Anthem

Clinical UM Guideline

Subject: Intraocular Anterior Segment Aqueous Drainage Devices (without extraocular reservoir)
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Description

This document addresses intraocular anterior segment aqueous humor drainage devices (without extraocular reservoir) used in the treatment of glaucoma (open-angle glaucoma; refractory, primary and secondary) to reduce intraocular pressure (IOP). Intraocular anterior segment aqueous drainage devices include:

- Ex-PRESS® Glaucoma Filtration Device, previously known as the Ex-PRESS™ Mini Glaucoma Shunt (Alcon®, Fort Worth, TX)
- Hydrus® Microstent (Ivantis, Inc., Irvine, CA)
- iStent infinite Trabecular Micro-Bypass System, Model iS3 (Glaukos® Corp., Aliso Viejo, CA)
- iStent inject® Trabecular Micro-Bypass System (Glaukos® Corp., Aliso Viejo, CA)
- iStent Trabecular Micro-Bypass Stent (Glaukos® Corp., Aliso Viejo, CA)
- XEN® Glaucoma Treatment System (Abbvie, North Chicago, IL)

This document does not address Food and Drug administration (FDA)-approved traditional aqueous humor shunting devices. Examples include:

- Baerveldt Glaucoma Shunt (Advanced Medical Optics, Inc., Santa Ana, CA);
- Ahmed™ Glaucoma Valve AGV™ (New World Medical, Inc., Rancho Cucamonga, CA);
- Krupin (Eagle Vision, Inc, Memphis, TN);
- Molteno Implant (Molteno Ophthalmic Ltd., Dunedin, New Zealand).

Note: For information about other proposed surgical procedures for treatment of glaucoma see:

- SURG.00095 Viscocanalostomy and Canaloplasty

Clinical Indications

Medically Necessary:

Insertion of the Ex-PRESS Glaucoma Filtration Device is considered **medically necessary** when the following criteria are met:

A. For the treatment of ***refractory open-angle glaucoma*** (primary and secondary); **and**
B. When medical therapies have failed to control intraocular pressure.

Insertion of the Hydrus Microstent, iStent Trabecular Micro-Bypass Stent system, or the iStent inject Trabecular Micro-Bypass System is considered **medically necessary** when the following criteria are met:

A. In conjunction with cataract surgery; **and**
B. As a treatment to reduce intraocular pressure in adults with mild to moderate ***open-angle glaucoma*; and**
C. When medical therapies have failed to control intraocular pressure.

Insertion of the XEN Glaucoma Treatment System is considered **medically necessary** when the following criteria are met:

A. For the treatment of ***refractory open-angle glaucoma;*** **and**
B. When both medical therapies and previous surgical treatment have failed to control intraocular pressure.

Insertion of the iStent infinite Trabecular Micro-Bypass Stent System, model iS3 is considered **medically necessary** when the following criteria are met:

A. For the treatment of ***primary open-angle glaucoma;*** **and**
B. When both medical therapies and previous surgical treatment have failed to control intraocular pressure.

Not Medically Necessary:

Insertion of the Ex-PRESS Glaucoma Filtration Device, Hydrus Microstent, iStent infinite Trabecular Micro-Bypass System (Model iS3), iStent Trabecular Micro-Bypass Stent, and the iStent inject Trabecular Micro-Bypass System is considered **not medically necessary** when above criteria are not met and for all other indications.

Insertion of anterior segment aqueous drainage devices inserted internally or externally without an extraocular reservoir (other than the Ex-PRESS Glaucoma Filtration Device, the Hydrus Microstent, the iStent infinite Trabecular Micro-Bypass System [Model iS3], the iStent Trabecular Micro-Bypass Stent, the iStent inject Trabecular Micro-Bypass System, and the XEN Glaucoma Treatment System) including the CyPass System is considered **not medically necessary** as a method to reduce intraocular pressure for the treatment of glaucoma.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When Services may be Medically Necessary when criteria are met(for the Ex-PRESS Glaucoma Filtration Device, the Hydrus Microstent, the iStent Trabecular Micro-Bypass Stent, the iStent inject Trabecular Micro-Bypass System, the iStent infinite Trabecular Micro-Bypass System, and the XEN Glaucoma Treatment System):

CPT	
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach [for example, Ex-PRESS Glaucoma Filtration Device]
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, 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 (eg, 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 (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device [for example, XEN Gel Stent]
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device [for example, XEN Gel Stent]
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
ICD-10 Procedure	
08123J4	Bypass right anterior chamber to sclera with synthetic substitute, percutaneous approach
08133J4	Bypass left anterior chamber to sclera with synthetic substitute, percutaneous approach
ICD-10 Diagnosis	
H40.10X0-H40.10X4	Unspecified open-angle glaucoma
H40.1110-H40.1194	Primary open-angle glaucoma
H40.1210-H40.159	Other open-angle glaucoma (low-tension, pigmentary, capsular with pseudoexfoliation of lens, residual stage)
H40.50X0-H40.53X4	Glaucoma secondary to other eye disorders

When Services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, and for all other diagnoses not listed.

When Services are also Not Medically Necessary:

CPT	
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space [CyPass system]
ICD-10 Diagnosis	
	All diagnoses

Discussion/General Information

Surgical intervention is indicated in the management of glaucoma when medication therapies have failed to adequately reduce IOP. Surgical procedures to which alternatives have been compared include trabeculectomy and cataract surgery. A trabeculectomy procedure creates a conjunctival reservoir or "filtering bleb" which reduces IOP by allowing aqueous humor to enter the subconjunctival space. Cataract surgery is also used to lower the IOP compared with the presurgical baseline. Resistance to the flow of aqueous fluid through the trabecular meshwork to Schlemm's canal is the primary mechanism that results in the development of elevated IOP and causes open-angle glaucoma (OAG). Devices to overcome this resistance and deliver aqueous fluid directly into the outflow system can result in lowering the intraocular pressure.

The American Academy of Ophthalmology (AAO) Preferred Practice Pattern® on Primary Open Angle Glaucoma (2020) provides recommendations for screening for primary open angle glaucoma (POAG) and the management of IOP:

> There are three main approaches to screening patients for PAOG; measuring the IOP, assessing the optic nerve head and retinal nerve fiber layer, and evaluating the visual field, either alone or in combination.
>
> When deciding to treat a glaucoma suspect patient, it is important to remember that the goal of treatment is to maintain the IOP in a range at which visual field loss is likely to significantly reduce a patient's health-related quality of life over his or her lifetime. The estimated upper limit of this range is considered the target pressure. The initial target pressure is an estimate and a means toward the ultimate goal of protecting the patient's vision. The target pressure should be individualized and may need adjustment further down or even up during the course of the disease.

Ex-PRESS Glaucoma Filtration Device, formerly known as Ex-PRESS™ Mini Glaucoma Shunt:
The Ex-PRESS Glaucoma Filtration Device is a single-piece, stainless steel implant which reduces IOP by diverting excess aqueous fluid from the anterior chamber to a subconjunctival bleb rather than an extraocular reservoir. The device is designed to regulate intraocular pressure in eyes suffering from glaucoma.

Maris and colleagues (2007) evaluated the Ex-PRESS implant in a single-center, retrospective, comparative study of 50 eyes in 49 participants treated with the Ex-PRESS shunt and compared their outcomes with 50 matched control eyes in 47 participants treated with trabeculectomy. Success was defined as intraocular pressure (IOP) greater than or equal to 5 mmHg and less than or equal to 20 mmHg with or without glaucoma medications, without further glaucoma surgery or removal of the implant. Average follow-up was 10.8 months (3.5-18) for the Ex-PRESS group and 11.2 months (3-15) for the trabeculectomy group. Although the mean IOP was higher in the early postoperative period in the Ex-PRESS group, the reduction of IOP was similar in both groups after 3 months. The

number of postoperative glaucoma medications was similar in both groups, and Kaplan-Meier survival cure analysis showed no significant difference in successful outcome between the two groups (p=0.59). However, postoperative hypotony and choroidal effusion were more frequent after trabeculectomy. This study was limited by its nonrandomized retrospective design and follow-up limited to less than 1 year.

A study by de Jong (2009) reported the results of a prospective, randomized trial of the Ex-PRESS mini implant. Seventy-eight participants (80 eyes) with primary open-angle glaucoma (POAG) were enrolled and randomized to either Ex-PRESS implantation under a scleral flap or trabeculectomy. Primary outcome measures were mean IOP, postoperative medication use, visual acuity, and incidence of complications. Complete success was defined as an IOP greater than 4 mmHg and less than 18 mmHg without the use of antiglaucoma medications. Postoperatively, 85% of individuals receiving the Ex-PRESS and 60% of individuals receiving trabeculectomy (p=0.0230) achieved complete success. At 1 year follow-up, complete success rates were 82% for Ex-PRESS and 47.5% for trabeculectomy (p=0.0020). Postoperative complications were similar in both groups. Although well designed, this single center trial limited measure of treatment durability to 1 year. At the present time, available evidence demonstrates the safety and efficacy of the Ex-PRESS Mini Glaucoma Shunt device for the treatment of OAG refractory to conventional medical management.

In 2011 de Jong and colleagues reported 5-year outcomes of the original randomized trial which compared Ex-PRESS implantation to trabeculectomy in participants with POAG. The authors concluded:

> The Ex-PRESS glaucoma filtration device controlled intraocular pressure 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 intraocular pressure medications after Ex-PRESS implantation, compared with 35.9% after trabeculectomy. The proportions became closer at year 5 (41% versus 53.9%). The responder rate was higher with Ex-PRESS and time to failure was longer. In addition, surgical interventions for complications were fewer after Ex-PRESS implantation.

The AAO preferred practice pattern on primary open-angle glaucoma (2020) indicated that:

> Retrospective studies and randomized clinical trials have reported similar IOP reduction and surgical success rates with trabeculectomy and Ex-PRESS. Several studies comparing Ex-PRESS with trabeculectomy found no significant differences in the rates of intraoperative and postoperative complications, but others have reported a higher incidence of early hypotony following trabeculectomy.

Hydrus Microstent
On August 10, 2018, Ivantis, Inc. received PMA approval for the Hydrus Microstent, indicated for use in conjunction with cataract surgery for the reduction of IOP in adults with mild to moderate POAG by acting as a support structure in one part of the natural drainage pathway of the eye (Schlemm's canal). The device is contraindicated for use in eyes with angle closure glaucoma, in eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle. The FDA approval was based on results from the Horizon study (NCT01539239); a 24-month multicenter, prospective, randomized, comparative study that enrolled 556 participants in a 2:1 fashion to undergo either implantation of Hydrus Microstent (HMS) after uncomplicated cataract surgery (Hydrus group; n=369) or cataract removal surgery alone without Hydrus Microstent (no microstent; [NMS]) (control group n=187) in one eye only. The primary effectiveness endpoints were the proportion of participants at 24 months demonstrating a 20% or greater reduction in unmedicated modified diurnal IOP (MDIOP) and change in mean MDIOP compared to baseline. Samuelson and colleagues (2019) reported the results from the Horizon study. The authors reported that:

> At 24 months, unmedicated MDIOP was reduced by ≥ 20% in 77.3% of HMS group eyes and in 57.8% of NMS group eyes (difference = 19.5%, 95% confidence interval [CI] 11.2%-27.8%, P < 0.001). The mean reduction in 24-month unmedicated MDIOP was -7.6±4.1 mmHg (mean ± standard deviation) in the HMS group and -5.3±3.9 mmHg in the NMS group (difference = -2.3 mmHg; 95% CI, -3.0 to -1.6; P < 0.001). The mean number of medications was reduced from 1.7±0.9 at baseline to 0.3±0.8 at 24 months in the HMS group and from 1.7±0.9 to 0.7±0.9 in the NMS group (difference = -0.4 medications; P < 0.001). There were no serious ocular adverse events related to the microstent, and no significant differences in safety parameters between the 2 groups.

The authors concluded that the “trial demonstrated superior reduction in MDIOP and medication use among subjects with mild-to-moderate POAG who received a Schlemm canal microstent combined with phacoemulsification compared with phacoemulsification alone.”

In 2022, Ahmed and colleagues published 5-year results of the HORIZON trial. In this prospective, multicenter, randomized controlled trial participants with cataract and POAG were randomized 2:1 to receive either HMS or no stent after successful cataract surgery. A total of 369 eyes received HMS treatment while 187 eyes received cataract surgery only. A 5-year follow-up was completed with 80% of participants available. The mean IOP was similar between the two treatment groups. At 5-year follow-up, the mean ± standard deviation IOP was 16.8 ± 3.1 mmHg in the HMS group and 17.2 ± 3.2 mmHg in the cataract surgery group. More participants remained medication free in the HMS group (66%) compared to the cataract surgery group (46%).

In 2023, Montesano and colleagues reported on an ad hoc analysis of participants from the HORIZON trial. Included was data regarding visual field progression for those participants with glaucoma who received cataract surgery alone versus cataract surgery with a Hydrus microstent. There were 556 participants who were randomized to either cataract surgery with Hydrus microstent (n=369) or cataract surgery alone (n=187). Participants were followed for 5 years. Primary outcome was the difference in the rate of progression of visual field damage between the two groups. The progression of visual field damage was faster in the cataract surgery alone group compared to those who received the Hydrus microstent along with cataract surgery.

iStent Trabecular Micro-Bypass Stent:
The iStent Trabecular Micro-Bypass Stent is implanted inside the eye during cataract surgery, the anterior segment aqueous drainage device is a small L-shaped titanium device inserted through a small temporal clear corneal incision, bypassing the trabecular meshwork and placed in into Schlemm’s canal at the lower nasal quadrant. This allows aqueous fluid from the anterior chamber to flow directly into the Schlemm’s canal toward the episcleral drainage system, thus avoiding or bypassing the trabecular meshwork. In addition the Hydrus Microstent and iStent inject Trabecular Micro-Bypass Stent System are other microstents implanted inside the eye during cataract surgery.

The iStent Trabecular Micro-Bypass Stent device is an anterior segment drainage device without an extraocular reservoir. It is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted using an internal approach into the trabeculum through the cornea creating a bypass between the anterior chamber and Schlemm’s canal. Aqueous fluid flows directly into the canal toward the episcleral drainage system. This device is designed to lower IOP without the formation of a filtering bleb. The iStent is the first microstent device to receive FDA approval for use in combination with cataract surgery to reduce pressure inside the eye in adults with a cataract and *mild* or *moderate* OAG that is currently being treated with medical therapy (ocular hypotensive medications [use of one to three medications]) to reduce IOP. The device approval was based on results from the iStent investigational device exemption (IDE) open-label multicenter randomized study reported to the FDA in 2010, with follow-up results reported at 12 months and 24 months. The

objective of the trial was to measure the incremental effect on IOP from iStent implantation over that of cataract surgery alone and to determine the potential benefit of combining two therapeutic treatments into one surgical event. The study included 240 eyes in 239 participants with mild to moderate OAG with IOP less than or equal to 24 mmHg controlled on 1 to 3 medications. Participants were required to have IOP of ≥ 22 mmHg and ≤ 36 mmHg after washout period of ocular hypotensive medications. At 1 year, 72% of participants in the treatment group (cataract surgery in conjunction with iStent) achieved study target IOP of 21 mmHg or lower without use of eye-pressure-lowering medications compared to 50% of the control group (difference 90% confidence interval [CI], p<0.001) who underwent cataract surgery alone. At 1 year, 66% of eyes in the treatment group and 48% of eyes in the control group achieved the secondary efficacy endpoint of an IOP reduction of 20% or more versus baseline IOP without medication (difference 90% CI, p=0.003). Authors reported safety results for the recent study and concluded that the iStent did not result in increased additional risk or adverse events (Samuelson, 2011). Although this study provides promising initial results for the iStent Trabecular Micro-Bypass stent and suggests it may be able to decrease IOP in individuals with mild to moderate OAG without use of medication for pressure management, intraocular medication can also be used to effectively maintain IOP ≤ 21 mmHg for the treatment of mild and moderate glaucoma.

In 2010, Fea reported results from a small prospective open-label clinical trial, with 36 participants randomized 2:1 to cataract surgery (control group [n=24]) or cataract surgery with iStent implantation (combined group [n=12]). The primary outcomes were IOP and reduction in medication use over 15 months and IOP after a 1-month washout with ocular hypotensive agents. The mean IOP was 15.7 ± 1.1 mmHg in the control group and 14.8 ± 1.2 mmHg in the combined group at 15 months, and IOP after washout period 19.2 ± 3.5 mmHg in the control group and 16.6 ± 3.1 mmHg in the combined group. The mean number of medications in the control group was 1.3 ± 1.0 and 0.4 ± 0.7 for the combined group (p=0.007); the proportion of participants on ocular hypotensive medications was 76% and 33%, respectively. The study was limited by small sample size and limited follow up. Additionally, the study measured IOP using a Goldmann tonometer calibrated in 2 mm segments with readings in between estimated and subject to rounding error. In 2015, Fea and colleagues reported results of the 4-year long-term follow-up; the authors concluded that “patients in the combination group maintained low IOP levels after long-term follow-up. Cataract surgery alone showed a loss of efficacy in controlled IOP over time. Both treatments reduced the number of ocular hypotensive medications prescribed.”

Craven and colleagues (2012) reported additional results from the same pivotal iStent study. The primary efficacy endpoint was target IOP 21 mmHg or less without ocular hypertensive medication at 12 months, and secondary efficacy endpoint was an IOP reduction of 20% or more versus baseline IOP without medications at 12 months. “The mean IOP was 17.0 ± 2.8 mmHg on a mean of 0.2 ± 0.6 medications in the stent group and 17.0 ± 3.1 mm Hg on a mean of 0.4 ± 0.7 medications in the control group.” At 24 months, the IOP ≤ 21 with medications target was reached in 61% of eyes in the treatment group (cataract surgery in conjunction with iStent) compared to 50% in the control group (p=0.036) (difference 90% CI). The secondary outcome of IOP reduction of 20% or more without medications was 53% in the treatment group versus 44% in the control group (p=0.09) (difference 90% CI). The mean number of medications used (0.3 vs. 0.5) in individuals with mild to moderate OAG were no longer significantly different between the iStent group and control group at 2 years. The IOP measurements were essentially identical in terms of the risk of progression of disease. While there are statistical differences in the 1-year and 2-year outcomes for individuals with mild to moderate OAG with an iStent compared to cataract surgery alone, the durability and clinical significance of these results remain uncertain. In addition, the iStent group required additional surgical procedures and it is unclear whether further procedures will be required after 2 years. Based on these concerns, additional studies with long term follow-up are required to determine the clinical significance of the differences reported, the durability of those differences and whether net health outcomes are improved by using the iStent device.

Arriola-Villalobos and colleagues (2013) published the findings of a small prospective case series study of the iStent device used in conjunction with cataract surgery. This study involved 20 participants with either POAG (n=8), ocular hypertension (n=8), or pseudoexfoliative glaucoma (n=4). The authors report that IOP was significantly reduced from 19.95 ± 3.07 mmHg preoperatively to 16.75 ± 2.24 mmHg at 1 year follow-up (p<0.001). A significant decrease in the use of glaucoma medications was also noted (p<0.001). No visual acuity loss was reported. Another small case series study was described by Patel in 2013. This study included 44 participants with pseudoexfoliative glaucoma (n=6), low-tension glaucoma (n=4), angle recession (n=2), and POAG (n=32). Of these, 40 underwent combined cataract surgery and iStent placement. The remaining 4 had iStent placement only. Eleven participants had previously undergone laser trabeculoplasty. Mean IOP decreased from 21.5 mmHg at baseline to 16.5 mmHg at 6 months post-procedure (p<0.0001). A significant decrease in eye drop use was also reported, from 2.3 drops at baseline to 0.59 drops post-procedure (p<0.0001). These findings are promising, but their use is limited by the lack of controls, blinding, randomization, and small study population.

Neuhann (2015) studied a consecutive 62 eyes of 43 participants to evaluate the long-term safety and efficacy of the iStent Trabecular Micro-Bypass Stent. At the time of publication, 41 eyes had been studied for 3 years with the remainder continuing to be followed. Mean pre-operative IOP was 24.1 mmHg on a mean of 1.8 medications. Analyses of eyes with no secondary surgical intervention indicated an IOP of 14.8, 14.5 and 14.9 mm Hg at 12, 24 and 36 months post-operatively. Five eyes required additional surgery. Medications were eliminated in 74% of eyes at 36 months. There were no complications. Long-term results of iStent in combination with cataract surgery proved safe and effective in participants with ocular hypertension or glaucoma as measured by a sustained reduction in IOP and medication use and an excellent safety profile through 3 years after surgery.

Malvankar-Mehta and colleagues (2015) conducted a meta-analysis on the impact of minimally invasive glaucoma surgeries, including the iStent, in lowering the IOP independent from lens extraction. Thirty-seven studies of 2495 eyes met inclusion criteria. A 4% IOP reduction from baseline occurred following phacoemulsification as a solo procedure compared to 9% for one iStent placement and phacoemulsification; 27% reduction followed two iStent placements and phacoemulsification. Additionally, compared to lens extraction alone, iStent with cataract removal showed a significant reduction in medication use with a standard mean difference of -0.65 (95% CI, -1.18, -0.12). The authors concluded that “iStent with phacoemulsification significantly outperforms phacoemulsification alone.”

The AAO (2020) practice guideline for the management of POAG in adults reviews treatment options, with medical therapy being the most common intervention for the management of individuals with glaucoma to reduce the IOP 20%-30% below baseline, adjusting as needed based on disease course and severity. “Adequate treatment of glaucoma requires a high level of adherence to therapy. Frequently this is not achieved, and studies indicate relatively poor adherence to therapy.” Authors summarized treatment options for glaucoma offering trabecular micro-bypass stent as an alternative treatment:

> The iStent is FDA approved for implantation in combination with cataract extraction in patients with mild to moderate OAG. Studies suggest that implantation of multiple stents may provide better IOP lowering than a single stent; however, placement of more than one first-generation iStent is considered off-label use in the United States.

In summary, the iStent Trabecular Micro-Bypass Stent device is safe and effective for the management of individuals with mild to moderate glaucoma for which *medical management* (topical ocular hypotensive agents) has not been effective.

iStent inject Trabecular Micro-Bypass System
Voskanyan and colleagues (2014) reported findings from a European, prospective, open-label study that evaluated the safety and IOP

efficacy of two Glaukos Trabecular Micro-Bypass iStent® inject second generation devices in participants with OAG. The study was comprised of 99 participants who underwent implantation of two iStent injects per eye using the G2-0 injector or the G2-M-IS injector, with 12-month data available in 93% of participants (n=92/99). The primary endpoint, IOP ≤ 18 mmHg at 12 months without medications, was achieved in 66% of participants. Eighty-one percent of participants achieved a secondary endpoint, IOP ≤ 18 mmHg at 12 months regardless of medication. Limitations of the study include lack of a comparator group and long-term follow-up.

On June 25, 2018, Glaukos Corporation received PMA approval for the iStent inject Trabecular Micro-Bypass System (model G2-M-IS), indicated for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate POAG. The FDA approval is based on unpublished data from the ongoing iStent inject U.S. IDE pivotal study (NCT01461291), a prospective, randomized, comparative, multicenter phase 2/3 study that evaluated the safety and efficacy of iStent inject Trabecular Micro-Bypass System in conjunction with cataract surgery versus cataract surgery only in treatment of individuals with mild to moderate POAG. The study enrolled 504 participants (505 eyes) with mild-to-moderate POAG. Eyes were randomized in 3:1 fashion to undergo implantation of the iStent inject Trabecular Micro-Bypass System after uncomplicated cataract surgery (iStent inject group; n=387 eyes) or to undergo cataract surgery with iStent (control group; n=118 eyes).

The IDE pivotal study data found that the study's primary effectiveness endpoint was met; 75.8% of eyes in the iStent inject group and 61.9% in the Control group achieved a clinically significant (greater than or equal to 20%) reduction in medication-free diurnal IOP from baseline at 24 months. The secondary endpoint, a clinically significant mean change in medication-free diurnal IOP from baseline at 24 months, was met with a mean medication-free IOP reduction of 7.0 mmHg for the iStent inject cohort. Additional observed data at 24 months show that the iStent inject cohort achieved a 31% reduction, or 7.7 mmHg, in medication-free IOP from a medication-free mean baseline IOP of 24.8 mmHg to 17.1 mmHg. The overall rate of adverse events through 24 months in the iStent inject cohort was similar to control group (Product Information Label, 2018).

Samuelson and colleagues (2019b) reported the 2-year results of those with primary open-angle glaucoma who received either the iStent inject in combination with cataract surgery (n=387) or cataract surgery alone (n=118). Follow-up was 2 years with the primary effectiveness outcome a ≥ 20% reduction in diurnal IOP from baseline. The preoperative mean medicated IOP was 17.5 mmHg in the treatment group and 17.5 mmHg in the control group. At 2 years, the primary effectiveness end point was met, with 75.8% (288/380) in the treatment group and 61.9% (73/118) in the control group achieving a clinically significant (20%) reduction in medication-free diurnal IOP from baseline.

XEN Glaucoma Treatment System
On November 21, 2016, the XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector) was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of POAG, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. The XEN stent is a 6 mm-long gelatin implant designed to be implanted with mitomycin C via an ab-interno approach across the anterior chamber angle, into the subconjunctival space. The pivotal trial (Grover, 2017) is a Phase 3, prospective, multi-center, single-arm, open-label study that enrolled 65 individuals with refractory glaucoma who had previously failed filtering procedures, cilioablative procedures or maximally tolerated medical therapy. Inclusion criteria included 45 years of age or older, maximally tolerated medicated IOP of at least 20 mmHg and equal to or less than 35 mmHg, visual field mean distance score of -3 dB or worse and Shaffer angle grade of at least 3 or higher. Most participants (63.1%) had a prior incisional glaucoma procedure (e.g., trabeculectomy, tube shunt, canaloplasty, trabeculotomy, AquaFlow), 14 (21.5%) had undergone prior laser trabeculoplasty without an incisional glaucoma procedure, and 10 (15.4%) had no prior glaucoma procedures and were not responsive to maximally tolerated medical therapy. At 12-month follow-up, 52 individuals were available for analysis and the IOP was reduced by 25.1 (± 3.7) mmHg to 15.9 (± 5.2) mmHg. The 52 participants who completed the 12-month visit were using on average 1.7 (± 1.5) IOP-lowering medications compared to a mean baseline of 3.5 (± 1.0), and no individuals were using more medications than at baseline. There were no intraoperative or surgical complications, although 9 individuals (13.8%) required intraoperative stent removal and replacement with 11 devices in order to ensure proper placement (i.e., due to too much length in the anterior chamber). No reports of migration, exposure, hypotony, endophthalmitis, or unanticipated events were seen in the 53 participants evaluated after the 12-month visit. The FDA also considered unpublished data from a 2016 abstract presented at the American Society of Glaucoma's 26th annual meeting, and post-marketing data from the European Union (XEN FDA Label, 2016). The clinical trials conducted were manufacturer sponsored.

Schlenker and colleagues (2017) conducted an investigator-initiated, international, multicenter, retrospective cohort study of consecutive eyes with uncontrolled glaucoma who underwent either standalone microstent insertion with mitomycin C (MMC) or trabeculectomy with MMC. The study enrolled a total of 354 eyes of 293 participants, 185 eyes of 159 participants received the microstent and 169 eyes of 139 participants received the trabeculectomy. The study enrolled eligible participants (30 - 90 years old) with multiple types of glaucoma, with above-target IOP on maximum medical therapy. Participants were excluded if they had prior incisional filtering glaucoma surgery or a history of neovascular glaucoma, uveitic glaucoma, iridocorneal endothelial syndrome, and Axenfeld-Rieger syndrome. In summary, the authors reported, "there was no detectable difference in risk of failure and safety profiles between standalone ab interno microstent with MMC and trabeculectomy with MMC." The authors concluded that the ab interno gelatin microstent with MMC was noninferior to trabeculectomy plus MMC.

In individuals with refractory open-angle glaucoma, when both medical therapies and previous surgical treatment have failed to control intraocular pressure, adequate evidence exists to assess the efficacy and safety of the XEN Glaucoma Treatment System, as it pertains to a meaningful improvement in the net health outcome. The XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector) *does not require cataract surgery*; the use of XEN can precede or delay premature cataract removal.

iStent infinite Trabecular Micro-Bypass System, Model iS3
In August 2022 Glaukos Corporation was granted 510K clearance from the FDA for the*iStent infinite Trabecular Micro-Bypass System, Model iS3*, which has the same intended use as the predicate device and other devices regulated within the generic type of device known as aqueous shunt and implantable device. The iStent infinite is not substantially different from the XEN implant predicate device. The iStent infinite is intended to reduce IOP of the eye. It is indicated for use in adults with POAG in whom previous medical and surgical treatment has failed. "Although the iStent infinite and the XEN do not share identical technological characteristics, those differences do not raise different questions of safety and effectiveness" (iStent infinite Product Label Information, 2022).

A 2023 study by Sarkisian and colleagues evaluated the iStent infinite Trabecular Micro-Bypass System for those with open-angle glaucoma who had prior failed intervention. In this prospective, multicenter, single-arm, open-label trial, 72 participants received the implant and were followed for 12 months (with 71 participants available for analysis). The two primary endpoints were: proportion of individuals who achieved a ≥ 20% reduction in mean diurnal IOP while remaining on the same or fewer medications (responder effectiveness endpoint) and the mean change from baseline in mean diurnal IOP. In terms of the responder effectiveness endpoint, there were 76.1% of participants who had ≥ 20% reduction in mean diurnal IOP. The mean reduction in diurnal IOP was 5.9 mmHg from baseline to 12 months. There were no serious ocular adverse events, no failed implant attempts, no intraoperative adverse

events, and no unanticipated adverse events from the device. While the study limitations include the single-arm and open-label design, the results support the procedure for those with primary open-angle glaucoma uncontrolled medically or surgically.

CyPass Micro-Stent system
On July 29, 2016 Alcon Laboratories, Inc. was granted premarket approval (PMA) for the CyPass Micro-Stent system, indicated for use in conjunction with cataract surgery for the reduction of IOP in adults with mild to moderate POAG. On August 29, 2018 Alcon Laboratories, Inc. announced voluntary withdrawal of all versions of the CyPass Micro-Stent from the global market. The manufacturer has advised eye care providers to immediately cease further implantation with the CyPass Micro-Stent and to return any unused devices. The decision to withdraw use of the device from the market is based on analysis of 5-year post-surgery data from the COMPASS-XT long-term safety study; at 5-years the CyPass Micro-Stent group experienced statistically significant endothelial cell loss compared to the group who underwent cataract surgery only.

EyePass™ Glaucoma Implant

An implant currently under study, the EyePass™ Glaucoma Implant (GMP Companies, Inc., Ft. Lauderdale, FL) is another anterior segment drainage device without an extraocular reservoir. This device has a bidirectional shunt that also diverts aqueous fluid from the anterior chamber directly into Schlemm's canal. According to experts in the field of glaucoma treatment, some of these newer devices and techniques may eventually surpass the results achieved with trabeculectomy, which is the current gold standard surgical treatment option for glaucoma. However, to date, there is insufficient scientific evidence to support the safety and efficacy of this new device still under study; currently the device has not been granted FDA approval to market in the United States.

Traditional aqueous shunting devices placed in the eye via either an anterior chamber or pars plana approach with tubes that communicate with a reservoir sutured to the sclera in the subconjunctival space. Although these devices have advantages of being less prone to infection and discomfort and are more amenable to contact lens wear than traditional trabeculectomy, their implantation is technically difficult and may cause diplopia, due to interference with the rectus muscles, and corneal damage.

According to the AAO (2021), glaucoma is the second leading cause of blindness worldwide with nearly 75 million people affected, and it is estimated to impact nearly 111 million people worldwide by 2040, with POAG affecting nearly 3% of adults 40 and older. Glaucoma is a group of diseases, which can damage the eye's optic nerve and result in vision loss and blindness. POAG, the most common type of glaucoma, is associated with a buildup of aqueous fluid pressure within the eye, which can lead to visual field loss and optic nerve damage usually without any associated pain or discomfort. There is no visible abnormality in the anterior chamber angle; however, the aqueous fluid is unable to flow correctly.

In the management of POAG, the goal is to reduce the IOP to slow the development of optic nerve damage. The IOP can be reduced by medical treatment or surgery (alone or in combination). In POAG, IOP above 21 mmHg has been shown to increase rates of visual field loss. Presently, conventional medical management of the individual principally involves medication therapies (ocular hypotensive medications) to reduce elevated intraocular pressures in order to prevent or delay visual loss. Drug therapy may include alpha-agonist, beta-blockers, carbonic-anhydrase inhibitors, miotic agents, and prostaglandin analogs. When the maximum tolerated medical therapy fails to control progression of glaucomatous optic neuropathy, surgical care is considered the next treatment option. Surgical procedures include laser trabeculoplasty and incisional or filtering surgery, such as trabeculectomy or drainage implants.

Definitions

Aqueous Humor (vitreous humor/fluid): The clear aqueous gel that fills the space between the lens and the retina in the anterior chamber of the eye where it flows continuously in and out of the chamber and nourishes nearby tissues; this aqueous fluid leaves the chamber at the open angle where the cornea and the iris meet and flows through a spongy meshwork drain.

Glaucoma: A group of eye diseases characterized by an increase in intraocular pressure which causes pathological changes in the optic disk and typical defects in the field of vision.

- Open-angle glaucoma (OAG): A progressive form of glaucoma in which the drainage channel for the aqueous humor composed of the attachment at the edge of the iris and the junction of the sclera and cornea remains open and in which serious reduction in vision occurs only in the advanced stages of the disease due to tissue changes along the drainage channel.
- Primary open-angle glaucoma: Also known as chronic glaucoma is the most common type of glaucoma. POAG is associated with a build-up of aqueous fluid pressure within the eye, which can lead to visual field loss and optic nerve damage usually without any associated pain or discomfort. There is no abnormality in the anterior chamber angle; however, the aqueous fluid is unable to flow correctly.
- Refractory glaucoma: A type of glaucoma when intraocular pressure remains above values which are selected to slow or halt progression of the disease, despite having used multiple classes of medications.
- Secondary open-angle glaucoma (SOAG): Open angle glaucoma resulting from other medical conditions (e.g. Pseudoexfoliative glaucoma, Pigmentary glaucoma) or trauma.

Hypotony: This condition refers to abnormally low intraocular pressure of the intraocular fluid; this condition usually occurs as a complication of an underlying ocular disorder, such as glaucoma.

Intraocular pressure (IOP): The pressure within the chambers of the eye which is maintained by a balance between aqueous fluid secretion and fluid outflow; in glaucoma, defects that interfere with aqueous humor outflow lead to a rise in intraocular pressure resulting in degenerative compromise of optic nerve function known as progressive optic nerve atrophy and vision loss.

Mild open-angle glaucoma: Optic nerve abnormalities consistent with glaucoma but no visual field abnormalities on visual field test.

Moderate open-angle glaucoma: Optic nerve abnormalities consistent with glaucoma and glaucomatous visual field abnormalities in one hemifield and not within five degrees of fixation.

Schlemm's Canal: A circular canal in the eye that drains aqueous humor from the anterior chamber of the eye into the anterior ciliary veins.

Trabeculectomy: A surgical filtration procedure in which a portion of the trabecular meshwork is surgically removed through a superficial flap of sclera to lower the IOP by creating an alternate pathway for the aqueous fluid to flow from the anterior chamber to a bleb created in the subconjunctival space; this is currently considered the gold standard treatment for glaucoma that is refractory to medical management.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.00103 to new Clinical Utilization Management Guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.