Molina Clinical Policy
XEN Gel Stent for Glaucoma: Policy No. 389

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Glaucoma is characterized by elevated intraocular pressure (IOP), which results in visual field loss and irreversible blindness if left untreated. Glaucoma is classified as open-or closed-angle, primary or secondary. Open angle glaucoma (OAG), the most common form of glaucoma, is a chronic, progressive, and irreversible multifactorial optic neuropathy. It is characterized by open angle of the anterior chamber, typical optic nerve head changes, progressive loss of peripheral vision, followed by central visual field loss (blindness) for which IOP is an important risk factor. The disease is usually bilateral, but asymmetry can be seen depending on the etiology. Pharmacologic, surgical, or combination treatment strategies for OAG are aimed at lowering IOP, the primary modifiable risk factor associated with disease progression.

Topical ophthalmic drops are often the first-line treatment for primary OAG. Pharmacologic therapy can involve multiple medications with the potential for additive or systemic side effects, poor compliance to therapy, and ocular toxicity. Surgical intervention may be indicated in individuals with glaucoma when the target IOP cannot be reached pharmacologically. Current standard surgical treatments for glaucoma include trabeculectomy or trabeculoplasty (incisional or laser). Trabeculectomy, an incisional surgery, is a well-established procedure and considered the gold standard; however, carries the risk of potential vision-threatening complications and may also fail over time such as scar formation at the drainage site. A repeat trabeculectomy is associated with a higher complication rate and an increased risk of subsequent failure.

Microinvasive 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 structure and/or mechanism of action. MIGS procedures use an ab interno approach and aim to lower IOP via four mechanisms:

1. Increasing trabecular outflow (Trabectome, iStent, Hydrus stent, gonioscopy-assisted transluminal trabeculotomy, excimer laser trabeculotomy).
2. Increasing outflow via suprachoroidal shunts (The CyPass micro-stent was voluntarily recalled by Alcon in October 2018 due to the potential to cause endothelial cell loss concluded by the COMPASS-XT study as data showed a statistically significant difference in endothelial cell loss at 5 years in patients who received the device with cataract surgery compared with those who underwent cataract surgery alone).
3. Reducing aqueous production (endocyclophotocoagulation).
4. **Subconjunctival filtration (XEN Gel stent).** A type of MIGS is sub-conjunctival filtration, or XEN Gel Stent, manufactured by Allergan, implanted through an ab interno approach without conjunctival dissection.

The XEN Gel Stent is currently the only FDA-approved sub-conjunctival MIGS procedure. The stent is composed of porcine-derived gelatin that has been formed into a tube and cross-linked with glutaraldehyde to retain its shape. Dry, the stent measures 6 millimeters in length and has inner and outer diameters of 45 and 150 microns, respectively. Hydration causes the stent to expand and become more flexible. Implantation of the XEN stent is performed as an outpatient procedure using standard ophthalmologic surgery techniques. The system consists of an injector, a single piece tube of porcine collagen/gelatin inserted permanently. The XEN45 Gel Stent creates a permanent channel through the sclera allowing aqueous flow from the anterior chamber to the subconjunctival space (Allergan, 2021).

XEN Gel Stent is contraindicated in closed angle glaucoma where the angle has not been surgically opened, previous glaucoma shunt/valve or conjunctival scarring/pathologies in the target quadrant, active inflammation, active iris neovascularization, anterior chamber intraocular lens, intraocular silicone oil, and vitreous in the anterior chamber. Complications may include choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention, and intraocular surgery complications. Safety and effectiveness in neovascular, congenital, and infantile glaucoma has not been established. XEN140 and/or XEN63 are no longer recommended by the manufacturer.

Regulatory
The XEN Glaucoma Treatment System (K161457) received FDA approval in October 2016 and is registered in the 510(k) Premarket Approval database under product code KYF as an implant, eye valve. XEN Glaucoma Treatment System 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."

COVERAGE POLICY

The XEN Glaucoma Treatment System **is considered experimental, investigational, or unproven** for any indication. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

SUMMARY OF MEDICAL EVIDENCE

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 open angle glaucoma (OAG) and intraocular pressure (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.

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 up 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 of patients have grade I hyphema (less than 1/3 of anterior chamber), which had 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.

Yang et al. (2022) conducted a systematic review and meta-analysis to evaluate the efficacy of the XEN gel stent implantation in glaucoma. A total of 78 studies were analyzed to reveal obvious IOP reduction after XEN stent implantation (SMD: 1.69, 95% CI 1.52 to 1.86, p value < 0.001) and number of anti-glaucoma medications reduction (SMD: 2.11, 95% CI 1.84 to 2.38, p value < 0.001). No significant difference was found with respect to time points, ethnicities, and economic status; between XEN treatment effect on primary open angle glaucoma and pseudo-exfoliative glaucoma eyes; between pseudo-phakic and phakic eyes; and between XEN and phaco-XEN surgery in terms of IOP after surgery (SMD: -0.01, 95% CI -0.09 to 0.08, p value 0.894). Compared to trabeculectomy, XEN implantation had similar after-surgery IOP, however bleb needling rate (RR: 2.42, 95% CI 1.33 to 4.43, p value 0.004) was higher. The authors concluded that XEN gel stent is effective in lowering both IOP and number of anti-glaucoma medications up to 48 months after surgery but does seem to lead to higher needling rates when compared to phaco-XEN or trabeculectomy. The authors highlighted the need for further research, studying complications of XEN gel stents on non-European ethnicities, especially on Asian, before XEN is widely applied.

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.

A Health Technology Assessment (2023) gave the XEN Glaucoma Treatment System in patients with OAG a C rating for potential but unproven benefit based on low-quality body of evidence suggesting that the XEN Glaucoma Treatment System may result in a reduction in intraocular pressure and medication use; however, the degree of this impact is variable. In addition, there is uncertainty about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns. The assessment included 7 observational studies which compared XEN treatment system with standard care, trabeculectomy, and the individual study quality ratings. Although the results demonstrated a reduction in IOP and medication use from baseline, reduction rates varied between studies suggesting that that XEN implantation led to a variable rate of treatment success across studies. In general, evidence comparing XEN implantation with trabeculectomy is insufficient to determine whether XEN implantation is equivalent or superior to trabeculectomy as there were only 2 studies evaluating this comparison, impairing any determination of consistency.

National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** (2020a, 2020b) practice guideline indicates that trabeculectomy is the preferred treatment for OAG that cannot be controlled by medication. It is also noted that MIGS are less effective than trabeculectomy in reducing IOP but may have fewer short-term complications. The summary benchmarks established by the Academy for the management of OAG did not mention any type of MIGS.

The 2020 AAO Preferred Practice Patterns on Primary OAG state that while several other glaucoma surgeries exist as alternatives to trabeculectomy and aqueous shunt implantation (e.g., nonpenetrating procedures, MIGS), the precise role of these procedures in the surgical management of glaucoma remains to be determined. iStent, iStent inject and XEN gel stent studies were of insufficient quality (i.e., the estimate of the effect is very uncertain) and therefore, the use of these devices should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient (Gedde et al. 2020).

The AAO Glaucoma Summary Benchmarks (2022) for the management of primary OAG stated that medical therapy is the most common intervention initial intervention to lower IOP. Trabeculectomy is the gold standard indicated when medications and appropriate laser therapy are insufficient to control disease, however it can be used as initial or adjunctive therapy in patients with primary OAG in selected cases. No reference is made in the guidelines to the XEN Gel Stent.

The **National Institute for Health and Care Excellence (NICE)** published an interventional procedures guidance [IPG612] (2018) providing evidence-based recommendations on microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma in adults. This procedure was described as '*involves putting a tiny gelatin tube (stent) under the skin at the base of the eye to create a new drainage channel for excess fluid*.' The guidance noted 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 microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma, including randomized studies. Further research should include details of 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 humour 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) Codes

CPT	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) Codes

HCPCS	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

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.*