Molina Clinical Policy
Minimally Invasive Glaucoma Surgeries
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OVERVIEW

Glaucoma describes a group of optic neuropathies, often characterized by elevated intraocular pressure (IOP), which can result in visual field loss and irreversible blindness if left untreated. Glaucoma can be classified as either open-angle or angle-closure glaucoma and may be further subdivided into primary (unidentifiable) or secondary (identifiable, such as pseudoexfoliative or pigmentary) causes. Open angle glaucoma (OAG), the most common form, is a chronic, progressive, and irreversible multifactorial optic neuropathy. It is characterized by an open-angle of the anterior chamber, characteristic optic nerve head changes, and progressive loss of peripheral vision followed by central visual field loss. Treatment strategies for OAG are aimed at lowering IOP, the primary modifiable risk factor associated with disease progression. Topical ophthalmic drops or laser trabeculoplasty are usually the first-line treatment for primary OAG. Surgical intervention may be indicated in individuals with severe visual field loss at baseline or when target IOP cannot be reached with pharmacologic or laser therapy. The standard surgical treatment for glaucoma is trabeculectomy, an incisional surgery. Repeat trabeculectomy is associated with a higher complication rate and an increased risk of subsequent failure (Jacobs 2024).

Minimally invasive glaucoma surgery (MIGS) has been defined as any glaucoma surgical procedure that avoids conjunctival dissection aiming to provide a safer and less invasive means of lowering IOP than traditional surgery. Although MIGS are collectively categorized as a class of interventions, each MIGS is unique in its mechanism of action. MIGS procedures typically use an ab interno approach, meaning surgery from inside the eye through a small corneal incision without the need for conjunctival dissection, and aim to lower IOP through at least one of the four mechanisms: increasing trabecular outflow, subconjunctival filtration, increasing uveoscleral outflow, or reducing aqueous humor production (Gurnani & Tripathy 2023).

Trabecular MIGS (e.g., Hydrus Microstent, iStent, iStent *inject*, iStent *infinite*) is designed to enhance aqueous humor outflow by bypassing the trabecular meshwork, which is the predominant site of resistance in primary OAG. Once implanted, the stent(s) typically span from the trabecular meshwork to the Schlemm's canal, where fluid can then be absorbed into the episcleral blood vessels, resulting in reduced IOP (Gurnani & Tripathy 2023).

Subconjunctival MIGS (e.g., XEN Gel Stent) is designed to lower IOP by creating a new drainage pathway from the anterior chamber of the eye to the subconjunctival space, where fluid can then absorb into surrounding tissue. During the procedure, a bleb (small reservoir) is formed beneath the conjunctiva to serve as an outlet for aqueous humor (Hayes, 2023; Traverso et al 2023).

Regulatory Status

The iStent Trabecular Micro-Bypass System (P080030) received FDA approval in 2012 for use in conjunction with cataract surgery for the reduction of IOP in adults with mild to moderate OAG currently treated with ocular hypotensive medication. The second-generation device, the iStent *inject* Trabecular Micro-Bypass system (P170043), received FDA approval in 2018, and the Hydrus Microstent (P170034) received FDA approval in 2018, both for use in conjunction with cataract surgery for the reduction of IOP in adults with mild to moderate OAG. All three devices are registered in the Premarket Approval database under product code OGO as intraocular pressure lowering implants. The iStent *infinite* Trabecular Micro-Bypass System received FDA clearance in 2022, indicated

for use in adult patients with primary OAG in whom previous medical and surgical treatment has failed, and is registered in the 510(k) database under product code KYF.

The XEN Glaucoma Treatment System (K161457) received FDA clearance in 2016 and is registered in the 510(k) Premarket Notification database under product code KYF as an eye valve implant. The device is approved for "the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy." The XEN Glaucoma Treatment System is currently the only FDA-cleared subconjunctival MIGS, and the 45-micron lumen (XEN45 Gel Stent) is the only FDA-cleared model of the device.

COVERAGE POLICY

Subconjunctival MIGS for Refractory Glaucoma

The XEN Glaucoma Treatment System (e.g., XEN45 Gel Stent) for the treatment of refractory glaucoma may be **considered medically necessary** when ALL the following are met:

1. Diagnosis of ANY of the following
   a. Primary open-angle glaucoma
   b. Pseudoexfoliative glaucoma with open angles
   c. Pigmentary glaucoma with open angles

2. Maximally tolerated medical therapy (topical and/or oral) has failed to control intraocular pressure or progressive damage

3. Previous surgical techniques have failed, including at least ONE of the following:
   a. Laser trabeculoplasty
   b. Trabeculectomy

Trabecular MIGS for Refractory Glaucoma

The iStent *infinite* Trabecular Micro-Bypass System for the treatment of refractory glaucoma may be **considered medically necessary** when ALL the following are met:

1. Member is ≥ 18 years old

2. Diagnosis of primary open-angle glaucoma

3. Maximally tolerated medical therapy (topical and/or oral) has failed to control intraocular pressure or progressive damage

4. Previous surgical techniques have failed, including at least ONE of the following:
   a. Laser trabeculoplasty
   b. Trabeculectomy

Trabecular MIGS for use with Cataract Surgery

The Hydrus Microstent, iStent Trabecular Micro-Bypass System, or iStent *inject* Trabecular Micro-Bypass System for the reduction of intraocular pressure for use in conjunction with cataract surgery may be **considered medically necessary** when ALL the following are met:

1. Member is ≥ 18 years old

2. Diagnosis of mild to moderate primary open-angle glaucoma

3. Device insertion is in conjunction with cataract surgery

4. Member is currently being treated with ocular hypotensive medication

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Ahmed et al. (2025) published the 6-months outcomes of the INTEGRITY study, a multicenter, double-masked, 24-month randomized controlled trial (RCT) comparing the safety and effectiveness of two current generation trabecular micro-bypass stents, the iStent *infinite* (three stents) and Hydrus Microstent (one stent), implanted as standalone procedures in adults with open-angle glaucoma (OAG). A total of 180 eyes from 107 patients with mild to moderate OAG were randomized, with 91 eyes to iStent Infinite and 89 eyes to Hydrus Microstent. Participants, aged 35-85, had baseline unmedicated mean diurnal intraocular pressure (IOP) between 21-36 mmHg after medication washout, and a medication IOP of $\leq$ 24 mmHg on 0-3 medications. At 6 months, both devices showed similar, high rates of clinical success, with 82.7 of iStent *infinite* eyes and 778.9% of Hydrus eyes achieving $\geq$ 20% reduction in IOP from baseline, regardless of medication use or surgical complications. When considering only unmedicated eyes without surgical complications, a statistically significant higher proportion of iStent *infinite* eyes (78.2%) achieved $\geq$20% IOP reduction compared to Hydrus (65.0%), with a treatment effect difference of 13.2% (95% CI 3.0%, 23.2%; p = 0.0111). While both groups achieved a final unmedicated mean diurnal IOP of approximately 16.4%, the iStent *infinite* group had a greater proportion of eyes achieving unmedicated mean diurnal IOP $\leq$ 21 mmHg (89.8% vs 75.9%; p = 0.0146). Surgical complication rates were significantly lower in the iStent *infinite* group (3.3%) than in the Hydrus group (16.9%), a difference of -13.6% (95% CI -23.8% to -3.4%). Overall ocular adverse events were also lower in the iStent *infinite* group (24.2% vs 36.0%), although the difference was not statistically significant. Both groups had similar visual acuity outcomes at 6 months, with over 96% achieving a 20/40 or better. The authors concluded that both the iStent *infinite* and Hydrus Microstent provided effective IOP reduction when implanted as standalone procedures in eyes with mild-to-moderate OAG. The trial will continue to follow participants through 23 months to assess long-term outcomes. (ClinicalTrials.gov NCT05127551).

Fan Gaskin et al. (2024) conducted an RCT to evaluate the efficacy and safety of the iStent *inject* combined with cataract surgery (CS) compared to CS alone in patients with mild-to-moderate open-angle glaucoma. The study enrolled 93 participants with a final primary analysis of 101 eyes (55 in the iStent group and 46 in the control group). Participants were aged 53-85 years and had visually significant cataract and glaucoma with baseline IOP between 12-30 mmHg on up to three medications. Primary outcomes were IOP and the number of ocular hypotensive medications at 24 months, with secondary endpoints including patient reported outcomes, such as the Ocular Surface Disease Index (OSDI) and Glaucoma Activity Limitation Questionnaire (GAL-9). At 24 months, eyes in the iStent *inject* group required significantly fewer glaucoma medications than the control group (mean 0.7 $\pm$ 0.9 vs 1.5 $\pm$ 1.9), with an adjusted difference of 0.6 fewer medications per eye (95% CI 0.2-1.1, p = 0.008), and 57% of iStent *inject*-treated eyes were medication-free compared to 36% in the CS only group. There was no statistically or clinically significant difference in IOP between the two groups at 24 months. Early IOP reductions at 4 weeks favored the iStent *inject* group, but this benefit did not persist over two years. While both groups showed improvement in patient-reported outcomes, no significant difference was found at 24 months. Visual acuity outcomes were excellent in both arms with 94% of eyes achieving 20/40 vision or better. Safety profiles were also comparable between groups. In the iStent group, 4 intraoperative events occurred including iris root tear and suboptimal stent placement. Secondary surgeries occurred at similar rates at approximately 8% in both groups, including trabeculectomy and selective laser trabeculoplasty. No cases of serious adverse events such as endophthalmitis, hypotony, or stent migration were reported. The authors concluded that adding the iStent *inject* to CS significantly reduced the need for ocular hypotensive medications over 2 years without increasing surgical risk. However, it did not yield sustained reductions in IOP compared to CS alone. (ClinicalTrials.gov NCT03106181).

Sheybani et al. (2023) conducted a prospective, randomized, multicenter, noninferiority study, called the Gold-Standard Pathway Study, which compared gel stents versus trabeculectomy for efficacy and safety over a 12-month period. Participants were randomized 2:1 gel stent implantation to trabeculectomy if they met the inclusion criteria of OAG and IOP 15 to 44 mm Hg on topical IOP-lowering medication. Primary end point was percentage of patients at month 12 achieving ≥20% IOP reduction from baseline without adverse events such as medication increase, clinical

hypotony, vision loss to counting fingers, or secondary surgical intervention (SSI) in a noninferiority test with 24% margins. Secondary end points were mean IOP and medication count, postoperative intervention rate, visual recovery, and patient-reported outcomes at month twelve. The results revealed the gel stent was statistically noninferior to trabeculectomy (between-treatment difference [Δ], −6.1%; 95% CI, −22.9%, 10.8%). Gel stents achieved the primary end point at 62.1% rate versus a 68.2% achievement rate of the trabeculectomy. Mean IOP and medication count reductions from baseline were significant (P<.001); and the IOP change-related Δ (2.8 mm Hg) favored trabeculectomy (P=.024). The gel stent resulted in fewer eyes requiring in-office postoperative interventions (P=.024 after excluding laser suture lysis), faster visual recovery (P≤.048), and greater 6-month improvements in visual function problems (P≤.022). The most common AEs were reduced visual acuity at any time (gel stent, 38.9%; trabeculectomy, 54.5%) and hypotony (IOP <6 mm Hg at any time) (gel stent, 23.2%; trabeculectomy, 50.0%). While the gel stent was statistically non-inferior at achieving the primary end point, resulted in fewer postoperative interventions, better visual recovery, and fewer AEs; trabeculectomy, however, achieved a statistically lower mean IOP, numerically lower failure rate, and numerically lower need for supplemental medications. (ClinicalTrials.gov NCT03654885).

Ahmed et al. (2022) published the 5-year results of the HORIZON trial, a multicenter RCT comparing a Schlemm's canal intracanalicular micro-stent (Hydrus Microstent) combined with CS versus CS alone, in adults with mild to moderate primary open-angle glaucoma. Participants were being treated with 1-4 glaucoma medications, had no prior incisional glaucoma surgery, and had a washed-out diurnal IOP of 22-34 mmHg. In total, 556 eyes were randomized 2:1, with 369 in the Hydrus+CS group and 187 in the CS group, with matching baseline characteristics. Primary outcome measured were IOP, glaucoma medication use, repeat glaucoma surgery, visual acuity, visual field, procedure-related adverse events, and corneal endothelial cell counts. At 5 years, a greater proportion of the Hydrus+CS group achieved optimal IOP control (≤ 18 mmHg) without medications compared to CS (49.5% vs 33.8%; p = 0.003), as well as a greater likelihood of unmedicated IOP reduction of ≥ 20% (54.2% vs 32.8%; p < 0.001). Medication use was consistently lower in the Hydrus+CS group (0.5 ± 0.9 vs 0.9 ± 0.9; p<0.001) and 66% of Hydrus+CS eyes were medication free at 5 years compared to 46% in the CS group (p < 0.001). The cumulative risk of incisional glaucoma surgery was lower in the Hydrus+CS group (2.4% vs 6.2%; p = 0.027) and no clinical or statistically significant differences were found in the rate of endothelial cell loss. The authors concluded that the Hydrus Microstent in conjunction with CS was safe through 5 years, reduced medication burden, increased the likelihood of achieving medication-free IOP targets, and lowered the risk of subsequent incisional glaucoma surgery compared with CS alone. (ClinicalTrials.gov NCT01539239).

Pfeiffer et al. (2015) conducted a multicenter RCT (HYDRUS II) comparing Hydrus Microstent implantation performed with CS versus CS alone in adults with open-angle glaucoma and cataracts. 100 eyes from 100 patients with medicated IOP ≤ 24 mmHg on ≤4 hypotensive medications and a washed-out diurnal IOP of 21-36 mmHg were randomized 1:1. Clinical improvement was measured as a ≥20% reduction from baseline in washed-out diurnal IOP at 12 months and 24 months, measured by the average of 3 Goldmann applanation measurements taken 4 hours apart in a single day after medication washout. At 24 months, a ≥ 20% reduction in washed-out diurnal IOP occurred in 80% of Hydrus+CS eyes versus 46% of CS eyes (p = 0.0008). Mean washed-out diurnal IOP was lower with Hydrus+CS than CS alone (16.9 ± 3.3 vs 19.2 ± 4.7mmHg; p = 0.0093). Hydrus+CS yielded a greater proportion of medication-free patients versus CS alone (73% vs 38%; p = 0.0008). Implantation succeeded in 96% of attempted cases, with no device loss, migration, or corneal/iris touch. The main device-related adverse event was focal peripheral anterior synechiae, which was more common with Hydrus+CS at 2 years versus CS alone (18.8% vs 2.0%; p = 0.0077), but without effect on IOP or medication outcomes. The authors concluded that over 2 years, Hydrus Microstent implantation combined with CS produced clinically and statistically greater reductions in washed-out diurnal IOP and medication burden than CS alone, with no between-group differences in visual acuity and an acceptable safety profile. (ClinicalTrials.gov NCT01818115).

Systematic Reviews and Meta-Analyses

Gan et al. (2024) conducted a systematic review to evaluate the complications and management of complications associated with XEN gel stent (XEN45) implantation. A total of 48 studies were included in the review, including 16 original retrospective or prospective studies, 28 case reports, and 4 case series. Overall, patients were followed for up to 5 years following implantation. Adverse events were categorized into three periods: early (within 30 days), mid-term (1-6 months), and late postoperative (6+ months). Early postoperative complications included hypotony maculopathy (1.9-4.6%), stent occlusion (3.9-8.8%), suprachoroidal hemorrhage, choroidal detachment (0-15%), malignant glaucoma (2.2%), bleb and wound leaks (2.1%), and conjunctival erosion or device exposure (1.1-2.3%).

Suprachoroidal hemorrhage required either conservative or surgical drainage due to hypotony and rapid IOP changes. Malignant glaucoma was associated with misdirection of aqueous humor and anterior displacement and typically required medical or surgical management. Mid-postoperative complications included device migration (1.5%), ptosis (1.2%), macular edema (1.5%), hypertrophic bleb formation (8.8%), subconjunctival stent fragmentation, and endophthalmitis (0.4-3%). Macular edema was usually transient and observed with combination surgeries for cataract removal and generally resolved without intervention. Endophthalmitis required prompt removal of the stent and antimicrobial therapy. Late complications, although rare, included spontaneous late device dislocation and intraocular device degradation. Dislocation typically occurred without preceding trauma and was possibly due to inadequate scleral support or repeated manipulations during implantation. Limitations of the review include a large proportion of case reports and case series which are prone to publication and reporting bias, and heterogeneity in study design, patient selection, and follow-up intervals. The authors concluded that long-term observational studies with follow-up periods of up to 5 years support the safety and efficacy of the device. Most complications were mild or transient and sufficiently managed with conservative therapy. However, some complications are potentially sight threatening, including suprachoroidal hemorrhage and endophthalmitis, highlighting the importance of thorough postoperative follow-up and early recognition of severe complications.

Betzler et al. (2023) conducted a systematic review and meta-analysis on the complications and post-op interventions in XEN45 gel stent implantation to treat open angle glaucoma. Thirty-three articles were included in the analysis, which met the inclusion criteria of pilot, cohort, observational studies, and RCTs that included at least 10 patients undergoing XEN45 surgery, for the treatment of open angle glaucoma. The primary outcomes were the rate of surgical complications and post-operative interventions, which were only analyzed if the outcomes were reported in three or more articles included. Outcomes were analyzed in 3062 eyes, with a diverse representation of ethnicity. The studies comprised of mainly case series design, 15 prospective studies and 18 retrospective studies. Maximum follow-up was 36 months, with most studies ending follow-up at 12 months. The results revealed that numerical hypotony was the most common post-operative complication, affecting 20% of patients (95% CI: 10-31%). Subsequent complication rates were post-operative gross hyphema occurring in 14% of patients (95% CI: 7-22%) and transient intra-ocular pressure (IOP) spikes (>30 mmHg) in 13% of patients (95% CI: 4-27%). The need for a XEN gel stent revision or re-implantation occurred in 5% of patients, while a XEN gel stent relocation procedure was performed in 3% of patients (95% CI: 1-7%). Approximately 11% of patients needed a subsequent glaucoma procedure, and 35% of patients (95% CI: 29-40%) required at least one bleb needling procedure. The authors highlighted that approximately 25% of the articles reviewed had moderate to high risk of bias, leading to the conclusion that while literature suggests the XEN45 gel stent is a relatively safe procedure that the overall body of evidence is of both low quality and volume.

Kahale et al. (2023) conducted a systematic review and meta-analysis to compare the outcomes of phacoemulsification combined with iStent implantation versus phacoemulsification alone in patients with ocular hypertension or OAG who also had cataracts. Both first-generation iStent (single stent) and the second-generation iStent *inject* (two stents) were included in the analysis. A total of 10 studies were included, for a total of 1,453 eyes (852 for combined iStent and 600 for phacoemulsification alone). Among these, eight studies were RCTs and two were retrospective. Mean follow-up was 21.9 months (ranging from 12-51 months) and primary outcomes were IOP reduction and the reduction in the number of glaucoma medications used postoperatively. Meta-analysis showed that the combined procedure resulting in a greater IOP reduction, with a weighted mean of IOP reduction of 4.7 $\pm$ 2.1 mmHg compared to a reduction of 2.8 $\pm$ 1.9 mmHg in the phacoemulsification only group. Similarly, glaucoma medication use was reduced more in the combined group, with a mean reduction of medications of 1.2 $\pm$ 0.3 versus 0.6 $\pm$ 0.6 in the phacoemulsification only group. A subgroup analysis suggested that the second generation iStent *inject* may offer greater IOP lowering efficacy, although too few studies were available to formally analyze this subgroup. The authors noted a high degree of heterogeneity (I^2 values > 80%) and possible publication bias as funnel plots showed asymmetry. The article was not funded by any external sources. The authors concluded that iStent combined with phacoemulsification results in a synergistic improvement in both IOP control and reduction of glaucoma medication burden compared to phacoemulsification alone.

Traverso et al. (2023) conducted a systematic review of the literature pertaining to the effectiveness and safety of XEN gel stent in glaucoma surgery. In reference to XEN45, the authors found multiple studies evaluating the IOP lowering effect of the XEN device, either alone or in combination with cataract surgery, in patients with glaucoma. The results, which used a pooled analysis with a random effects model, have shown a mean (95% CI) IOP lowering from baseline of −7.8 (−7.4 to −8.2) mmHg and −8.4 (−6.9 to −9.8) mmHg in the eyes of patients who underwent XEN-solo and XEN + Phaco, respectively. All patients were treated and followed as routine clinical practice between

May 2013 and February 2020. The mean sample size was 79 ± 67 and the average follow-up time was 17.0 ± 8.1 months. Regarding safety, the commonly reported complication of XEN45 is transient hypotony (defined as IOP <6 mmHg) at an incidence rate of 9.59%. In most patients, hypotony is successfully resolved without additional surgery interventions and the rate of chronic hypotony is extremely low. The second most common adverse event is hyphema at an incidence rate of 5.53%. Most patients have grade I hyphema (less than 1/3 of anterior chamber), which resolved spontaneously by the first week after surgery. In summation, the authors concluded that XEN was variable but effective at lowering IOP and had a safe procedure profile. The authors disclosed that the systemic review was funded by AbbVie, with AbbVie participating in its writing and reviewing.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Sarkisian et al. (2023) conducted a prospective, multicenter, single-arm, open-label pivotal clinical trial evaluating the safety and efficacy of the iStent *infinite* Trabecular Micro-Bypass System as a standalone surgical intervention in patients with OAG who had not achieved adequate control with prior incisional or cilioablative surgery, or with maximum tolerated medical therapy. A total of 72 eyes from 72 participants were enrolled, with 61 in the failed surgery subgroup and 11 in the maximum medical therapy subgroup. Participants had a mean preoperative medicated IOP of 23.4 mmHg on 3.1 IOP-lowering medications, and a mean 2.3 prior glaucoma surgeries. At 12 months, 76.1% of patients (73.4% of the failed surgery subgroup and 90.9% of the maximum medical therapy subgroup) met the primary effectiveness endpoint, defined as a ≥ 20% reduction in mean diurnal IOP from baseline on the same or fewer medication classes and without significant safety events. The mean reduction in mean diurnal IOP was 5.9 mmHg overall (5.5 mmHg in the failed surgery subgroup and 8.1 mmHg for the maximum medical therapy subgroup. In a secondary analysis, 53.0% of patients achieved a ≥ 30% IOP reduction and 74.2% had an IOP of ≤ 18 mmHg at month 12. 93% of patients maintained or reduced their medication use, with the average medication count dropping from 3.10 to 2.70. No intraoperative complications occurred and 52.8% of patients had no postoperative ocular adverse events. The most common adverse events were mild and included ocular surface disease, perioperative inflammation, and transient IOP spikes (with each occurring in ≤ 9.7% of patients). No patients required explantation or repositioning of the stents and 3 eyes (4.2%) required subsequent glaucoma surgery, none of which were related to the device. The authors concluded that the iStent *infinite* system demonstrated clinically meaningful IOP reduction and a favorable safety profile in a difficult to treat glaucoma population who had exhausted conventional surgical and medical options.

Saheb et al. (2021) published the 5-year outcomes of a prospective, multi-surgeon, interventional single-arm study evaluating standalone implantation of the first-generation iStent trabecular micro-bypass stent in eyes with OAG not controlled by medication. Thirty-nine eyes met study criteria, receiving two implants per eye. Thirty eyes completed the 5-year follow-up. Effectiveness was measured by mean diurnal IOP measured by Goldmann applanation and medication use, with annual medication washouts when applicable. The primary endpoint was the proportion of eyes achieving ≥ 20% reduction in unmedicated mean diurnal IOP from baseline. The secondary endpoint was achieving unmedicated mean diurnal IOP ≤ 18 mmHg. Both endpoints were without glaucoma medications or secondary glaucoma surgery. Preoperative mean IOP on 1 medication was 20.6 ± 2.0 mmHg and post-washout unmedicated IOP was 24.1 ± 1.4 mmHg at baseline. At 5-years, medication-free mean diurnal IOP was 14.5 ± 2.2 mmHg, a 40% decrease from unmedicated baseline and a 30% decrease from medicated baseline IOP ($p < 0.001$). At Month 60, 89.7% of eyes achieved the primary efficacy endpoint and 86.2% achieved the secondary efficacy endpoint of IOP, without medication or secondary glaucoma surgery. Throughout the 5-year follow-up period, 89.7 to 91.3% of eyes were on no medications. The authors concluded that standalone implantation of two first-generation iStent devices produced persistent 5-year reductions in IOP and substantial medication freedom with a favorable safety profile.

Gillman et al. (2019) conducted a prospective, interventional study in a tertiary glaucoma center to evaluate the XEN gel stent in pseudoexfoliative glaucoma over a two-year period. Eighty-five participants, totaling 110 eyes [53 pseudoexfoliative glaucoma (PEXG) vs 57 primary open angle glaucoma (POAG)], with uncontrolled IOP despite medical treatment underwent combined XEN+cataract surgery or standalone XEN surgery. Primary end point was surgical success as defined by complete surgical success was defined as an unmedicated IOP≤12-, 15-, 16-, or 18-mm Hg at 2 years, both with and without a 20% reduction from baseline. Secondary end points evaluated were mean IOP, mean number of medications, needling rates, and incidence of adverse effects were compared between the 2 groups. Combined XEN+cataract surgery was performed in 72% of POAG and 76% of PEXG eyes (P=0.67), the remainder underwent standalone XEN surgery. Primary end point revealed no statistical difference in surgical success. Secondary endpoints revealed mean medicated IOP were 19.8±5.8 mm Hg (POAG) versus 19.8±8.2 mm Hg (PEXG) at baseline (P=0.98), and 14.5±3.6 mm Hg (-26.8%) versus 14.2±3.8 mm Hg (-28.3%), respectively, at 2 years (P=0.75). Mean medications concomitantly dropped from 1.9±1.6 (POAG) versus 2.0±1.3 (PEXG) to 0.6±0.9

versus 0.4±0.7, respectively (P=0.29). By 24 months, needling was performed in 42.8% (POAG) and 43.2% (PEXG) (P=0.64), with an average time to needling of 162.8 and 134.9 days, respectively (P=0.46), and additional glaucoma surgeries were conducted in 14.3% (POAG) versus 15.9% (PEXG) (P=0.89). Adverse event rates were similar at 30.6% (POAG) and 36.4% (PEXG) (P=0.66) respectively. The authors concluded the XEN gel implant as a standalone or combined procedure demonstrated similar efficacy and safety results in PEXG and POAG eyes.

Marcos Parra et al. (2019) conducted a retrospective, single-center, comparative study to evaluate the XEN gel stent versus trabeculectomy in open angle glaucoma patients. Ninety-one patients, totaling 121 eyes, were included in the study, and divided into four groups: XEN alone, XEN+PHACO; TRAB alone; TRAB+PHACO. For statistical purposes, groups 1 and 2 were combined (65 XEN implant), while groups 3 and 4 were also combined (56 TRAB surgery). Primary end point was intraocular pressure reduction. The main outcome measure was intraocular pressure. IOP reduction was - 6.7 (- 10.4 to - 3.0) mmHg, p = 0.0013; - 3.5 (- 5.0 to - 2.0) mmHg, p < 0.0001; - 8.1 (- 10.4 to - 5.9) mmHg, p < 0.0001l; and - 7.3 (- 9.3 to - 5.3) mmHg, p < 0.0001 in the XEN alone, XEN+PHACO, TRAB alone, and TRAB+PHACO, respectively. At month 12, an IOP ≥ 6 and ≤ 16 mm without treatment was achieved by 44 (67.7%) and 43 (76.8%), p = 0.2687 in the XEN implant and the TRAB surgery groups, respectively. The mean number of antiglaucoma medications was significantly reduced in all the study groups (p < 0.0001 each). Needling occurred in 20.0% (13/65) of eyes in the XEN implant group, while hyphema occurred in 30.4% (17/56) of eyes in the TRAB group. The authors concluded XEN implant alone or in combination with phacoemulsification, significantly reduces IOP and the number of antiglaucoma medications at a similar rate than trabeculectomy, but with a better safety profile.

Reitsamer et al. (2019) conducted a 2-year prospective, non-randomized, open-label, multicenter study to evaluate XEN gel implants in medically uncontrolled primary open angle glaucoma. Two-hundred and two eyes (of 218 implanted) with medicated baseline IOP 18-33 mmHg on 1-4 topical medications were included. One hundred and twenty eyes were treated with the XEN implant only versus 98 eyes treated with phacoemulsification + XEN implant. Overall, results were similar in both treatment arms. The mean changes in IOP from medicated baseline were − 6.6 (5.6) and − 6.4 (5.0) mmHg at month 12 and − 6.4 (5.2) and − 5.9 (4.6) mmHg at month 24 in the implant alone and phaco + implant groups, respectively (P > 0.50). In these groups, the mean changes in IOP-lowering medication count were − 1.8 (1.3) and − 1.6 (1.2) at month 12 and − 1.5 (1.5) and − 1.5 (1.2) at month 24, respectively (P > 0.48). The mean percentage changes in IOP from medicated baseline were − 29.6 (month 12) and − 28.2% (month 24) in the former group and − 29.1 (month 12) and − 27.2% (month 24) in the latter. The authors concluded the XEN implant effectively reduced IOP, medication needs, and have an acceptable safety profile.

Fea et al. (2017) conducted a prospective, case series to compare the reduction of IOP and use of glaucoma medications following selective laser trabeculoplasty (SLT) versus stand-alone placement of the Hydrus Microstent. The study enrolled 56 eyes from 56 patients with uncontrolled POAG and IOP >21 mm Hg, with 25 eyes receiving 360-degree SLT and 31 receiving stand-alone Hydrus Microstent implantation. Patients were evaluated at baseline, 1 day, 1 week, and at 1, 3, 6, and 12-month follow-ups. The primary outcome was a between-group reduction in mean diurnal IOP, measured using Goldmann applanation tonometry. Secondary outcomes included the proportion of patients using glaucoma medication, change in medication count, and surgical success defined as maintaining IOP within a predefined target without medications. All glaucoma drops were stopped after the procedure in both groups, with medications allowed to be restarted if IOP exceeded 21 mmHg. Baseline characteristics between groups were similar for age, sex, medication burden, angle grade, lens status, and visual acuity. At 12 months, both groups showed significant within-group IOP reductions relative to baseline, with no significant between-group difference at any visit. At 12 months, average IOP in the SLT group was 15.9 ± 2.49 mmHg (mean change -7.3 ± 2.3 mmHg; -31%) versus 16.5 ± 2.6 mmHg (mean change -6.6 ± 5.62 mmHg; -26%) in the Hydrus group (p = 0.57). A clinically meaningful IOP drop, measured as > 20% from baseline, occurred in 88% of SLT eyes and 90% of Hydrus eyes, at 12 months. Medication outcomes favored Hydrus, where at 12 months the SLT group averaged 2.0 ± 0.91 medications (mean change -0.5 ± 1.05) versus 0.9 ± 1.04 (mean change -1.4 ± 0.97) in the Hydrus group, yielding a between-group difference of 0.9 fewer medications per Hydrus patient (p = 0.004). There were no complications in the SLT group and no significant changes in visual acuity from baseline at 12 months in either group. In the Hydrus group, 2 patients (6.45%) had day-1 IOP spikes managed with oral acetazolamide which resolved by day 3; 3 patients (9.68%) had temporary ≥ 2-line visual acuity decrease on day 1 due to transient hyphema or corneal edema secondary to IOP spiking, with all complications resolving by day 7. Limitations with the study include small sample size, nonrandomized and unmasked allocation to treatments at different centers and baseline disease-severity imbalance (worse visual fields in the Hydrus group at baseline). The authors concluded that both 360-degree SLT and stand-alone Hydrus Microstent implantation reduced IOP over 12 months without serious adverse events, and

that Hydrus produced significantly greater reduction in glaucoma medication dependence at 12 months compared with SLT. (ClinicalTrials.gov NCT02512133).

National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** *Preferred Practice Pattern on Primary Open-Angle Glaucoma* indicates that pharmacologic and laser therapy are typically first-line treatments for open-angle glaucoma, and that trabeculectomy is generally indicated when these treatment options fail or as a first-line treatment in select cases. When trabeculectomy fails to effectively control IOP or when it's unlikely to succeed, aqueous shunts have traditionally been used. MIGS are less invasive with favorable safety profiles; however limited long-term data exists. Data shows MIGS results in modest IOP reduction and is less effective in lowering IOP than trabeculectomy and aqueous shunt surgery. While MIGS appears to have a more favorable safety profile in the short-term when compared to traditional surgery (Gedde et al. 2020).

MIGS procedures typically target the trabecular meshwork/Schlemm's canal or the subconjunctival space. For trabecular MIGS, the IOP-lowering effect is limited by the resistance in distal outflow pathways and by episcleral venous pressure. Trabecular MIGS are commonly combined with phacoemulsification for cataracts, including that in research. Since no RCTs to date have included a comparison group of phacoemulsification alone, it is unclear how much IOP reduction is provided by the Trabectome versus the cataract extraction portion of the procedure. In randomized trials, trabecular micro-bypass stents (e.g. iStent, iStent *inject*) have shown comparable efficacy to pharmacologic therapy. Additionally, a 2019 Cochran Systematic Review found very low-quality evidence that the iStent system may achieve better IOP reduction or control than pharmacologic therapy. Therefore, therapy selection should be left to the discretion of the treating ophthalmologist and the patient. For subconjunctival MIGS, while several models have been studied, the 45-micron lumen Xen Gel Stent is the only FDA-approved device for refractory glaucoma. The authors note that similarly with trabeculectomy, the use of intraoperative antifibrotic agents enhance surgical success. Such as with trabecular micro-bypass stents, treatment selection should be left to the discretion of the treating ophthalmologist and individual patients. Transient postoperative hypotony is a common complication and often requires needling to remediate (Gedde et al. 2020).

The **AAO** *2024 Glaucoma Summary Benchmarks* for the management of primary open-angle glaucoma state that medical pharmacologic therapy is the most common initial intervention to lower IOP; however, IOP can be lowered by medical treatment, laser therapy, or incisional surgery alone or in combination. Laser trabeculoplasty may be used as an initial or adjunctive therapy in patients with primary open-angle glaucoma (AAO et al. 2024).

The **National Institute for Health and Care Excellence (NICE)** (2018) published an interventional procedure guidance [IPG612] providing evidence-based recommendations on microinvasive, or minimally invasive, subconjunctival insertion of trans-scleral gelatin stents for primary open-angle glaucoma in adults. The guidance states that the "evidence on the safety and efficacy of microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research." NICE encourages further research into this procedure with an emphasis on patient selection and long-term outcomes.

SUPPLEMENTAL INFORMATION

Intraocular pressure (IOP): IOP refers to the pressure of the fluid inside the eye; regulated by the balance of aqueous humor synthesis and secretion into the eye and outflow from the eye; therefore, most therapies for glaucoma aim to lower IOP to avoid disease progression. Elevated IOP is the crucial modifiable risk factor in the development of primary OAG.

Hypotony: Low IOP; or an IOP below which the eye does not maintain its normal shape and may subsequently lose vision. Hypotony is usually defined as an IOP of 5 mm Hg or less. Low IOP is associated with a number of complications, including corneal decompensation, accelerated cataract formation, maculopathy, and discomfort.

Trabeculectomy: Referred to as filtration surgery; A surgical procedure used in the treatment of glaucoma to relieve IOP by removing part of the eye's trabecular meshwork and adjacent structures. It is the most common glaucoma surgery and allows drainage of aqueous humor from within the eye to beneath the conjunctiva, where it is absorbed.

This is currently considered the gold standard treatment for glaucoma that is resistant to medical management; however, it is a technically complex procedure that can result in a range of adverse outcomes.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
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)
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/08/2025	Policy revised. Title changed to "Minimally Invasive Glaucoma Surgeries." Broadened policy from XEN Gel Stent only to include other MIGS devices and added a coverage stance for trabecular shunts (e.g., Hydrus Microstent, iStent, iStent *inject*, iStent *infinite*). Changed coverage stance for XEN Gel Stent to medically necessary. IRO peer reviewed on September 30, 2025 by a practicing physician board certified in ophthalmology.
10/09/2024	Policy reviewed. No changes to coverage criteria. IRO Reviewed on September 24, 2024 by a practicing physician board certified in Ophthalmology.
12/13/2023	Policy reviewed. No changes to coverage criteria. Updated overview, summary of medical evidence, and references.
12/14/2022	Policy reviewed and updated. No changes in coverage criteria. Updated references.
12/08/2021	Policy reviewed and updated. No changes in coverage criteria. Updated references. Converted to new format.
12/09/2020	New policy. IRO Peer Review. 10/16/20. Practicing Physician. Board certified in Ophthalmology.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

This policy contains prior authorization requirements.