaluated the evidence for the Surgical System, VISCO360, and TRAB360 in adults with OAG, including studies that enrolled at least 15 adults who were aged 18 years or older and at least 80% diagnosed with OAG. Overall, 29 publications that represented 22 unique studies and over 2,375 eyes were included, with sample sizes ranging from 17 to 541 eyes and follow-up durations of 6 to 36 months. Interventions involved the Surgical System used alone or combined with cataract surgery, and the primary end point was treatment success, which was defined as an IOPR of at least 20% from baseline. Random-effects meta-analyses using standardized MDs showed significant IOPRs at 6 months (-2.61; 95% CI, -4.11 to -1.11; $p < 0.01$), 12 months (-2.54; 95% CI, -3.71 to -1.38; $p < 0.01$), and overall (-2.57; 95% CI, -3.47 to -1.68; $p < 0.01$). Mean IOP values ranged from 11.5 to 17.2 mm Hg at 12 months, and medication use decreased from 0.9 to 3.4 at baseline to 0.1 to 2.2 at month 12, with 30% to 88% of individuals being medication free. The prespecified secondary end points included medication use, AEs, secondary surgical interventions, economic outcomes, and quality-of-life measures. The Surgical System demonstrated a favorable safety and efficacy profile and is a beneficial treatment option for individuals with POAG. Key limitations include the absence of RCTs, which prevented formal risk-of-bias assessment using standard tools. There are limitations, including unspecified glaucoma severity in several studies and inconsistent scales used to classify disease severity, which may reduce comparability and generalizability. Additional limitations involved variable study quality, with some single-cohort designs and patient loss during follow-up, as well as differences in geographic location, populations of individuals, and follow-up durations.

Zhu et al. (2025) conducted a systematic review and meta-analysis that evaluated stand-alone canaloplasty and trabeculotomy using the OMNI Surgical System in adults with OAG and a baseline IOP of greater than 18 mm Hg. Five studies that were published between 2021 and 2025 were included, encompassing 290 eyes in individuals from the United States, Poland, and Germany, with four retrospective and one prospective design. Random-effects models were used to assess IOP change at 1 month, 6 months, 1 year, and 2 years as well as changes in topical medication use and the proportion of medication-free individuals at 1 year. Mean IOPRs were 7.40 mm Hg at 1 month (95% CI, -10.61 to -4.20 mm Hg; $p < 0.0001$), 7.25 mm Hg at 6 months (95% CI, -9.60 to -4.89 mm Hg; $p < 0.0001$), 7.49 mm Hg at 1 year (95% CI, -9.47 to -5.50 mm Hg; $p < 0.0001$), and 8.77 mm Hg at 2 years (95% CI, -10.35 to -7.19 mm Hg; $p < 0.0001$). At 1 year, the mean reduction in topical medications was 0.77 (95% CI, -1.44 to -0.09; $p = 0.025$), and 46.2% of individuals were medication free (95% CI, 35.6%-57.2%). AEs were generally mild and self-limited, including hyphema, IOP spikes, and transient inflammation, with no device-related serious events reported. The authors concluded that stand-alone OMNI significantly reduced IOP and medication burden across multiple time points and demonstrated a favorable safety profile, which supports its efficacy as a stand-alone procedure for OAG and its potential value in individuals who are seeking to reduce reliance on topical therapy. Key limitations include the predominance of retrospective designs, lack of comparison groups, small sample sizes, and relatively short follow-up durations, with few studies extending beyond 2 years. There are limitations related to heterogeneity in baseline characteristics, selection of individuals, surgical techniques, and variability in treatment extent and standardized surgical protocols that may have influenced outcomes. Additional limitations include incomplete masking of outcome assessors, potential attrition bias from unpaired data, and limited statistical handling of pre-post changes in studies without control groups. The overall evidence base was further constrained by the absence of repeated measures, incomplete accounting for follow-up loss, and limited generalizability due to differences in intervention consistency and individuals' representativeness.

An ECRI Evidence Analysis (2024) of the Streamline Surgical System for treating glaucoma evaluated only one available case series that was described in two publications. The study reported that Streamline reduced IOP at up to 12 months after surgery in individuals, and approximately half of the treated individuals did not require IOP medication. However, the available study is at a 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.

Goldberg et al. (2024) reported on interim results of the VENICE multicenter RCT (NCT05280366) that compared Streamline canaloplasty with iStent *inject* W (iStent W) implantation in participants with mild to moderate POAG who were undergoing phacoemulsification. Participants (n = 72 eyes) were randomized; 35 underwent Streamline canaloplasty, and 37 were implanted with the iStent W. Overall, 70 eyes completed the 6-month follow-up. The results showed that both the mean morning postwashout baseline IOP between Streamline 24.86 ±3.05 mm Hg and iStent W 25.16 ±3.41 mm Hg and the mean IOP at 6 months between Streamline eyes (16.52 ±3.63 mm Hg) and iStent W eyes (16.08 ±3.19 mm Hg) 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 with the iStent W group (78.4%). In medication-free eyes, the mean IOP was reduced from 24.80 ±2.79 mm Hg to 16.00 ±3.40 mm Hg and 24.60 ±3.18 mm Hg to 15.80 ±2.21 mm Hg in the Streamline and iStent W groups, respectively ($p = 0.752$). Both groups had a reduction in IOP-lowering medications at every visit. The authors concluded that the IOP-lowering efficacy and reduction of IOP-lowering medications were

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

similar between groups. Adverse effects were also similar between groups and generally categorized as minor and self-limiting. This study is ongoing, and 12-month results in 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 W. The limitations of the study include short-term follow-up and potential bias due to a manufacturer-sponsored study; additionally, analysis was not designed to test noninferiority (findings could be due to type 2 error), and the a priori primary outcome was not yet reported in the publication.

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 20 eyes that underwent incisional goniotomies and Schlemm canal viscodilation following phacoemulsification. The outcomes in this interim analysis included mean reduction in IOP and medications through 6 months of follow-up as well as the proportion of eyes that achieved a reduction of ≥ 20% from baseline. At 6 months, a mean IOPR of ≥ 20% from baseline was achieved in 89.5% of eyes. The mean IOP was significantly reduced from baseline through 6 months of follow-up to 14.7 (2.4) mm Hg ($p < 0.001$), representing an IOPR of 8.8 mm Hg (36.9%). Overall, 57.9% of eyes (11 of 19) had decreased dependence on IOP-lowering medications by at least one medication, and 42.1% (eight of 19) were medication free. The 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 that preliminary outcomes of incisional goniotomies and Schlemm canal viscodilation compare favorably with outcomes of other trabecular meshwork bypass implants and commercialized forms of canaloplasty. The limitations of the study include the study design (lack of contemporary controls), small sample size, lack of long-term outcomes, and possible conflict of interest in a manufacturer-sponsored study.

Toneatto et al. (2022) evaluated the effectiveness of ab interno microcatheterization and 360° viscodilation of the Schlemm canal performed with the OMNI Surgical System in 73 patients with OAG. Overall, 80 eyes were assessed and divided into two groups. Group 1 had 50 eyes that underwent ab interno microcatheterization and Schlemm canal viscodilation, while 30 eyes in group 2 underwent glaucoma surgery plus cataract extraction. Prior to the operation, 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 that was equal to or greater than 25% from baseline at the 12-month follow-up visit; the eyes that reached this goal without any medical treatment were considered a complete success. The baseline IOP in all eyes was an average of 22.5 ±5.3 mm Hg. The authors found that after 12 months, the mean IOP was reduced to 15.0 ±3.6 mm Hg, which was statistically significant. However, the reduction in medications at 12 months was not significantly significant between the two groups; the averages in 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. The authors found that approximately 15% of eyes achieved an IOP of 18 mm Hg or lower with no medications and an overall success rate of 71.8%. The authors concluded that Schlemm canal viscodilation with the OMNI device appears to be promising for controlling IOP; however, further studies are needed to report long-term outcomes and complications. Limitations include the lack of comparison with other glaucoma treatments, small sample size, lack of long-term outcomes, and retrospective design.

An ECRI review (2021; updated 2023) on the OMNI Surgical System (Sight Sciences, Inc.) for treating OAG evaluated three studies (four publications), which reported on a total of 217 individuals. Those included case series, including three retrospective and one 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 individuals with mild to moderate OAG when performed alone or during cataract surgery. No studies compared OMNI with other OAG treatments. RCTs that compare 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 the 2023 update, which included a systematic review, the assessment showed that OMNI is safe and reduces IOP and medication use at up to the 24-month follow-up when used alone or during cataract surgery in individuals with mild or moderate OAG based on low-quality evidence from seven studies. OMNI compared with other OAG treatments cannot be determined because comparative studies are at a 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 participants with OAG. Eligible participants had cataract and mild-moderate OAG with an IOP of ≤ 33 mm Hg on one to four hypotensive medications. The effective outcomes included mean IOP and medications. The safety outcomes included AEs, BCVA, and secondary surgical interventions. Overall, 137 participants were enrolled and treated. The mean DIOP after washout was 23.8 ±3.1 mm Hg at baseline. At month 6, 78% of participants (104 of 134) were medication free, with an IOP of 14.2 mm Hg and a mean reduction of 9.0 mm Hg (38%). In total, 100% (104 of 104) had a ≥ 20% reduction in IOP, and 86% (89 of 104) had an IOP of ≥ 6 and ≤ 18 mm Hg. The mean number of medications at screening was 1.8 ±0.9 and 0.6 ±1.0 at month 6. AEs included transient hyphema (4.6%) and an IOP elevation of ≥ 10 mm Hg (2%). There

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

were no AEs for loss of BCVA or recurring hyphema. There were no secondary surgical interventions. The authors concluded that canaloplasty followed by trabeculotomy and performed concomitantly with phacoemulsification has favorable intra- and perioperative safety and significantly reduces IOP and antiglaucoma 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 participants with mild-moderate OAG and cataracts. At month 12, 84.2% of eyes achieved IOPRs of > 20% from baseline, 80% of eyes were medication free, and 76% of eyes achieved an IOP between 6 and 18 mm Hg 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 DIOP and medication use 12 months post operation, with an excellent safety profile. Limitations of this study include a lack of a control group or comparison of OMNI with other procedures.

Grabska-Liberek et al. (2021) conducted a case series study to characterize the clinical outcomes of combined viscodilation of the Schlemm canal and collector channels and 360° trabeculotomy using the OMNI Surgical System as a stand-alone procedure or combined with cataract surgery in eyes with mild to moderate OAG. Eligible participants were adults who were aged 45 years or older; had either visually significant cataract or pseudophakia; had OAG (including primary, pigmentary, and PEX); had an IOP of > 21 mm Hg; and were using up to three topical IOP-lowering medications. The primary outcome was the proportion of eyes with an IOPR of ≥ 20% from baseline using the same number or fewer IOP-lowering medications compared with baseline at month 24. The secondary outcomes included the proportion of eyes with an IOP of ≤ 18 mm Hg and the proportion with an IOP of ≤ 15 mm Hg (and IOP ≥ 6 mm Hg in both cases) at month 12; the proportion of eyes that were medication free or on at least one fewer medication compared with 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 that were performed for IOP control. The safety end points included the nature and incidence of ocular AEs. Participants were reevaluated at 1 week and 1, 3, 6, 12, and 24 months post operation. Among 17 eyes in 15 participants, the mean IOP was reduced from 20.4 mm Hg to 12.7 to 13.7 mm Hg through 12 months of follow-up ($p < 0.001$ at every time point), and mean medications were reduced from 2.5 to 0.1 to 0.6 ($p < 0.001$ at every time point). IOPRs in eyes that were undergoing stand-alone surgery were approximately 2 to 4 mm Hg greater at each time point compared with eyes that were undergoing surgery combined with phacoemulsification; this may be related to a higher baseline IOP in the former eyes (22.1 vs 18.5 mm Hg). Six eyes developed hyphema, of which three required washout 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 the Schlemm canal and collector channels, paired with ab interno trabeculotomy performed with a single integrated instrument (OMNI), whether as a stand-alone or combined with phacoemulsification, effectively lowered both IOP and the need for IOP-lowering medications through 12 months of follow-up. The authors also mentioned that this study is ongoing and that 24-month data will be reported when available. Limitations of this study include its design, a case series design that lacked a contemporaneous comparison group, small sample size, all surgeries being performed by the same surgeon, and the unexpectedly high rate of hyphema. Additional randomized studies that include larger sample sizes and longer follow-up periods are still needed to clarify the efficacy and safety of this technology.

Klabe and Kaymak (2021) analyzed a case series in 27 patients who were approximately 67 years of age and underwent 360° viscodilation followed by up to 360° trabeculotomy as a stand-alone procedure. The primary goal of this analysis was to distinguish changes in IOP and IOP medication. Overall, 38 eyes underwent the surgical procedure; 30 eyes were available for analysis at 1 year; and 26 eyes were available for analysis at 2 years. The authors found that at 24 months, 88.5% of eyes (23 of 26) had an IOP below 18 mm Hg, with 14 of these (61%) without medication. In addition, 84.6% of eyes were using at least one less medication than at baseline, and 57.7% were medication free. AEs included transient postoperative hyphema in 17 eyes; other AEs included choroidal effusion, anterior synechiae, and transient lens-cornea touch that was associated with a shallow anterior chamber. Limitations include the 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 et al., 2021). The OMNI device was used following phacoemulsification to perform a sequential ABiC followed by a trabeculotomy in 128 participants 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 that 95% of participants experienced an overall reduction in IOP; 91% of the participants experienced an IOPR of at least 3 mm Hg, and 86% of participants experienced a reduction in IOP of at least 20%. It was concluded that participants with OAG can benefit from an overall decrease in IOP for 12 months after surgical treatment. Limitations include the lack of a comparison group and inability to generalize the assessment to other minimally invasive glaucoma surgery procedures and implants.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Goniotomy or Trabeculotomy for Adults

Charytonowicz et al. (2025) conducted a systematic review that evaluated the efficacy and safety of iStent microbypass implantation and KDB goniotomy combined with phacoemulsification in adults with OAG. Eligible studies were prospective or retrospective clinical trials that included individuals who were aged 18 years or older with primary open-angle, normal-tension, or secondary glaucoma and at least 6 months of follow-up. Overall, 11 studies, encompassing 1,925 eyes, were analyzed, with five directly comparing phaco-iStent and phaco-KDB procedures. The primary outcomes were percentage reduction in IOP and antiglaucoma medication use at the end of follow-up, with success defined as achieving an IOP below 18 mm Hg, with or without medications. Across studies, both interventions significantly reduced IOP and medication burden, with greater reductions observed in the phaco-KDB group, such as a mean IOP decrease of 5.0 mm Hg vs 2.3 mm Hg and medication reduction of 63% vs 46% in one study. The secondary end points were surgical success and complication rate. The authors concluded that iStent implantation and KDB goniotomy combined with phacoemulsification effectively lower IOP and reduce medication use in individuals with OAG, with both methods showing high safety and few complications that generally resolved without intervention. There are limitations, including the absence of long-term follow-up data, which leaves the lasting effects of KDB goniotomy uncertain. Key limitations involve substantial variability driven by differences in glaucoma severity, number of eyes analyzed, baseline IOP, medication use, surgical expertise, and demographic characteristics. Another limitation is that most studies lacked a preoperative washout period, making it difficult to determine untreated IOP. The lack of unified methodological standards limits the clarity, consistency, and comparability of findings across studies.

Guedes et al. (2025) conducted a systematic review and meta-analysis that compared 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. An initial search yielded 223 articles; only 14 studies met the criteria, with a total of 1,959 eyes (958 phaco-KDB and 1,000 phaco-Stent, including 753 phaco-iStent and 207 phaco-iStent *inject*). The results demonstrate that the KDB-phaco group may have better surgical success than the phaco-Stent group (OR, 0.75; 95% CI, 0.13-4.13; p = 0.74; I^2 = 47%). However, by 12 and 24 months, the IOPR between the two groups became comparable. Meanwhile, both procedures demonstrated similar safety profiles, including the rates of hyphema and IOP spikes. With the Cochrane risk-of-bias assessment tool, only one study was determined to have a low risk; one study was deemed to pose a serious risk of bias regarding measurement outcomes; and the remaining 12 studies were assessed at a moderate risk of bias. All 13 observational studies were found to have a 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 that compare these two canal-based MIGS procedures are warranted. The limitations of the studies include that only one RCT was included in the analysis; 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 end points. 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 that examined the IOP-lowering effects of the KDB goniotomy combined with phacoemulsification and phacoemulsification alone in individuals with OAG or ocular hypertension. The review included 26 studies that reported on 1,659 individuals; 684 individuals underwent phacoemulsification alone, and 975 underwent combined KDB goniotomy with phacoemulsification. The results showed that 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 individual with phacoemulsification alone was 0.36 (95% CI, 0.06-0.66) compared with a mean reduction in the number of glaucoma eye drops per individual 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 was 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 < 0.01) indicates a significant difference in the mean reduction of glaucoma eye drops used between studies that reported on phacoemulsification as a solo procedure and those that reported on combined strategy. The most common complications reported in individuals who underwent the combination of procedures included postoperative IOP spikes and hyphema. The authors concluded that KDB goniotomy, when combined with phacoemulsification, has a synergistic beneficial effect on both IOPR and glaucoma drop reduction. Despite the statistically significant outcomes that indicate the favorable safety profile of 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 IOP; its protective influence on the optic nerve; and the potential duration that it can postpone the necessity for subsequent, more intrusive glaucoma surgical interventions. The limitations of the studies in this review include the inclusion of only one

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

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 that compared the KDB goniotomy and ab interno trabeculotomy with microhook for morphological changes of the trabecular meshwork. The secondary outcomes included IOP changes, number of medications, and complication rate. Participants with POAG and exfoliative glaucoma eyes were randomized into two groups, the KDB group (n = 27) and microhook group (n = 25), with a 12-month follow-up. The incisional cross-sectional area of the KDB group was significantly larger at 1 week and at 1, 6, and 12 months ($p < 0.01$) post operation. 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 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 that 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 post operation. The limitations of the study are a small sample size; participant type, which included both with and without stable IOP control; and 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. During a 12-month postoperative period, data were collected from 11 surgeons at 11 centers in the United States, Mexico, and Switzerland. The study reported on 40 eyes in a varied population with severe or refractory glaucoma that underwent stand-alone (52.5%) or combined KDB goniotomy (47.5%). The outcomes showed that at 12 months, 37.5% (n = 15) achieved an IOPR of 20% or more, with fewer medications than prior to the operation. Qualified success was achieved in 15% of eyes using a 12 mm Hg or less definition, while 67.5% and 82.5% of eyes achieved a medicated IOP of ≤ 16 mm Hg and ≤ 18 mm Hg. In total, 17.5% (n = 7) were classified as complete failure due to an uncontrolled IOP above 18 mm Hg despite medical treatment. The authors concluded that KDB has a favorable safety profile, which makes it a potential useful primary or adjunctive procedure in high-risk eyes; however, its efficacy decreases over time, and further prospective and randomized studies are required to characterize the long-term efficacy and safety of the dual blade as a stand-alone procedure. The limitations of the study include the lack of a 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 postoperative IOP changes and ocular hypotensive medications in three surgical cohorts. The study included 138 eyes with OAG, comparing cataract surgery alone (n = 84), cataract with trabecular microbypass (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 1 month post operation and variable results at 3 and 6 months. The change in ocular hypotensive medications was not statistically different between the surgical groups at any postoperative visit. The authors concluded that trabecular bypass and goniotomy, when added to cataract surgery, resulted in a modest effect on IOP and a minimal effect on medication burden compared with cataract surgery alone in patients with glaucoma. The study limitations include the lack of randomization and small sample size.

Aktas et al. (2021) evaluated a retrospective case series in 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 removal. The baseline evaluation in all patients included a detailed ophthalmic examination and Goldmann applanation tonometry. Surgical success was defined as an IOP of ≤ 21 and ≥ 6 mm Hg. Postoperative visits were conducted the day after surgery, and then data were collected in the 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 mm Hg; however, the need for medication did increase over the follow-up period. Limitations include the lack of a comparison group that was 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. Overall, 33 eyes in 32 patients were included, with a mean patient age of 49 ±16 years. The data were collected through chart review and communication with eye health professionals who were involved in patient follow-up. The primary outcome was a reduction in IOP of ≤ 18 mm Hg and one of the following: IOP within 1 mm Hg of baseline on fewer glaucoma medications compared with baseline or a 30% IOPR from baseline on the same or fewer glaucoma medications. After a 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

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

comparisons to other glaucoma surgical procedures; in addition, the sample size was small and lacked long-term outcomes.

A 2021 ECRI Clinical Evidence Assessment was conducted on the Trabectome, which is an electrosurgical platform that is intended to reduce IOP in individuals 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 Schlemm canal, 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 two systematic reviews and six additional nonrandomized comparison studies. Three other nonrandomized comparison studies were at too high of a risk of bias to determine how well Trabectome works compared with ab externo trabeculectomy. Additional RCTs that compare Trabectome with MIGS are needed to validate findings. Evidence limitations include a high risk of bias, small study size, retrospective design, single-center focus, and lack of randomization and masking.

Hu et al. (2021) conducted a search of CENTRAL, Ovid MEDLINE, Ovid Embase, the ISRCTN registry, ClinicalTrials.gov, and the World Health Organization ICTRP for RCTs of ab interno trabecular bypass surgery with the Trabectome procedure compared with other MIGS or 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 that properly designed RCTs are needed to assess the long-term efficacy and safety of this technique. Key limitations include the incomplete methodological detail that obscures the study design, selection of individuals, and analytic procedures, creating uncertainty about internal validity and reproducibility. There are limitations, including the lack of explicit results data, which prevents independent verification of findings and reduces transparency and interpretability. Another limitation is the absence of any described risk-of-bias assessment, hindering evaluation of study quality and diminishing confidence in the reliability of the evidence.

Sharkawi et al. (2021) reported on the outcomes of a noncomparative, prospective case series in 103 eyes in 84 participants with PEX glaucoma. The participants underwent a 360° ab interno trabeculotomy procedure with gonioscopic assistance. The 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 participant experiencing transient hypertony. The combination of cataract surgery and GATT maintained the same effectiveness as GATT alone in pseudophakic participants. Post operation, IOP was reduced by 52%. The authors concluded that the study demonstrated that GATT safely and effectively lowers IOP in PEX glaucoma, whether performed alone or in addition to cataract surgery. Limitations include the absence of a comparative group and lack of long-term outcomes.

Ventura-Abreu et al. (2021) conducted a single-center longitudinal RCT to evaluate the efficacy and safety of the KDB ab interno trabeculectomy combined with phacoemulsification compared with those of stand-alone conventional cataract surgery. Overall, 42 eyes in 33 participants who were 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 mm Hg and from 17.3 ±2.5 to 15 ±3.2 mm Hg at the last visit in the treatment and control groups (p = 0.47). The use of glaucoma medications was reduced from a median (IQR) of 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 that the KDB ab interno trabeculectomy, along with cataract surgery, might not offer additional IOP and glaucoma medication reduction compared with 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 a small sample size, which could have been too small to detect clinically significant differences, and lack of investigation of systematic medications and medication washout.

Guo et al. (2020) performed a systematic review and meta-analysis of 10 studies to evaluate the safety and efficacy of GATT in individuals with OAG; 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 in IOP, and the authors found that most individuals following the surgery still needed antiglaucoma medication. However, the pooled results showed a significant decrease in medications. The most common complication seen was hyphema, which was observed in all the studies. Limitations include the lack of a comparison group and variances among the studies, including baseline IOP, individuals' 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 that RCTs that include larger sample sizes should be conducted before drawing any final conclusions.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Falkenberry et al. (2020) conducted a multicenter prospective RCT to compare the reduction in IOP and IOP-lowering medication in eyes that were undergoing excisional goniotomy with KDB vs iStent (first generation) implantation, both combined with phacoemulsification in eyes with mild to moderate OAG. The study included 164 eyes in 164 participants who were randomized to analyze visual acuity, IOP, IOP-lowering medications, and AEs post operation on day 1, week 1, and months 1, 3, 6, and 12. The primary outcome that is stated on ClinicalTrials.gov was percent reduction in mean IOP at 12 months, but in the publication, it was the proportion of eyes at 12 months with an IOPR of 20% or greater or IOP medication of one or more compared with baseline. The results showed that the composite outcome was attained in 74 of 79 participants with KDB eyes (93.7%) and 65 of 78 participants with iStent eyes (83.3%) ($p = 0.04$). As this outcome was not listed a priori on ClinicalTrials.gov, these findings should be considered as resulting from post hoc analyses and should be taken cautiously. The mean percentage IOPRs from 1 month onward were not significantly different at any point after day 1. The mean postoperative 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% of eyes (KDB) and 33.3% of eyes (iStent); 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 that both procedures lowered both IOP and the need for IOP-lowering medications. Significantly more KDB-phaco eyes than iStent-phaco eyes met the primary outcome of 20% or greater IOPR or more than one 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 IOPR, as evidenced by the relatively low baseline IOP in the eyes in the KDB-phaco group. Limitations in the study include a relatively small sample size; study design that prevented testing for noninferiority; lack of masking, which could have impacted the number of medications ordered; absence of long-term outcomes; and possible conflict of interest in a manufacturer-sponsored study.

ElMallah et al. (2019) performed a retrospective cohort study to analyze the efficacy and safety of combined cataract extraction with excisional goniotomy performed with the KDB (phaco-KDB group) compared with those of 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 in 230 adults who were treated with one or more IOP-lowering medications (190 eyes in the phaco-KDB group and 125 eyes in the phaco-iStent group) and required no subsequent surgical intervention for IOP control through 12 months. Data included visual acuity, IOP, and IOP-lowering medications prior to and post operation at week 1 and months 1, 3, 6, and 12 as well as AEs. The primary outcome was the proportion of patients who were achieving ≥ 20% IOPR and at least one medication reduction at month 12. The results showed that at month 12, IOPRs of ≥ 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 at least one medication were achieved by 80.4% and 77.4% ($p = 0.522$). However, baseline IOP was significantly higher in the phaco-KDB group than the phaco-iStent group [18.2 (0.3) vs 16.7 (0.3) mm Hg; $p = 0.001$]. AEs included transient IOP elevations, transient anterior chamber inflammation, corneal edema, and posterior capsule opacification. Transient blood reflux was seen in 38 eyes in the phaco-KDB group (19.8%) and in five 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 the study design, small sample size, lack of randomization of treatment groups, short-term outcomes, and possible conflict of interest in the manufacturer-sponsored study. Furthermore, significant group differences existed at baseline (age, ethnicity, and 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 in 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 two groups. The overall percentage of IOPR 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 that phacoemulsification in combination with either iStent implantation or goniotomy using the KDB both achieved statistical significance in IOPR and the number of glaucoma medications at the 12-month follow-up. Limitations in the study include a small sample size, which could have been insufficient to detect clinically significant group differences (type 2 error), and short-term follow-up.

Dorairaj et al. (2018) performed a multicenter, retrospective, observational comparative study that compared IOP outcomes in eyes with cataract and glaucoma that were undergoing phacoemulsification in combination with goniotomy using the KDB or implantation of a single iStent trabecular bypass device. Preoperative, intraoperative, and postoperative data for IOP and IOP-lowering medications were collected through 6 months of follow-up in 435 eyes in 318 patients receiving phaco-goniotomy with KDB (n = 237) or phaco-iStent (n = 198). The results showed that mean IOPs were not statistically different between groups at all time points (1 day, 1 week, and 1, 3, and 6 months) post operation. The percent change in IOP from baseline identified statistically significantly greater reduction in the phaco-goniotomy with KDB group vs the phaco-iStent group at all time points ($p < 0.001$). Additionally, the proportion of eyes that achieved an IOPR

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

of ≥ 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 ≤ 0.011). IOP-lowering medication reduction was greater in the phaco-goniotomy with KDB group than the phaco-iStent group (1.1 vs 0.9 medications, respectively; p = 0.001). The most common AE was IOP spikes that occurred 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 with the dynamic range in the phaco-goniotomy with KDB group. The authors concluded that goniotomy with the KDB combined with cataract surgery significantly lowers both IOP and the need for IOP-lowering medications compared with cataract extraction with iStent implantation in glaucomatous eyes through 6 months. The authors noted that some surgeons are implanting two iStent devices to optimize the IOP-lowering effect. Future studies that compare the use of double iStent implants with goniotomy using the KDB should be examined. Limitations in the study include 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 the 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 the clinical outcomes of stand-alone KDB trabeculectomy. The evidence demonstrated large gaps, with limited conclusions on the safety and effectiveness of the stand-alone trabeculectomy. These publications consistently reported favorable outcomes with KDB; however, the findings indicated a 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 groups of individuals because of the variability in glaucoma etiologies and individuals' characteristics. The studies lacked outcomes beyond 3 years and independent validation; therefore, comparative effectiveness was not achievable. The report concluded that large, prospective studies that compare KDB with microstenting, laser surgery, or other ab interno surgical approaches and have 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 in patients with various types of OAG who underwent 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) who were between 24 and 89 years of age and had an IOP of ≥ 18 mm Hg underwent GATT. Patients were stratified into six groups: (1) POAG with no prior cataract extraction, receiving only GATT; (2) POAG with no prior cataract extraction, receiving combined GATT and cataract extraction; (3) POAG with prior cataract extraction, receiving only GATT; (4) other glaucoma with no prior cataract extraction, receiving only GATT; (5) other glaucoma with no prior cataract extraction, receiving combined GATT and cataract extraction; and (6) other glaucoma with prior cataract extraction, receiving only GATT. At 24 months, patients with POAG (groups 1-3; n = 72) had an average IOP decrease of 9.2 mm Hg 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 14.1mm Hg 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 six study groups at all five postoperative time points (3, 6, 12, 18, and 24 months), the mean IOP and reduction in glaucoma medications were significantly reduced from baseline (p < 0.001), with the exception of one time point (e.g., the POAG prior cataract extraction 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 were 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. Additional limitations include 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, and inaccuracies and lacks a control. Multicenter RCTs that include 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 combined with phacoemulsification or as a stand-alone procedure. Overall, 197 eyes were included in the analysis, with a wide range of glaucoma types. At 12 months, only 140 eyes remained due to attrition among those who received KDB goniotomy (n = 16) or KDB goniotomy with phacoemulsification (n = 124). The most common complications included postoperative IOP spike and transient hyphema. At 12 months, the KDB goniotomy combined with phacoemulsification cataract surgery (phaco-KDB) group's mean IOP was reduced from 16.7 mm Hg on 1.9 medications to 13.8 mm Hg on 1.5 medications. In the KDB goniotomy alone (KDB-alone) group, the mean IOP reduced from 20.4 mm Hg on 3.1 medications to 14.1 mm Hg on 2.3 medications. The success rate was 71.8% in the phaco-KDB group and 68.8% in 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.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Study limitations include the study design (lack of comparison group undergoing interventions and other and KDB), lack of long-term follow-up, small sample size, and possible conflict of interest.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The 2020 (updated 2025) 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 are currently available for MIGS, given its relatively recent introduction. Modest IOPR has been reported following MIGS, and postoperative pressures are typically in the middle to upper teens. Currently available MIGSs include procedures that target the trabecular meshwork/Schlemm canal and the subconjunctival space. They are commonly combined with phacoemulsification; some are only U.S. Food and Drug Administration approved to be performed concurrently with phacoemulsification.

The guideline states that modest reductions in IOP and glaucoma medical therapy have been observed in patients who are undergoing cataract surgery alone. Studies have found that similar surgical complications occur with the iStent and iStent *inject*, with hyphema, IOP spikes, corneal injury, peripheral anterior synechiae formation, and cyclodialysis cleft being reported in RCTs. The AAO guideline also states that minimally invasive bleb surgery, trabeculectomy, and aqueous shunts (such as the XEN Gel Stent) have the potential for greater IOPR and that they are generally used in cases of moderate to advanced glaucoma. The guideline also states that the Hydrus Microstent is approved for use in patients with mild to moderate POAG who are undergoing concurrent phacoemulsification. Studies have demonstrated IOPRs in the mid-teens, with a decreased need for glaucoma medications after Hydrus Microstent implantation combined with cataract surgery compared with cataract surgery alone. 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 states the following:

- 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 that was published in 2002 found moderate-quality evidence that separating the cataract and glaucoma incisions results in lower IOP than a one-site combined procedure, but the differences in outcomes were small. Subsequent publications have found no difference between the two approaches (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 that is comparable to 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 procedures guidance published by NICE concludes that after a systematic review and meta-analysis of multiple clinical studies in almost 3,100 patients, the 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, and 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 U.S. Food and Drug Administration approved for glaucoma treatment in the U.S.

Moreno-Valladares et al. (2025) conducted a retrospective, multicenter, interventional case series that evaluated adults with ocular hypertension or glaucoma who were undergoing the combined phaco-ELIOS (Excimer Laser Intraocular

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

System) procedure, with data collected from baseline to 12 months post operation. Overall, 112 eyes in 82 patients were included, with a mean age of 70.6 years; 51.2% were female, with most diagnosed with POAG. All patients had clinically significant cataracts and were treated with antihypertensive drugs before surgery, which combined phacoemulsification with ELIOS using a 308-nm excimer laser to create 10 microchannels. The primary outcome was the mean change in medication use compared with baseline, which was analyzed using Fisher exact, Wilcoxon, or t tests and Kaplan-Meier survival analysis. Mean medication use decreased from 1.8 ±0.8 to 0.4 ±0.7 at 12 months, a reduction of 1.5 ±1.0 ($p < 0.0001$), with 78.4% of eyes being medication free at 12 months. The secondary end points included IOP change, acute postoperative IOP elevation, BCVA, and surgical success at 1 year. The authors concluded that the ELIOS procedure combined with phacoemulsification resulted in significant IOP and medication reduction, improved visual acuity, and a low rate of postoperative IOP elevations, demonstrating efficacy in treating patients with mild to moderate glaucoma. There are limitations, including the absence of reported safety data and the relatively short 1-year follow-up, which may overestimate effectiveness and fail to capture long-term outcomes. Key limitations include the lack of a control group for direct comparison, which limits the interpretation of IOP changes relative to phacoemulsification alone. The study also focused solely on the combined phaco-ELIOS procedure, which prevented assessment of the individual contributions of phacoemulsification and ELIOS to medication reduction and pressure control.

A Hayes report (2024; updated 2026) evaluated evidence related to OCT-guided laser trabeculotomy for the treatment of glaucoma. An updated review of abstracts suggests that there continues to be a lack of published, peer-reviewed literature to evaluate the evidence for a full assessment. Hayes did not identify any clinical studies or position statements or guidelines that are related to the use of OCT-guided laser trabeculotomy in individuals with glaucoma. Therefore, based on the limited available evidence, 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 AEs and IOP changes in noninvasive glaucoma surgery using FLIGHT (femtosecond laser, image-guided, high-precision trabeculotomy). Overall, 18 eyes in 12 participants were enrolled in the study; 11 participants (17 eyes) returned at 24 months. The results demonstrated anticipated AEs 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 three 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 mm Hg ($p < 5e-5$), with an average of 2.0 ±1.2 hypotensive medications compared with 2.2 ±1.1 at baseline ($p = 0.22$). Fourteen of the 17 study eyes (82.3%) achieved a ≥ 20% reduction in IOP at 24 months compared with baseline. The authors concluded that the initial safety profile of FLIGHT is favorable. Further multicenter, 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 a small sample size, single-arm study design, lack of randomization, and risk of bias.

Deubel et al. (2021) performed a cohort study that analyzed 512 individuals who underwent ELT or combined ELT with cataract surgery at a German institution from November 2000 until March 2011. Only individuals with POAG, PEX glaucoma, and ocular hypertension were included. The use 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 mm Hg or less; and no achievement of a reduction of 20% from the baseline. The results showed that after 656 days, 87% (combined surgery) and 66% (ELT) of individuals did not have to undergo another IOP-lowering intervention; 47 or 31% were classified as a qualified success and 31 or 11% as a complete success. However, the IOP-lowering medications could not be significantly reduced in that time period. The authors concluded that ELT compared with 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 similar to that seen with more invasive procedures. Limitations in the study include the 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 ELT. Eight studies along with two additional non-referenced publications met the inclusion criteria which included one randomized controlled trial, four prospective case series, five retrospective studies. The authors concluded that the evidence showed an IOP-lowering effect with 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 the lack of controls, small sample sizes, washout IOP, variable loss to follow-up, and failure to show long-lasting response after initial surgery.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Lavia et al. (2017) conducted a systematic review and meta-analysis to analyze 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 a competitor device in participants with OAG who are undergoing cataract surgery. More information is located at: http://clinicaltrials.gov/ct2/show/NCT06246136. (Accessed May 29, 2026)

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

ELT as an invasive surgical procedure has shown favorable outcomes compared with other MIGS procedures. Several limitations have been identified in 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, and clinical studies are pending in both Canada and the United States (Berlin et al., 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 May 29, 2026)

The Canaloplasty Ophthalmic Microcannula or iTRACK (K062259) is a flexible microcannula that is designed to allow atraumatic cannulation of spaces in the eye, such as the anterior chamber and posterior segment, to receive 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 May 29, 2026)

The OMNI Surgical System is a handheld, manually operated device that is used by ophthalmologists to access, microcatheterize, and viscodilate the Schlemm canal (canaloplasty) and to reaccess the Schlemm canal 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 May 29, 2026)

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 May 29, 2026)

Glaucoma Drainage Devices

The EX-PRESS mini glaucoma shunt (K030350), which is indicated for use in the reduction of intraocular pressure (IOP) in patients with glaucoma in whom medical and conventional surgical treatments have failed, received 510(k) approval on March 26, 2002. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

Predicate devices include the Molteno implant (K890598 and K902489), Baerveldt glaucoma implant (K905129 and K955455), Krupin Eye Valve (K885125 and K905703), and Ahmed Glaucoma Valve implant (K925636). Additional

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

information under product code KYF (Implant, Eye Valve) is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

The iStent trabecular microbypass stent system, model GTS100R/L, was approved by the FDA on June 25, 2012. This device is approved for use in combination with cataract surgery to reduce IOP in adult patients with mild to moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce IOP. The iStent *inject* trabecular microbypass system (model G2-M-IS) received FDA approval through the premarket approval process (P170043) on June 21, 2018. The device is approved only for use in conjunction with cataract surgery; use in a stand-alone procedure would be considered off label. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

The 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 primary open-angle glaucoma. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

The XEN Glaucoma Treatment System (K161457) was approved by the FDA on November 21, 2016. This device is used to reduce IOP for the management of glaucoma. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

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. (Accessed May 29, 2026)

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 that is emitted by an Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy) and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, iridotomy, and SLT. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 29, 2026)

References

Abbas J, Haider F, Arooj H, et al. Comparison of 360-degree trabeculotomy versus traditional angle surgery in primary congenital glaucoma: a systematic review and meta-analysis. J Glaucoma. February 23, 2026. Online ahead of print.

Ahmed IIK, De Francesco T, Rhee D, et al. HORIZON Investigators. Long-term outcomes from the HORIZON randomized trial for a Schlemm's canal microstent in combination cataract and glaucoma surgery. Ophthalmology. 2022 Jul;129(7):742-751.

Ahmed IIK, Fea A, Au L, et al. A prospective randomized trial comparing Hydrus and iStent micro-invasive glaucoma surgery implants for standalone treatment of open-angle glaucoma: the COMPARE sStudy. Ophthalmology. 2019;18:S0161-64202020 Jan;127(1):52-61.

Ahmed IIK, Rhee DJ, Jones J, et al.; HORIZON Investigators. Three-year findings of the HORIZON trial: a Schlemm canal microstent for pressure reduction in primary open-angle glaucoma and cataract. Ophthalmology. 2021 Jun;128(6):857-865.

Aktas Z, Ucgul AY, Ozdek S, et al. Outcomes of gonioscopy-assisted transluminal trabeculotomy in vitrectomized patients with secondary glaucoma after silicone oil removal. J Glaucoma. 2021 Mar;30(3):e114-e118.

American Academy of Ophthalmology (AAO). American Academy of Ophthalmic Executives; Fact sheet: goniotomy. January 2023a.

American Academy of Ophthalmology (AAO). Eye Wiki; Cyclodestructive procedures in treatment of glaucoma. September 2023e. Available at: https://eyewiki.org/Cyclodestructive_Procedures_in_Treatment_of_Glaucoma#:~:text=7%20References-,Introduction,targeted%20destruction%20with%20less%20inflammation. Accessed June 8, 2026.

American Academy of Ophthalmology (AAO). Eye Wiki; Iridoplasty. January 2025. Available at: https://eyewiki.org/Iridoplasty. Accessed June 8, 2026.

American Academy of Ophthalmology (AAO). Eye Wiki; Laser peripheral iridotomy. December 2023b. Available at: https://eyewiki.org/Laser_Peripheral_Iridotomy. Accessed June 8, 2026.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

American Academy of Ophthalmology (AAO). Eye Wiki; Laser trabeculoplasty: ALT vs SLT. December 2023c. Available at: https://eyewiki.org/Laser_Trabeculoplasty:_ALT_vs_SLT. Accessed June 8, 2026.

American Academy of Ophthalmology (AAO). Eye Wiki; Microinvasive glaucoma surgery (MIGS). May 2023d. Available at: https://eyewiki.org/Microinvasive_Glaucoma_Surgery_(MIGS). Accessed June 8, 2026.

American Academy of Ophthalmology (AAO). Preferred Practice Pattern Guidelines. Primary open-angle glaucoma. AAO PPP Glaucoma Committee. 2020. Updated February 2026. Available at: https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp. Accessed June 8, 2026.

Ang BCH, Lim SY, Dorairaj S. Intra-operative optical coherence tomography in glaucoma surgery-a systematic review. Eye (Lond). 2020 Jan;34(1):168-177.

Arimura S, Iwasaki K, Orii Y, et al. Randomised clinical trial for morphological changes of trabecular meshwork between Kahook dual-blade goniotomy and ab interno trabeculotomy with a microhook. Sci Rep. 2023 Nov;13(1):20783.

Baskaran M, Kumar RS, Friedman DS, et al. The Singapore asymptomatic narrow angles laser iridotomy study: five-year results of a randomized controlled trial. Ophthalmology. 2022 Feb;129(2):147-158.

Baykara M, Poroy C, Erseven C. Surgical outcomes of combined gonioscopy-assisted transluminal trabeculotomy and cataract surgery. Indian J Ophthalmol. 2019 Apr;67(4):505-508.

Bayliss JM, Ng WS, Waugh N, et al. Laser peripheral iridoplasty for chronic angle closure. Cochrane Database Syst Rev. 2021 Mar;3(3):CD006746.

Belkin A, Chaban YV, Waldner D, et al. Gonioscopy-assisted transluminal trabeculotomy is an effective surgical treatment for uveitic glaucoma. Br J Ophthalmol. 2023 May;107(5):690-697.

Bengtsson B, Heijl A, Aspberg J, et al. The glaucoma intensive treatment study (GITS): a randomized controlled trial comparing intensive and standard treatment on 5 years visual field development. Am J Ophthalmol. 2024 Oct;266:274-288.

Berlin M, Harms-Toeteberg M, Kim E, et al. Excimer laser trabeculostomy: an effective microinvasive glaucoma surgery procedure for open-angle glaucoma. Laser Surgery Education Center. American Academy of Ophthalmology. December 19, 2013.

Bravetti GE, Gillmann K, Salinas L, et al. Surgical outcomes of excisional goniotomy using the Kahook Dual Blade in severe and refractory glaucoma: 12-month results. Eye (Lond). 2023 Jun;37(8):1608-1613.

Buffault J, Baudouin C, Labbé A. XEN® Gel Stent for management of chronic open angle glaucoma: a review of the literature. J Fr Ophtalmol. 2019 Feb;42(2):e37-e46.

Charytonowicz A, Błażowski J, Konopińska J. Evaluation of iStent Micro-Bypass vs. Kahook Dual Blade goniotomy with phacoemulsification in open-angle glaucoma: a systematic review. J Clin Med. 2025 Aug;14(16):5819.

Chavez MP, Guedes GB, Pasqualotto E, et al. Selective laser trabeculoplasty versus medical therapy for the treatment of open angle glaucoma or ocular hypertension: a systematic review and meta-analysis of randomized controlled trials. J Glaucoma. 2024 Dec;33(12):973-986.

Chen KY, Chan HC, Chan CM. What is the long-term efficacy and safety of selective laser trabeculoplasty in the management of primary open-angle glaucoma? A systematic review and meta-analysis. Photodiagnosis Photodyn Ther. 2025 Dec;56:104743.

Chen MF, Kim CH, Coleman AL. Cyclodestructive procedures for refractory glaucoma. Cochrane Database Syst Rev. 2019 Mar;3(3):CD012223.

Chen TC, Chen PP, Francis BA, et al. Pediatric glaucoma surgery: a report by the American Academy of Ophthalmology. Ophthalmology. 2014 Nov;121(11):2107-2115. Updated 2020.

Chen XZ, Liang ZQ, Yang KY, et al. The outcomes of XEN Gel Stent implantation: a systematic review and meta-analysis. Front Med (Lausanne). 2022 Feb;9:804847.

Chopra V, Takusagawa HL, Rosdahl JA, et al. Aqueous shunts with extraocular reservoir for open-angle adult glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology. 2024 Feb;131(2):227-239.

Dahlgren T, Ayala M, Zetterberg M. Predictors of selective laser trabeculoplasty efficacy: results from the Swedish optimal selective laser trabeculoplasty multicenter randomized controlled trial. Ophthalmol Glaucoma. 2026 Jan-Feb;9(1):15-25.

De Gregorio A, Pedrotti E, Russo L, et al. Minimally invasive combined glaucoma, and cataract surgery: clinical results of the smallest ab interno gel stent. Int Ophthalmol. 2018 Jun;38(3):1129-1134.

de Jong L, Lafuma A, Aguadé AS, et al. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. Clin Ophthalmol. 2011;5:527-533.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Deubel C, Böhringer D, Anton A, et al. Long-term follow-up of intraocular pressure and pressure-lowering medication in patients following excimer laser trabeculotomy. Graefes Arch Clin Exp Ophthalmol. 2021 Apr;259(4):957-962.

Dorairaj SK, Kahook MY, Williamson BK, et al. A multicenter retrospective comparison of goniotomy versus trabecular bypass device implantation in glaucoma patients undergoing cataract extraction. Clin Ophthalmol. 2018 Apr;12:791-797.

Durr GM, Töteberg-Harms M, Lewis R, et al. Current review of excimer laser trabeculostomy. Eye Vis (Lond). 2020 May;7:24.

ECRI. Hydrus Microstent (Alcon, Inc.) for treating open-angle glaucoma. Plymouth Meeting (PA): ECRI Institute; 2019 Jul 31. (Clinical Evidence Assessment). Updated August 2024.

ECRI. iStent Inject Trabecular Microbypass System (Glaukos Corp.) for treating open-angle glaucoma during cataract surgery. Plymouth Meeting (PA): ECRI Institute; 2019 Nov 25. (Custom Product Brief).

ECRI. Kahook Dual Blade GLIDE (New World Medical, Inc.) for treating glaucoma. Plymouth Meeting (PA): ECRI; 2018 Aug 28. (Custom Product Brief). Updated April 2023.

ECRI. Omni Surgical System (Sight Sciences, Inc.) for treating open-angle glaucoma. Plymouth Meeting (PA): ECRI; 2021 Jan 29. (Clinical Evidence Assessment). Updated December 2023.

ECRI. Streamline Surgical System (New World Medical) for treating glaucoma. Plymouth Meeting (PA): ECRI Institute; 2024 Aug 27. (Clinical Evidence Assessment).

ECRI. Trabectome (MicroSurgical Technology, Inc.) for treating glaucoma. Plymouth Meeting (PA): ECRI; 2021 Jan 26. (Clinical Evidence Assessment).

ECRI. XEN Gel Stent (Allergan plc) for treating open-angle glaucoma. Plymouth Meeting (PA): ECRI; 2021 Mar 2. (Clinical Evidence Assessment). Updated March 2025.

ElMallah MK, Seibold LK, Kahook MY, et al.; KDB Goniotomy Study Group. 12-month retrospective comparison of Kahook dual blade excisional goniotomy with iStent trabecular bypass device implantation in glaucomatous eyes at the time of cataract surgery. Adv Ther. 2019 Sep;36(9):2515-2527.

Falkenberry S, Singh IP, Crane CJ, et al. Excisional goniotomy vs trabecular microbypass stent implantation: a prospective randomized clinical trial in eyes with mild to moderate open-angle glaucoma. J Cataract Refract Surg. 2020 Aug;46(8):1165-1171.

Fan Gaskin JC, Bigirimana D, Kong GYX, et al. Glaucoma Investigation and Research Unit, Royal Victorian Eye and Ear Hospital. Prospective, randomized controlled trial of cataract surgery vs combined cataract surgery with insertion of iStent Inject. Ophthalmol Glaucoma. 2024 Jul-Aug;7(4):326-334.

Gagrani M, Garg I, Ghate D. Surgical interventions for primary congenital glaucoma. Cochrane Database Syst Rev. 2020 Aug;8:CD008213.

Gallardo MJ, Pyfer MF, Vold SD, et al. Canaloplasty and trabeculotomy combined with phacoemulsification for glaucoma: 12-month results of the GEMINI study. Clin Ophthalmol. 2022 Apr;16:1225-1234.

Gallardo MJ, Sarkisian SR Jr, Vold SD, et al. Canaloplasty and trabeculotomy combined with phacoemulsification in open-angle glaucoma: interim results from the GEMINI study. Clin Ophthalmol. 2021 Feb;15:481-489.

Gallardo MJ, Supnet RA, Ahmed IIK. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clin Ophthalmol. 2018a Oct;12:2149-2155.

Gan L, Wang L, Chen J, et al. Complications of XEN gel stent implantation for the treatment of glaucoma: a systematic review. Front Med (Lausanne). 2024 May;11:1360051.

Gazzard G, Congdon N, Azuara-Blanco A, et al. GLAUrious study group. Randomized noninferiority trial of direct selective laser trabeculoplasty in open-angle glaucoma and ocular hypertension: GLAUrious study. Ophthalmology. 2025 Oct;132(10):1091-1104.

Gazzard G, Konstantakopoulou E, Garway-Heath D, et al.; LiGHT Trial Study Group. Laser in Glaucoma and Ocular Hypertension (LiGHT) trial: six-year results of primary selective laser trabeculoplasty versus eye drops for the treatment of glaucoma and ocular hypertension. Ophthalmology. 2023 Feb;130(2):139-151.

Gedde SJ, Bowden EC, Challa P, et al.; American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Committee. Primary open-angle glaucoma Preferred Practice Pattern®. Ophthalmology. 2026 Apr;133(4):P1-P103.

Ghate D and Wang X. Surgical interventions for primary congenital glaucoma. Cochrane Database Syst Rev. 2015 Jan;1:CD008213.

Goldberg DF, Orlich C, Flowers BE, et al. A randomized controlled trial comparing STREAMLINE canaloplasty to trabecular micro-bypass stent implantation in primary open-angle glaucoma. Clin Ophthalmol. 2024 Oct;18:2917-2928.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Grabska-Liberek I, Duda P, Rogowska M, et al. 12-month interim results of a prospective study of patients with mild to moderate open-angle glaucoma undergoing combined viscodilation of Schlemm's canal and collector channels and 360° trabeculotomy as a standalone procedure or combined with cataract surgery. Eur J Ophthalmol. 2022 Jan;32(1):309-315.

Grover DS, Smith O, Fellman RL, et al. Gonioscopy-assisted transluminal trabeculotomy: an ab interno circumferential trabeculotomy: 24 months follow-up. J Glaucoma. 2018 May;27(5):393-401.

Guedes J, Amaral DC, de Oliveira Caneca K, et al. Kahook dual blade goniotomy versus iStent implantation combined with phacoemulsification: a systematic review and meta-analysis. J Glaucoma. 2025 Mar;34(3):232-247.

Guedes RAP, Gravina DM, Lake JC, et al. Intermediate results of iStent or iStent inject implantation combined with cataract surgery in a real-world setting: a longitudinal retrospective study. Ophthalmol Ther. 2019 Mar;8(1):87-100.

Guo CY, Qi XH, Qi JM. Systematic review and meta-analysis of treating open angle glaucoma with gonioscopy-assisted transluminal trabeculotomy. Int J Ophthalmol. 2020 Feb;13(2):317-324.

Gupta S, Panigrahi A, R A, et al. Outcomes of circumferential versus hemi-gonioscopy-assisted transluminal trabeculotomy for congenital glaucoma. Am J Ophthalmol. 2025 Mar;271:149-155.

Hayes, Inc. Evidence Analysis Research Brief. Optical coherence tomography-guided laser trabeculotomy for treatment of glaucoma. Hayes, Inc. May 31, 2024. Updated January 26, 2026.

Hayes, Inc. Health Technology Assessment. Canaloplasty for open-angle glaucoma. Hayes, Inc. January 13, 2020. Updated April 2023.

Hayes, Inc. Health Technology Assessment. XEN Glaucoma Treatment System (Allergan) for treatment of open-angle glaucoma. Hayes, Inc. December 2019. Updated April 2023.

Healey PR, Clement CI, Kerr NM, et al. Standalone iStent trabecular micro-bypass glaucoma surgery: a systematic review and meta-analysis. J Glaucoma. 2021 Jul;30(7):606-620.

Hengerer FH, Auffarth GU, Riffel C, et al. Prospective, non-randomized, 36-month study of second-generation trabecular micro-bypass stents with phacoemulsification in eyes with various types of glaucoma. Ophthalmol Ther. 2018 Dec;7(2):405-415.

Hengerer FH, Kohnen T, Mueller M, et al. Ab interno gel implant for the treatment of glaucoma patients with or without prior glaucoma surgery: 1-year results. J Glaucoma. 2017 Dec;26(12):1130-1136.

Hirsch L, Cotliar J, Vold S, et al. Canaloplasty and trabeculotomy ab interno with the OMNI system combined with cataract surgery in open-angle glaucoma: 12-month outcomes from the ROMEO study. J Cataract Refract Surg. 2021 Jul;47(7):907-915.

Hu K, Shah A, Virgili G, et al. Ab interno trabecular bypass surgery with Trabectome for open-angle glaucoma. Cochrane Database Syst Rev. 2021 Feb;2(2):CD011693.

Hu R, Guo D, Hong N, et al. Comparison of Hydrus and iStent microinvasive glaucoma surgery implants in combination with phacoemulsification for treatment of open-angle glaucoma: systematic review and network meta-analysis. BMJ Open. 2022 Jun;12(6):e051496.

Huang H, Bao WJ, Yamamoto T, et al. Postoperative outcome of three different procedures for childhood glaucoma. Clin Ophthalmol. 2018 Dec;13:1-7.

Hubayni R, Qedair J, Aljahdali FF, et al. Efficacy and safety of ab-externo approach versus ab-interno approach of XEN45 Gel Stent implantation: a systematic review and meta-analysis. Clin Ophthalmol. 2026 Feb;20:575562.

Hughes T and Traynor M. Clinical results of ab interno canaloplasty in patients with open-angle glaucoma. Clin Ophthalmol. 2020 Oct;14:3641-3650.

Inatani M, Hirai T, Sasaki N, et al. A 3-year post-marketing surveillance study of EX-PRESS™ Glaucoma Filtration Device in Japanese eyes. Adv Ther. 2026 Jan;43(1):184-199.

Islamaj E, Wubbels RJ, de Waard PWT. Primary Baerveldt versus trabeculectomy study after 5 years of follow-up. Acta Ophthalmol. 2020 Jun;98(4):400-407.

Ji PX, Pickel L, Balas M, et al. Progression of primary angle closure suspects: a systematic review and meta-analysis. Eye (Lond). 2025 Apr;39(5):899-905.

Jones J, Koch DD, Vold S, et al. Results from the United States cohort of the HORIZON trial of a Schlemm canal microstent to reduce intraocular pressure in primary open-angle glaucoma. J Cataract Refract Surg. 2019 Sep;45(9):1305-1315.

Kahale F, Chanbour W, El Zein L, et al. Phacoemulsification with and without iStent: a systematic review and meta-analysis of comparative studies. Ophthalmic Res. 2023;66(1):1020-1029.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Kailani O, Mosaed S, Hengerer FH, et al. Systematic review and meta-analysis of the clinical effectiveness, safety, humanistic and economic burden of the OMNI® surgical system and its predecessors. Eur J Ophthalmol. 2026 Mar;36(2):282-295.

Klabe K and Kaymak H. Standalone trabeculotomy and viscodilation of Schlemm's canal and collector channels in open-angle glaucoma using the OMNI Surgical System: 24-month outcomes. Clin Ophthalmol. 2021 Jul;15:3121-3129.

Krupin T, Ritch R, Camras CB, et al. A long Krupin-Denver valve implant attached to a 180 degrees scleral explant for glaucoma surgery. Ophthalmology. 1988 Sep;95(9):1174-1180.

Lavia C, Dallorto L, Maule M, et al. Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: A systematic review and meta-analysis. PLoS One. 2017 Aug 29;12(8):e0183142.

Lazcano-Gomez G, Garg SJ, Yeu E, et al. Interim analysis of STREAMLINE® Surgical System clinical outcomes in eyes with glaucoma. Clin Ophthalmol. 2022 Apr;16:1313-1320.

Le C, Kazaryan S, Hubbell M, et al. Surgical outcomes of phacoemulsification followed by iStent implantation versus goniotomy with the Kahook Dual Blade in patients with mild primary open-angle glaucoma with a minimum of 12-month follow-up. J Glaucoma. 2019 May;28(5):411-414.

Lee YJ, Ha A, Kang D, et al. Comparative efficacies of 13 surgical interventions for primary congenital glaucoma in children: a network meta-analysis of randomized clinical trials. Int J Surg. 2023 Apr;109(4):953-962.

Luo N, Liu M, Hao M, et al. Comparison of tube shunt implantation and trabeculectomy for glaucoma: a systematic review and meta-analysis. BMJ Open. 2023 Apr;13(4):e065921.

Martínez-de-la-Casa JM, Marcos-Parra MT, Millá-Griñó E, et al. Three-year outcomes and safety of the XEN63 Gel Stent: a multicenter prospective study in primary open-angle glaucoma. J Clin Med. 2026 May;15(9):3528.

McNiel CL, Sanchez FG, Rees JP, et al. Intraocular pressure, and medication burden with cataract surgery alone, or cataract surgery combined with trabecular bypass or goniotomy. J Glaucoma. 2022 Jun;31(6):423-429.

Miura Y and Fukuda K. Comparison of different procedures in a combination of ab interno microhook trabeculotomy and cataract surgery. J Clin Med. 2022 Jan;11(3):738.

Moreno-Valladares A, Vinokurtseva A, González-Rodríguez JM, et al. 12-month intraocular pressure and hypotensive medications outcomes after phaco-ELIOS procedure-a real world study. J Glaucoma. 2025 Aug;34(8):585-590.

Myers JS, Lamrani R, Hallaj S, et al. 10-year clinical outcomes of tube shunt surgery at a tertiary care center. Am J Ophthalmol. 2023 Sep;253:132-141.

Nagy ZZ, Kranitz K, Ahmed IIK, et al. First-in-human safety study of femtosecond laser image-guided trabeculotomy for glaucoma treatment: 24-month outcomes. Ophthalmol Sci. 2023 Apr;3(4):100313.

National Institute for Health and Care Excellence (NICE). Ab externo canaloplasty for primary open-angle glaucoma. Interventional procedures guidance. Sep 2017.

National Institute for Health and Care Excellence (NICE). Ab interno canaloplasty for primary open-angle glaucoma. Interventional procedures guidance. Nov 2022.

National Institute for Health and Care Excellence (NICE). Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension. Apr 2009. Updated November 2017.

National Institute for Health and Care Excellence (NICE). Trabecular stent bypass microsurgery for open angle glaucoma. Interventional procedures guidance (IPG 575). Feb 2017.

Nguyen HX, Nguyen ND, Nguyen HT, et al. Comparing combined laser iridoplasty and surgical iridectomy with trabeculectomy in treatment of refractory acute primary angle closure without significant cataract: a randomized controlled trial. Eye (Lond). 2023 Jul;37(10):2139-2144.

Ondrejka S and Körber N. 360° ab-interno Schlemm's canal viscodilation in primary open-angle glaucoma. Clin Ophthalmol. 2019 Jul;13:1235-1246.

Ondrejka S, Körber N, Dhamdhere K. Long-term effect of canaloplasty on intraocular pressure and use of intraocular pressure-lowering medications in patients with open-angle glaucoma. J Cataract Refract Surg. 2022 Dec;48(12):1388-1393.

Otarola F, Virgili G, Shah A, et al. Ab interno trabecular bypass surgery with Schlemm’s canal microstent (Hydrus) for open angle glaucoma. Cochrane Database Syst Rev. 2020 Mar;3(3):CD012740.

Otsuka M, Tojo N, Yamazaki H, et al. Compared to trabeculectomy, Ex-Press® surgery significantly decreased the loss of corneal endothelial cell density in low-intraocular-pressure glaucoma: 3-year follow-up. Clin Ophthalmol. 2024 Oct;18:3009-3015.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, et al. A randomized trial of a Schlemm's canal microstent with phacoemulsification for reducing intraocular pressure in open-angle glaucoma. Ophthalmology. 2015 Jul;122(7):1283-1293.

Popovic M, Campos-Moller X, Saheb H, et al. Efficacy and adverse event profile of the iStent and iStent Inject trabecular micro-bypass for open-angle glaucoma: a meta-analysis. J Curr Glaucoma Pract. 2018 May-Aug;12(2):67-84.

Prum BE Jr, Rosenberg LF, Gedde SJ, et al. Primary open-angle glaucoma Preferred Practice Pattern (®) guidelines. Ophthalmology. 2016 Jan;123(1):P41-P111.

Pyfer MF, Gallardo M, Campbell A, et al. Suppression of diurnal (9AM-4PM) IOP fluctuations with minimally invasive glaucoma surgery: an analysis of data from the prospective, multicenter, single-arm GEMINI study. Clin Ophthalmol. 2021 Sep;15:3931-3938.

Qiao Y, Tan C, Chen X, et al. Gonioscopy-assisted transluminal trabeculotomy versus goniotomy with Kahook Dual Blade in patients with uncontrolled juvenile open-angle glaucoma: a retrospective study. BMC Ophthalmol. 2021 Nov;21(1):395.

Qin J, Zhang Y, Zhang C, et al. Efficacy and safety of laser peripheral iridoplasty with different energy levels and locations in the treatment of primary angle closure disease assessed by swept-source anterior segment optical coherence tomography. BMC Ophthalmol. 2023 Apr;23(1):149.

Radhakrishnan S, Chen PP, Junk AK, et al. Laser peripheral iridotomy in primary angle closure: a report by the American Academy of Ophthalmology. Ophthalmology. 2018 Jul;125(7):1110-1120.

Radwan L, El Jalbout JD, Trad K, et al. Outcomes of phacoemulsification with or without Kahook Dual Blade goniotomy for glaucoma patients with cataract. J Glaucoma. 2024 Oct;33(10):769-779.

Raja A, Bhimani S, Alim Ur Rahman H, et al. Meta-analysis of Molteno glaucoma implants and Ahmed glaucoma valves: insights into efficacy and safety for complex glaucoma. Front Ophthalmol (Lausanne). 2023 Dec;3:1307439.

Rauchegger T, Angermann R, Willeit P, et al. Two-year outcomes of minimally invasive XEN Gel Stent implantation in primary open-angle and pseudoexfoliation glaucoma. Acta Ophthalmol. 2021 Jun;99(4):369-375.

Salimi A, Matar B, Harasymowycz P. Five-year outcomes of a Schlemm's canal microstent (Hydrus Microstent) with cataract surgery in open angle glaucoma: real-world results. Can J Ophthalmol. 2026 Apr;61(2):309-318.

Samuelson T. Combined glaucoma procedures. Cataract & Refractive Surgery Today. July 2008.

Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: the HORIZON study. Ophthalmology. 2019b Jan;126(1):29-37.

Samuelson TW, Katz LJ, Wells JM, et al., US iStent Study Group. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. Ophthalmology. 2011 Mar;118(3):459-467.

Samuelson TW, Sarkisian SR Jr, Lubeck DM, et al. Prospective, randomized, controlled pivotal trial of iStent inject trabecular micro-bypass in primary open-angle glaucoma and cataract: two-year results. Ophthalmology. 2019a Jun;126(6):811-821.

Sharif RK, Aljahdali FF, Aljabri HM, et al. Phacoemulsification versus laser peripheral iridotomy for treating primary angle closure glaucoma: a systematic review and meta-analysis. Clin Ophthalmol. 2024 Apr;18:1023-1032.

Sharkawi E, Lindegger DJ, Artes PH, et al. Outcomes of gonioscopy-assisted transluminal trabeculotomy in pseudoexfoliative glaucoma: 24-month follow-up. Br J Ophthalmol. 2021 Jul;105(7):977-982.

Sieck EG, Epstein RS, Kennedy JB, et al. Outcomes of Kahook Dual Blade goniotomy with and without phacoemulsification cataract extraction. Ophthalmol Glaucoma. 2018 Jul-Aug;1(1):75-81.

So S, Wang TQ, Thind A, et al. Selective laser trabeculoplasty compared to medication for open-angle glaucoma patients: a systematic review and meta-analysis. J Ophthalmol. 2026 Jan;2026:9102711.

SooHoo JR, Seibold LK, Kahook MY. Ab interno trabeculectomy in the adult patient. Middle East Afr J Ophthalmol. 2015 Jan-Mar;22(1):25-29.

Sun Y, Zhang B, Zhou R, et al. Trabeculectomy and EX-PRESS implantation in open-angle glaucoma: an updated meta-analysis of randomized controlled trials. J Ophthalmol. 2019 Sep;2019:2071506.

Takusagawa HL, Hoguet A, Sit AJ, et al. Selective laser trabeculoplasty for the treatment of glaucoma. A report by the American Academy of Ophthalmology. Ophthalmology. 2024 Jan;131(1):37-47.

Tan NE, Tracer N, Terraciano A, et al. Comparison of safety and efficacy between ab interno and ab externo approaches to XEN gel stent placement. Clin Ophthalmol. 2021 Jan;15:299-305.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.

Tokumo K, Okada N, Onoe H, et al. Ex-PRESS implantation versus trabeculectomy for long-term maintenance in patients with open-angle glaucoma. Clin Ophthalmol. 2023 Aug;17:2525-2537.

Toneatto G, Zeppieri M, Papa V, et al. 360° ab-interno Schlemm's canal viscodilation with OMNI viscosurgical systems for open-angle glaucoma-midterm results. J Clin Med. 2022 Jan;11(1):259.

Ventura-Abreu N, García-Feijoo J, Pazos M, et al. Twelve-month results of ab interno trabeculectomy with Kahook Dual Blade: an interventional, randomized, controlled clinical study. Graefes Arch Clin Exp Ophthalmol. 2021 Sep;259(9):2771-2781.

Vold SD, Williamson BK, Hirsch L, et al. Canaloplasty and trabeculotomy with the OMNI system in pseudophakic patients with open angle glaucoma: the ROMEO study. Ophthalmol Glaucoma. 2021 Mar-Apr;4(2):173-181.

Wong HJ, Sheng J, Anggreni D, et al. Comparative efficacy of standalone ab-interno canaloplasty versus ab-interno canaloplasty combined with phacoemulsification: a systematic review and meta-analysis. Clin Exp Ophthalmol. May 5, 2026. Online ahead of print.

XEN® Gel Stent manufacturer's website. Available at: https://hcp.xengelstent.com/. December 2023. Accessed May 5, 2026.

Zhu D, Shah P, Zhang C, et al. Standalone canaloplasty and trabeculotomy using the OMNI surgical system in patients with open angle glaucoma: a systematic review and meta-analysis. J Glaucoma. 2025 Nov;34(11):949-958.

Policy History/Revision Information

Date	Summary of Changes
09/01/2026	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0443LL

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.

Proprietary Information of UnitedHealthcare. Copyright 2026 United HealthCare Services, Inc.