Molina Clinical Policy
FSYX Ocular Pressure Adjusting Pump for Open-Angle Glaucoma: MEDICARE
Policy No. 489b

Initial Approval: 10/21/2026
Next Review Due By: October 2027

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 the Federal government or CMS for Medicare. 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 describes a group of progressive optic neuropathies characterized by structural changes to the optic nerve and loss of retinal ganglion cells, which can result in irreversible visual field loss and blindness if left untreated. **Open angle glaucoma (OAG)**, the most common form, is a chronic disease in which the anterior chamber angle remains open, but drainage of aqueous humor through the trabecular meshwork loses efficiency. This can lead to increased intraocular pressure (IOP), progressive optic nerve damage, and vision loss over time. However, a subset of patients may have normal-tension (low-tension) glaucoma, a form of OAG characterized by optic nerve damage despite IOP being within the normal range. Regardless, treatment strategies for OAG are aimed at lowering IOP, the primary modifiable risk factor associated with disease progression ([1]Jacobs & Lin 2026).

Topical ophthalmic drops or laser trabeculoplasty are typical first-line treatment for primary OAG. Pharmacologic therapy may include prostaglandin analogs, carbonic anhydrase inhibitors, beta-blockers, cholinergic agonists, or other drugs. 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 invasive incisional surgery ([2]Jacobs & Lin 2026). Minimally invasive glaucoma surgeries, such as subconjunctival or trabecular drainage devices, are less invasive options intended to increase aqueous humor outflow and lower IOP (Gurnani & Tripathy 2023).

IOP naturally rises during sleep, typically by 10-20%; therefore, some patients may have well-controlled IOP during the daytime but will continue to experience disease progression associated with nocturnal elevations in IOP. As a result, treatments aimed to improve nighttime IOP control for patients with OAG have been developed (Hayes 2026).

The **FSYX Ocular Pressure Adjusting Pump** is an adjunctive, noninvasive device intended to reduce IOP during sleep in adults who have normal daytime IOP. The system consists of goggles connected to a programmable pump with pneumatic tubing. During sleep, the device applies mild negative pressure around the eyes to lower IOP. Negative pressure can be independently programmed for each eye by a healthcare professional. The goggles are available in multiple sizes with an adjustable nose bridge and head strap and are replaced approximately every 30 days. The device was previously called the Multi-Pressure Dial in earlier research (Hayes 2026).

Regulatory Status

In 2024, the FSYX Ocular Pressure Adjusting Pump system (Balance Ophthalmics, Inc.) was granted FDA De Novo classification (DEN230055) under product code QQJ. In 2026, the device received FDA clearance through the 510(k) premarket notification process (K252455) and is regulated as an external ocular negative pressure system and Class II device under product code QQJ. The device is indicated for the reduction of IOP during sleep in adult patients with OAG and IOP $\leq$ 21 mmHg who are currently using or have undergone another IOP-lowering treatment.

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RELATED POLICIES

MCP-389: Minimally Invasive Glaucoma Surgeries

COVERAGE POLICY

The FSYX Ocular Pressure Adjusting Pump for the treatment of any condition, including open-angle glaucoma, is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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

Ferguson et al. (2025) conducted the HERCULES study, a multicenter, double-masked, randomized controlled trial (RCT) evaluating the safety and effectiveness of an ocular pressure adjusting pump in patients with normal-tension glaucoma. The study enrolled 186 eyes in 93 participants with bilateral normal-tension glaucoma, ≥ 40 years old, and with a baseline intraocular pressure (IOP) > 12 and ≤ 21 mmHg. For each participant, one eye was randomized to negative pressure treatment and the contralateral eye served as an untreated control. Mean baseline IOP was 14.7 ± 2.0 mmHg in study eyes and 14.8 ± 2.2 mmHg in control eyes. Patients were instructed to wear the device nightly for 52 weeks and existing glaucoma medications were permitted. Of 93 participants, 60 completed all required visits without protocol deviations and were included in the analysis. The primary endpoint was the proportion of eyes achieving an IOP reduction ≥ 20% during negative pressure application at week 52. This endpoint was achieved in 88.3% of study eyes versus 1.7% of control eyes, for a between-group difference of 86.7% (95% confidence interval [CI] 73.7%-94.1%, $p < 0.001$). Additionally, mean in-clinic IOP decreased from 18.0 ± 3.2 to 11.4 ± 3.0 mmHg, a 6.6 mmHg reduction, in study eyes at week 52, compared to a 1.6 mmHg reduction in control eyes. Ocular adverse events occurred in 26.9% (25/93) of study eyes versus 14.0% (13/93) of control eyes, with the most frequently reported adverse events being eyelid edema (11.8% of study eyes versus 1.1% of control eyes) and periorbital edema (12.9% of study eyes versus 1.1% of control eyes). Two participants experienced bilateral periorbital contact dermatitis and discontinued treatment. All ocular and periorbital adverse events either resolved or were considered stable at study completion, and no unresolved events were considered device related. Device adherence data demonstrated a mean nightly wear time of 5.5 to 5.6 hours throughout the study. Study limitations include the absence of patient-reported outcomes, limited sample sizes for subgroup analyses, and the contralateral-eye study design which may not reflect real-world bilateral device use or its potential effects on treatment adherence. The authors concluded that the ocular pressure adjusting pump provides statistically and clinically significant reduction in daytime and nocturnal IOP in patients with normal-tension glaucoma, with a favorable safety profile and no device-related serious adverse events. The study was funded by Balance Ophthalmics, Inc., the manufacturer of the device.

Ferguson et al. (2024) conducted a single-center, open-label pilot RCT to evaluate whether the FSYX Ocular Pressure Adjusting Pump (OPAP) could provide sustained IOP lowering over 8 hours of use. A total of 18 eyes (9 participants) with bilateral open-angle glaucoma (OAG) successfully completed the study. For each participant, one eye randomized to treatment with negative pressure set at 60% of baseline pneumotonometry IOP, and the other eye serving as an intra-subject control programmed to 0 mmHg. IOP was measured using Excursion tonometry, once at baseline, then immediately after negative pressure began, and every 2 hours throughout the 8-hour study. Mean baseline IOP in the treated eye was 21.4 ± 4.3 mmHg. At hours 0, 2, 4, 6, and 8, mean IOP was 13.3, 15.0, 15.1, 14.1, and 14.7 mmHg, corresponding to reductions of 38%, 30%, 29%, 34%, and 31%, respectively, with all reductions being statistically

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significant compared to baseline IOP ($p < 0.01$). Across the full treatment period, the mean treated-eye IOP was 14.4 ± 2.6 mmHg, corresponding to an average 7.0 mmHg (32%) reduction from baseline IOP. After negative pressure was stopped mean IOP was 23.1 ± 3.5 mmHg, which was not significantly different from baseline ($p = 0.41$). Mean baseline IOP in the control eye was 20.4 ± 3.6 mmHg and subsequent measurements throughout the 8-hour study were not significantly different from baseline. One participant developed a corneal abrasion which was detected after the end of the 8-hour session, and the investigators attributed it to the repeated IOP measurements rather than negative pressure treatment. Study limitations include a very small sample size, open-label and single-center design, and the reliance on the relatively new, Excursion tonometry method, designed specifically for use with OPAP, to measure effectiveness rather than conventional tonometry. The authors concluded that OPAP produced a sustained IOP reduction exceeding 25% throughout 8 hours of continuous wear, without evidence of tachyphylaxis or a significant post-treatment IOP spike. The study was sponsored by Balance Ophthalmics Inc., the manufacturer of the device, with one of the authors being the founder and owner of the company, and multiple authors being consultants for the company.

Samuelson et al. (2023) conducted multicenter RCT, named the EXPLORER trial, to evaluate the safety and effectiveness of the Multi-Pressure Dial (MPD) system, the original name for the FSYX OPAP, for lowering IOP. Participants included adults aged ≥ 22 years with suspected glaucoma, ocular hypertension, or OAG (including primary open-angle, normal tension, pseudoexfoliative, and pigmentary glaucoma). A total of 116 eyes (58 participants) completed the 90-day study. For each participant, one eye was randomized to receive negative pressure while the other served as an intra-subject control with 0 mmHg negative pressure. Participants used the device nightly with a mean wear time of 4.1 ± 0.2 hours per night. The primary endpoint was the proportion of eyes achieving ≥ 20% IOP reduction during negative-pressure application on day 90 compared with IOP immediately before negative pressure during the same visit. On days 30 and 60, ≥ 20% reductions occurred in 82.8% and 89.7% of treated eyes, respectively, compared with 1.7% and 5.2% of control eyes. On day 90, 89.7% of treated eyes achieved ≥ 20% IOP reduction versus 3.4% of control eyes, resulting in a between-group difference of 86.2% (95% CI 64.4-100%, $p < 0.001$). A ≥ 25% reduction was achieved by 77.6% of treated eyes versus 1.7% of controls ($p < 0.001$). Mean IOP decreased from 19.4 ± 3.6 to 12.9 ± 3.2 mmHg during negative-pressure application in treated eyes, a 33.4% reduction, versus a 3.4% reduction in control eyes. The authors noted that the effects occurred during active device use and that IOP returned toward pretreatment levels after negative pressure was discontinued. Device-related ocular or periocular events were reported in 34.4% of treated eyes and 23.4% of control eyes. The most common events were lid edema (17.2% treated eyes vs. 7.8% control) and periorbital edema (14.1% treated vs. 10.9% control). In treated eyes, dry-eye signs or symptoms occurred in 4.7%, eye pain occurred in 4.7%, and periorbital contact dermatitis occurred in 1.6%. Four participants withdrew because of difficulty with overnight device wear, and 1 participant withdrew because of periorbital dermatitis attributed to silicone allergy. Limitations include relatively small sample size, short follow-up duration, the use of in-clinic IOP measurements as a surrogate for nocturnal home-use effects, and the reliance on the relatively new Excursion Test method to measure effectiveness during negative pressure rather than conventional tonometry. Additionally, a 14-day trial was required for participants during the screening period to demonstrate the ability to wear the device ≥ 3 hours per night before randomization. The authors concluded that localized periocular negative pressure with the MPD safely, effectively, and predictably lowered IOP in patients with suspected glaucoma, ocular hypertension, and OAG. The study was funded by Equinox Ophthalmic, the former name of Balance Ophthalmics Inc., the manufacturer of the device. The company designed and conducted the collection, management, and interpretation of the study data.

Ferguson et al. (2020) conducted a single-site, open-label RCT to evaluate the overnight safety and tolerability of the MPD system in adults with OAG. A total of 20 eyes (10 participants) completed the study. For each participant, one eye was randomized to receive -10 mmHg of periocular negative pressure while the other eye received 0 mmHg and served as an intra-subject control. Participants were instructed to wear the MPD device overnight for 7 consecutive nights. Safety assessments included IOP, best-corrected visual acuity (BCVA), slit-lamp and dilated fundus examinations, retinal nerve fiber layer optical coherence tomography, and adverse events. IOP was measured with pneumotonometry using an excursion test with the MPD in place. Baseline mean IOP in the study eye, before the 7-night wear period, was 18.1 ± 2.7 mmHg, which decreased to 14.0 ± 2.1 mmHg with negative pressure, corresponding to a 4.1 mmHg (23%) reduction ($p < 0.01$). Baseline mean IOP in the control eye was 18.2 ± 3.8 mmHg and decreased to 17.9 ± 4.2 mmHg with 0 mmHg of negative pressure. After 7 days of nightly use, mean study-eye IOP without negative pressure was 16.9 ± 4.1 mmHg and decreased to 13.5 ± 3.7 mmHg with negative pressure, corresponding to a 3.4 mmHg (20%) reduction ($p < 0.01$). In the control eye, mean IOP was 16.9 ± 4.3 mmHg and increased to 17.4

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± 4.4 mmHg with 0 mmHg of negative pressure. Using Goldmann applanation tonometry, IOP (without negative pressure applied) remained unchanged from baseline (17.1 mmHg in the study eye and 17.0 mmHg in the control eye) to the conclusion of the 7-day study (17.0 mmHg in the study eye and 17.2 in the control eye). BCVA did not significantly change. Slit lamp and fundus examinations showed no new abnormalities, including no optic nerve edema, conjunctival hyperemia, or vessel engorgement. Retinal nerve fiber layer thickness showed no significant or qualitative change over the study period. Patient tolerability was rated on a 1 to 10 scale, with 1 being most favorable and 10 being least favorable, with a mean score of 3.2 ± 0.5. Three adverse events were reported involving periorbital edema, with one participant electing to discontinue the study after the sixth consecutive night. Limitations include small sample size, a short 7-day study duration, and the use of one negative pressure setting (-10 mmHg). The authors concluded that the MPD system was safe and tolerable for nightly use for up to 7 consecutive days, but longer-term studies are needed to establish the safety and efficacy of extended use. The study was funded by Equinox Ophthalmic, the former name of Balance Ophthalmics Inc., the manufacturer of the device.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Goldberg et al. (2021) conducted a prospective, nonrandomized controlled interventional study to evaluate the short-term safety and feasibility of the MPD system for reducing nocturnal IOP in adults with bilateral OAG. While prior studies have evaluated overnight safety and tolerability of MPD, this study aimed to determine whether application of negative pressure could produce a measurable reduction in IOP during the nocturnal period while in supine position. 22 eyes of 11 participants completed the study. For each participant, one eye was designated as the treatment eye (whichever eye had a higher baseline supine IOP) and the other was designated as the control eye. The treatment eye received negative pressure at 3 different time points during the study period, set at 60% of baseline IOP, while the control eye received 0 mmHg of negative pressure. All participants were currently being treated with a topical prostaglandin analog. The primary outcome was mean IOP during active negative-pressure application, measured with pneumotonometry using a modified investigational method called Excursion tonometry. At 10:30 PM, mean IOP decreased from 22.5 ± 3.2 to 14.0 ± 2.4 mmHg in the treatment eye, corresponding to a 38% reduction ($p < 0.001$). At 2:00 AM, it decreased from 21.8 ± 2.22 to 14.3 ± 2.3 mmHg, a 34% reduction ($p < 0.001$). At 5:30 AM, it decreased from 22.2 ± 2.2 to 14.4 ± 2.1 mmHg, a 35% reduction ($p < 0.001$). Across all 3 measurements, mean treatment-eye IOP decreased from 22.2 ± 2.5 to 14.2 ± 2.2 mmHg, a mean 35% reduction ($p < 0.001$). Every participant achieved a > 20% IOP reduction in their treatment eye at all 3 time points, and 82% of participants had an average reduction of ≥ 30%. Control eyes also showed a small reduction in IOP during the study, from an overall mean IOP of 21.8 ± 2.5 to 19.5 ± 2.4 mmHg. The authors noted this as an unexpected control eye reduction that had not been observed in prior studies and warrants further investigation. Two adverse events occurred, with one participant developing eye pain associated with anterior uveitis that was treated with topical therapy and the other developing diarrhea. Study limitations include a very small sample size, a single study visit and short-term duration, and nonrandomized design. Notably, the IOP-lowering effect was present only while negative pressure was being applied. IOP returned to baseline after device removal. The authors concluded that the MPD system produced significant short-term reductions in nocturnal supine IOP and could potentially serve as a noninvasive adjunctive or independent treatment option for nocturnal IOP control. The study was funded by Equinox Ophthalmic, the manufacturer of the device.

National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** published the *Primary Open-Angle Glaucoma Preferred Practice Pattern* (Gedde et al. 2026). The AAO mentions the FSYX OPAP as a novel device, along with “other therapies” like herbal medicines and nutritional supplements but does not provide a recommendation for its use in the treatment of OAG. The AAO lists laser surgery, pharmacologic therapy, and incisional surgery (alone or in combination) as the primary treatment options for OAG and emphasizes that trabeculectomy remains the most effective surgical procedure to lower IOP. Trabeculectomy is generally indicated when medications and laser surgery are insufficient to control the disease.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
E2403	External ocular negative pressure pump, electric

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A6614	Supplies and accessories for use with an external ocular negative pressure pump, any type, per month

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APPROVAL HISTORY

10/21/2026 New policy. IRO peer reviewed on September 28, 2026 by a practicing physician board certified in ophthalmology.

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