

Local Coverage Determination (LCD): Micro-Invasive Glaucoma Surgery (MIGS) (L38223)

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LCD Information

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Source Proposed LCD

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N/A

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for microinvasive glaucoma surgery (MIGS). Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for MIGS and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 14, Medical Devices, Section 10 Coverage of Medical Devices
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 23 Fee Schedule Administration and Coding Requirements, Section 30 Services paid under the Medicare Physicians Fee Schedule
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13 Local Coverage Determinations,
 - Section 13.5.3 Evidentiary Content
 - Section 13.5.4 Reasonable and necessary provisions in LCDs

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Primary open-angle glaucoma (POAG) is a chronic, progressive optic neuropathy in adults in which there is a characteristic acquired atrophy of the optic nerve and loss of retinal ganglion cells and their axons. A risk factor associated with POAG is increased intraocular pressure (IOP) due to a buildup of aqueous fluid within the eye which can lead to visual field loss and optic nerve damage, usually without any associated pain or discomfort. The increased IOP is secondary to an imbalance between aqueous fluid secretion and fluid outflow despite an open angle. Although many patients with POAG present with increased IOP, nearly 40% of those with otherwise characteristic POAG may not have elevated IOP measurements.

The goal in POAG 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. When the maximum tolerated medical therapy fails to control progression of glaucomatous optic neuropathy, surgical care is considered the next treatment option.

Traditional External Filtration Surgery

IOP should be lowered by improving outflow of eye fluid. This is the mechanism used by traditional glaucoma surgeries, such as trabeculectomy or tube shunt surgeries with aqueous drainage implants. These procedures are performed from outside the eye, or an ab externo approach. Trabeculectomy uses the patient's own sclera to create a fistula to the subconjunctival space over the sclera superiorly. Aqueous drainage implants use silicone/plastic tubing and large plates to shunt aqueous to the subconjunctival space in the equatorial region of the eyeball.

Micro-Invasive or Minimally Invasive Glaucoma Surgery (MIGS)

The term MIGS refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications.

Covered Indications

Glaucoma surgical aqueous drainage devices will be considered medically reasonable and necessary when approved by the FDA and used within accordance of the FDA-approved/cleared indications.

1. A single insertion per eye of an anterior segment aqueous drainage device(s), without extraocular reservoir, via internal approach into the trabecular meshwork or with creation of intraocular reservoir into the supraciliary space is considered medically reasonable and necessary in conjunction with cataract surgery for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication.
2. A single insertion per eye of an aqueous drainage device(s) without extraocular reservoir, via internal approach into the subconjunctival space is considered medically reasonable and necessary as a standalone treatment for refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and/or mean diurnal medicated IOP greater than or equal to 20 mmHg) on maximally tolerated medical therapy (i.e., greater than or equal to 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).

Limitations

The following are considered not medically reasonable and necessary:

1. Glaucoma drainage devices that do not have FDA approval/clearance and/or devices that have been recalled.
2. Glaucoma drainage devices used outside of the FDA approval/clearance.
3. Insertion of an anterior segment aqueous drainage device without extraocular reservoir, via internal approach into the suprachoroidal space.
4. Additional insertions of anterior segment aqueous drainage device(s) without extraocular reservoir, via internal approach into the trabecular meshwork.
5. Additional insertions of aqueous drainage device(s) without extraocular reservoir, via internal approach into the subconjunctival space.
6. A single insertion of an FDA-approved/cleared anterior segment aqueous drainage device(s) without extraocular reservoir, via internal approach into the trabecular meshwork or with creation of intraocular reservoir via internal approach into the supraciliary space not performed in conjunction with cataract surgery.
7. Goniotomy procedure performed in conjunction with the insertion of a glaucoma drainage device. Routine performance of goniotomy with insertion of a glaucoma drainage device may be subject to focused medical review.
8. Trabeculectomy procedure performed in conjunction with the insertion of a glaucoma drainage device. Routine performance may be subject to focused medical review.
9. Insertion of glaucoma drainage device(s) (i.e. one or two microstents) into the trabecular meshwork or into the supraciliary space are limited to one insertor per eye when performed in conjunction with cataract surgery and when the medically reasonable and necessary criteria as stated above are met.
 - Additional insertor use for device insertions on one eye is considered not medically reasonable and necessary.
10. Insertion of glaucoma drainage device(s) into the subconjunctival space are limited to one insertion per eye per day when the medically reasonable and necessary criteria as stated above are met.
 - Additional device insertions are considered not medically reasonable and necessary.

Provider Qualifications

Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. This training and expertise must have been acquired within the frame work of an accredited residency and/or fellowship program in the applicable specialty/subspecialty or must reflect extensive continued medical education activities. If these skills have been acquired by way of continued medical education, the courses must be comprehensive, offered or sponsored or endorsed by an academic institution in the United States and/or by the applicable specialty /subspecialty society in the United States, and designated by the American Medical Association (AMA) as Category I Credit.

• Provider Specialties

- Insertion of glaucoma drainage devices addressed in this LCD must be performed by a qualified physician (MD or DO) who is a board certified ophthalmologist having completed a residency and/or fellowship program and maintains ongoing certification in ophthalmology.
- In addition, insertion of a substitute standalone drainage device into the subconjunctival space without associated cataract extraction must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

Published pivotal trials for FDA Approved/Cleared Glaucoma Drainage Devices:

- **iStent® Study Group**

A prospective, randomized, open-label, controlled multicenter clinical trial to assess the safety and efficacy of the iStent trabecular micro-bypass stent (Glaukos Corporation, Laguna Hills, CA) in combination with cataract surgery in subjects with mild to moderate open-angle glaucoma was conducted.¹ A total of 240 eyes with mild to moderate open-angle glaucoma with IOP less than or equal to 24 mmHg controlled on 1 to 3 medications were randomized to undergo cataract surgery with iStent implantation (treatment group) or cataract surgery only (control). The study results met the primary outcome, with 72% of treatment eyes versus 50% of control eyes achieving the criterion (P less than 0.001). At 1 year, IOP in both treatment groups was statistically significantly lower from baseline values. Sixty-six percent of treatment eyes versus 48% of control eyes achieved greater than or equal to 20% IOP reduction without medication (P equal to 0.003). The overall incidence of adverse events was similar between groups with no unanticipated adverse device effects. The authors concluded that pressure reduction on fewer medications was clinically and statistically significantly better 1 year after stent plus cataract surgery versus cataract surgery alone, with an overall safety profile similar to that of cataract surgery alone. TRIAL REGISTRATION: ClinicalTrials.gov NCT00323284.

- **iStent® Study Group 2 year follow-up**

A prospective randomized controlled multicenter clinical trial to assess the long-term safety and efficacy of a single trabecular micro-bypass stent with concomitant cataract surgery versus cataract surgery alone for mild to moderate open-angle glaucoma was conducted.² Eyes with mild to moderate glaucoma with an unmedicated IOP of 22 mmHg or higher and 36 mmHg or lower were randomly assigned to have cataract surgery with iStent trabecular micro-bypass stent implantation (stent group) or cataract surgery alone (control group). Patients were followed for 24 months postoperatively. The results showed the incidence of adverse events was low in both groups through 24 months of follow-up. At 24 months, the proportion of patients with an IOP of 21 mmHg or lower without ocular hypotensive medications was significantly higher in the stent group than in the control group (P equal to .036). Overall, the mean IOP was stable between 12 months and 24 months (17.0 mmHg plus or minus 2.8 [SD] and 17.1 plus or minus 2.9 mmHg, respectively) in the stent group but increased (17.0 plus or minus 3.1 mmHg to 17.8 plus or minus 3.3 mmHg, respectively) in the control group. Ocular hypotensive medication was statistically significantly lower in the stent group at 12 months; it was also lower at 24 months, although the difference was no longer statistically significant. The authors concluded that patients with combined single trabecular micro-bypass stent and cataract surgery had significantly better IOP control on no medication through 24 months than patients having cataract surgery alone. Both groups had a similar favorable long-term safety profile.

- **CyPass® Study Group - The COMPASS Trial**

A multicenter (24 US sites), interventional randomized clinical trial (RCT) (ClinicalTrials.gov identifier, NCT01085357) was conducted to evaluate the CyPass® device.³ Subjects were enrolled beginning July 2011, with study completion in March 2015. Subjects had POAG with mean diurnal unmedicated IOP 21-33 mmHg and were undergoing phacoemulsification cataract surgery. After completing cataract surgery, subjects were intraoperatively randomized to phacoemulsification only (control) or supraciliary microstenting with phacoemulsification (microstent) groups (1:3 ratio). Microstent implantation via an ab interno approach to the supraciliary space allowed concomitant cataract and glaucoma surgery. The study of 505 subjects showed that 131 were randomized to the control group and 374 were randomized to the microstent group. Baseline mean IOPs in the control and microstent groups were similar: 24.5 plus or minus 3.0 and 24.4 plus or minus 2.8 mmHg, respectively (P greater than 0.05); mean medications were 1.3 plus or minus 1.0 and 1.4 plus or minus 0.9, respectively (P greater than 0.05). There was early and sustained IOP reduction, with 60% of controls versus 77% of microstent subjects achieving greater than or equal to 20% unmedicated IOP lowering versus baseline at 24 months (P equal to 0.001; per-protocol analysis). Mean IOP reduction was down 7.4 mmHg for the microstent group versus down 5.4 mmHg in controls (P less than 0.001), with 85% of

microstent subjects not requiring IOP medications at 24 months. Mean 24-month medication use was 67% lower in microstent subjects (P less than 0.001); 59% of control versus 85% of microstent subjects were medication free. Mean medication use in controls decreased from 1.3 plus or minus 1.0 drugs at baseline to 0.7 plus or minus 0.9 and 0.6 plus or minus 0.8 drugs at 12 and 24 months, respectively, and in the microstent group from 1.4 plus or minus 0.9 to 0.2 plus or minus 0.6 drugs at both 12 and 24 months (P less than 0.001 for reductions in both groups at both follow-ups vs. baseline). No vision-threatening microstent-related AEs occurred. Visual acuity was high in both groups through 24 months; greater than 98% of all subjects achieved 20/40 best-corrected visual acuity or better. The authors concluded that this RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication use after microinterventions surgical treatment for mild-to-moderate POAG.

CyPass® Voluntary Recall

Alcon Research issued a voluntary market withdrawal of the CyPass® Micro-Stent from the global market. The firm announced the voluntary market withdrawal, based on five-year post-surgery data from the COMPASS-XT long-term safety study, demonstrating a clinically and statistically significant increase in corneal endothelial cell loss reported in the CyPass® Micro-Stent group compared to the cataract surgery-only control group.

- **XEN45® Gel Stent**

The XEN45® device received 510(k) FDA clearance based on having a similar mechanism (subconjunctival pathway) to “gold standard” filtration procedures (i.e., trabeculectomy and tube shunts), demonstrating “substantial equivalence” in the pivotal prospective study of patients with refractory glaucoma.⁴ The study design was a single-arm, open-label, multicenter clinical study to evaluate the intraocular pressure (IOP)-lowering performance and safety of an ab interno gelatin stent (XEN45® Gel Stent, Allergan plc, Irvine, California, USA), a minimally invasive glaucoma surgery device, in refractory glaucoma. Following mitomycin C pretreatment, the stent was placed ab interno in patients who failed prior filtering/cilioablative procedure or had uncontrolled IOP on maximum-tolerated medical therapy, with medicated IOP greater than or equal to 20 and less than or equal to 35 mmHg and visual field mean deviation less than or equal to -3 dB. Primary performance outcomes: patients (%) achieving greater than or equal to 20% IOP reduction from baseline on the same or fewer medications and mean IOP change from baseline at month 12. Procedure-related complications and ocular adverse events (AEs) were assessed. The results show sixty-five patients were implanted (intent-to-treat/safety population). At 12 months, 75.4% (46/61; observed data) reported greater than or equal to 20% IOP lowering from baseline on the same or fewer medications. Mean IOP change from baseline was -9.1 mmHg (95% confidence interval [CI]: -10.7, -7.5) (n equal to 52; observed data) at 12 months, excluding patients with missing data (n equal to 4) and those requiring a glaucoma-related secondary surgical intervention (n equal to 9). Mean medication count decreased from 3.5 (baseline) to 1.7 (12 months). No intraoperative complications or unexpected postoperative AEs were reported. Most AEs were mild/moderate; common AEs included needling (without sight-threatening complications), nonpersistent loss of best-corrected visual acuity, and transient hypotony (requiring no surgical intervention). The authors concluded that the gelatin stent reduced IOP and medication use without raising unexpected safety concerns, offering a minimally invasive surgical option for refractory glaucoma patients.

- Equivalency was further established by a relatively large retrospective cohort study comparing XEN45® with trabeculectomy, finding “no detectable difference in risk of failure and safety profiles”.⁵ The study design was an International, multicenter, retrospective interventional cohort study to compare the efficacy, safety, and risk factors for failure of standalone ab interno gel microstent implantation with mitomycin C (MMC) versus trabeculectomy with MMC. The participants included three hundred fifty-four eyes of 293 patients (185 microstent and 169 trabeculectomy) with no prior incisional surgery. Consecutive eyes with uncontrolled glaucoma underwent microstent or trabeculectomy surgery from January 1, 2011 through July 31, 2015 at 4 academic ophthalmology centers. The results reported baseline characteristics were similar, except more men (56% vs. 43%), younger patients (average, by 3 years), better preoperative visual acuity (22% vs. 32% with 0.4 logarithm of the minimum angle of resolution vision or worse), and more trabeculoplasty (52% vs. 30%) among microstent eyes. The adjusted HR of failure of the microstent relative to trabeculectomy was 1.2 (95% confidence interval [CI], 0.7-2.0) for complete success and 1.3 (95% CI, 0.6-2.8) for qualified success, and similar for other outcomes. Time to 25% failure was 11.2 months (95% CI, 6.9-16.1 months) and 10.6 months (95% CI, 6.8-16.2 months) for complete success and 30.3 months (95% CI, 19.0-infinite months) and 33.3

months (95% CI, 25.7-46.2 months) for qualified success. Overall, white ethnicity was associated with decreased risk of failure (adjusted HR, 0.49; 95% CI, 0.25-0.96), and diabetes was associated with increased risk of failure (adjusted HR, 4.21; 95% CI, 2.10-8.45). There were 117 and 165 distinct interventions: 43% and 31% underwent needling, respectively, and 50% of trabeculectomy eyes underwent laser suture lysis. There were 22 and 30 distinct complications, although most were transient. Ten percent and 5% underwent reoperation (P equal to 0.11). The authors concluded that there was no detectable difference in risk of failure and safety profiles between standalone ab interno microstent with MMC and trabeculectomy with MMC.

- **iStent inject® Pivotal Trial under Investigational Device Exemption (IDE)**

The aim of the iStent inject® Pivotal Trial (Protocol GC-008) under IDE G100326 was to establish a reasonable assurance of safety and effectiveness of the iStent inject for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (OAG). Data from this clinical study were the primary basis for the PMA approval decision.

The iStent inject® U.S. IDE pivotal study was a prospective, randomized, multicenter clinical trial that included 40 investigational sites and 505 mild-to-moderate POAG eyes that were randomized to receive iStent inject in combination with cataract surgery (n equal to 387) or cataract surgery only (n equal to 118.) The pivotal trial data show that the iStent inject® achieved a statistically significant reduction in unmedicated diurnal IOP in patients undergoing cataract surgery at 24 months as 75.8% of the iStent inject® cohort achieved a 20% or greater reduction in unmedicated IOP and the mean unmedicated IOP reduction was 7.0 mmHg for the iStent inject cohort. In addition to meeting the study's primary and secondary effectiveness endpoints, at 24 months, observed data show the iStent inject cohort achieved a 31% mean reduction, or 7.7 mmHg, in unmedicated IOP from an unmedicated mean baseline IOP of 24.8 mmHg to 17.1 mmHg. Finally, through 24 months, the overall rate of adverse events for the iStent inject cohort was similar to cataract surgery alone.

- **Prospective Randomized Trial comparing Hydrus Microstent and iStent**

Microinvasive Glaucoma Surgery Implants for Standalone Treatment of open-Angle Glaucoma: The COMPARE Study. Comparison of clinical outcome (lowering of IOP and reduction in medication requirements) for 154 patients randomized to receive either 1 Hydrus Microstent or 2 iStent Trabecular Micro Bypass devices for treatment of open-angle glaucoma (OAG) was made to compare efficacy of the two devices. Previous studies (Katz, Donnenfeld, Voskanyan, Fes, Pfeiffer, Samuelson [Horizon]) utilizing one device (iStent) have suggested inferiority of a single iStent compared to a single Hydrus Microstent in both standalone and with Cataract Extraction procedures. Decrease in IOP was contradictory in two studies (Katz, Donnenfeld) related to the placement of a second device when baseline IOP was equivalent (20+.1). However, the addition of the second iStent (in the non-randomized studies) appears to allow for similar reduction in IOP and medication reduction in both standalone and with CE. The COMPARE Study of the two standalone MIGS in OAG, without CE, resulted in a higher surgical success rate and fewer medications for patients treated with the Hydrus Microstent compared with the 2-iStent Procedure.

Evidence-Based Guideline:

- According to the 2015 American Academy of Ophthalmology (AAO) POAG Preferred Practice Pattern (PPP), the "potential benefits of a combined procedure (cataract extraction with IOL implantation and trabeculectomy) are protection against the IOP rise that may complicate cataract surgery alone, the possibility of achieving long-term glaucoma control with a single operation, and elimination of the risk of bleb failure with subsequent cataract surgery when glaucoma surgery is performed first. Therefore, an ophthalmologist may reasonably choose to perform a combined surgery because of these perceived advantages to an individual patient. Other types of glaucoma surgery can also be combined with cataract surgery, such as implantation of aqueous shunts, nonpenetrating glaucoma surgery, minimally invasive glaucoma surgery, and endocyclophotocoagulation."

Analysis of Evidence

(Rationale for Determination)

Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma.

A number of devices known as micro-stents have received FDA approval for minimally invasive glaucoma procedures. While these devices differ in their material composition and site of insertion for accomplishing enhanced drainage of aqueous humor, randomized clinical trials, cost effectiveness and quality of life studies have shown that these devices may offer a reduction in IOP, decreased dependence on glaucoma medications and an excellent safety profile.

However, stents and tensioning devices are only able to reduce IOP to the mid-teens, and may be inadequate when very low IOP is needed to reduce glaucoma damage. Evaluation of outcomes of the use of micro-stents in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication is ongoing.

The FDA approved indications for insertion of the iStent®, and iStent inject®, as well as the Hydrus Microstent glaucoma drainage devices (based on pivotal trial criteria summarized above) is for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery. In that setting, these procedures offer a reduction in IOP, decreased dependence on glaucoma medications, and an excellent safety profile. However, their role within the glaucoma treatment algorithm continues to be clarified and differs from the role of more invasive, external filtration glaucoma surgeries such as trabeculectomy or external aqueous drainage implants.

The FDA 510(k) clearance indication for insertion of the XEN45® glaucoma drainage device (based on the pivotal trial criteria summarized above) is for the management of refractory glaucomas, 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 FDA-approved/cleared indication for use of these glaucoma drainage devices serves as the basis for medical necessity and all other indications are considered not reasonable and necessary at this time. Glaucoma drainage devices that do not have FDA approval/clearance are considered not medically reasonable and necessary for treating glaucoma. The studies of Katz (18 mo follow-up) as well as Donnenfeld (36 mo follow-up) demonstrate the IOP and medication reductions of a single iStent Trabecular Micro Bypass device to be inferior to other FDA approved procedures and devices available for similar patients, both undergoing Cataract Extraction (CE) and as a standalone procedure. As of the time of publication of this Local Coverage Determination, no FDA clearance or indication for either the iStent Micro Bypass or the Hydrus Microstent as a standalone procedure has been established; whereas coverage is delineated for use as a standalone procedure, as well as conjunctive procedure to CE, for the XEN45® in patients with mild to moderate OAG. Subsequently, the placement of 2 iStents utilizing the iStent Inject, will be considered medically necessary since it appears to allow for an increased reduction in IOP and medication reduction to that achieved by using a single iStent device and appears to achieve similar reduction in IOP and medication reduction to other available procedures.

Please refer to the CyPass® recall for further information on this device.

Contractors Advisory Comment Summary

After review of the literature, the CAC advisory panel discussed various treatment options utilizing Micro-Invasive Glaucoma Surgery (MIGS). The CAC panel discussed the need for MIGS trials that adhere to the World Glaucoma Association Guidelines as the current published studies of MIGS devices do not adhere to these guidelines, which hinders meaningful evaluation of these technologies. Additionally, MIGS devices are not designed to curtail risk of glaucoma exacerbation associated with cataract extraction. Rather, they are designed to reduce intra-ocular pressure

(IOP) and/or reduce glaucoma medication burden in those patients with mild to moderate glaucoma undergoing cataract extraction. The CAC panel agrees that MIGS devices have shown evidence of lowering IOP and/or reducing the number of drops needed to achieve target IOP both of which are important in slowing glaucoma progression and impact quality of life. Further, the primary benefit of MIGS is reducing the burden of IOP lowering drops and extending out the timeline for avoiding more invasive surgeries. The CAC panel mentioned utilizing data from Intelligent Research in Sight (IRIS), developed by the American Academy of Ophthalmology, would generate an improved evidence base and improve care for the Medicare population affected by glaucoma and/or associated anterior chamber procedures.

General Information

Associated Information

Please refer to Local Coverage Article: Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) (A56633), for all coding information.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Contractor's Policies

CGS Administrators, LLC LCD L37578 Micro-Invasive Glaucoma Surgery (MIGS)

National Government Services, Inc. LCD L37244 Micro-Invasive Glaucoma Surgery (MIGS)

Palmetto GBA DL37531 Proposed Local Coverage Determination (LCD): Micro-Invasive Glaucoma Surgery (MIGS)

Contractor Medical Directors

Bibliography

1. Samuelson TW, Katz LJ, Wells JM, et al. US iStent Study Group. Randomized Evaluation of the Trabecular Micro-Bypass Stent with Phacoemulsification in Patients with Glaucoma and Cataract. *Ophthalmology*. 2011;118(3):459-67.
2. Craven ER, Katz LJ, Wells JM, Giamporcaro JE. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: Two-year follow-up. *Journal of Cataract & Refractive Surgery*. 2012;38(8):1339-1345. doi:10.1016/j.jcrs.2012.03.025.
3. Vold S, Ahmed IIK, Craven ER, et al. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. *Ophthalmology*. 2016;123(10):2103-2112. doi:10.1016/j.ophtha.2016.06.032.
4. Schlenker MB, Gulamhusein H, Conrad-Hengerer I Efficacy, Safety, and Risk Factors for Failure of Standalone Ab Interno Gelatin Microstent Implantation versus Standalone *Trabeculectomy*. *Ophthalmology*. 2017;124(11):1579-1588.
5. Grover DS, Flynn WJ, Bashford KP, et al. Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months. *Am J Ophthalmology*. 2017;183:25-36. Published by Elsevier INC.
6. Recall: CyPass Micro-Stent Withdrawn Amid Concerns of Endothelial Cell Loss. (August 29, 2018). Retrieved from <https://www.glaucoma.org/news/recall-cypass-micro-stent-withdrawn-amid-concerns-of-endothelial-cell-loss.php>.

7. Aetna Policy Number 0484. Glaucoma Surgery. Last review 12/01/2017.
8. Prum BE, Rosenberg LF, Gedde SJ. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. *American Academy of Ophthalmology (AAO)*. 2016;123(1):41-111. doi:<https://doi.org/10.1016/j.optha.2015.10.053>
9. Eliassi-Rad B, Ridha F, Tripathy K. Microinvasive Glaucoma Surgery (MIGS). Eyewiki. [http://eyewiki.aao.org/Microinvasive_Glaucoma_Surgery_\(MIGS\)](http://eyewiki.aao.org/Microinvasive_Glaucoma_Surgery_(MIGS)). Accessed December 21, 2018.
10. Anthem Medical Policy SURG.00103. Intraocular Anterior Segment Aqueous Drainage Devices (without extraocular reservoir). Publish date 02/28/2018. Last review date 01/25/2018.
11. Arriola-Villalobos P, Martinez-De-La-Casa JM, Diaz-Valle D, Morales-Fernandez L, Fernandez-Perez C, Garcia-Feijoo J. Glaukos iStent inject® Trabecular Micro-Bypass Implantation Associated with Cataract Surgery in Patients with Coexisting Cataract and Open-Angle Glaucoma or Ocular Hypertension: A Long-Term Study. *Journal of Ophthalmology*. 2016;2016:1-7. doi:10.1155/2016/1056573
12. BCBSMA Medical Policy Number 223. Aqueous Shunts and Stents for Glaucoma. Last reviewed 1/2018.
13. Berdahl J, Voskanyan L, Myers JS, et al. Implantation of two second-generation trabecular micro-bypass stents and topical travoprost in open-angle glaucoma not controlled on two preoperative medications: 18-month follow-up. *Clinical & Experimental Ophthalmology*. 2017;45(8):797-802. doi:10.1111/ceo.12958
14. Caprioli J, Kim JH, Friedman DS, et al. Special Commentary: Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery. *Ophthalmology*. 2015;122(9):1795-1801. doi:10.1016/j.optha.2015.02.029
15. Gregorio AD, Pedrotti E, Russo L, Morselli S. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. *International Ophthalmology*. 2017;38(3):1129-1134. doi:10.1007/s10792-017-0571-x
16. Giamporcaro JE, Solomon K, Voskanyan L, et al. A prospective 3-year follow-up trial of implantation of two trabecular microbypass stents in open-angle glaucoma. *Clinical Ophthalmology*. 2015:2057-2065. doi:10.2147/opth.s91732
17. Giamporcaro, Sanchis JIB, Chang L, et al. Prospective unmasked randomized evaluation of the iStent inject® versus two ocular hypotensive agents in patients with primary open-angle glaucoma. *Clinical Ophthalmology*. 2014:875-882. doi:10.2147/opth.s59932
18. Florida Blue Medical Coverage Guideline (MCG) 01-92000-24 Aqueous Shunts and Stents for Glaucoma. Revised 12/15/2017.
19. Galal A, Bilgic A, Eltanamly R, Osman A. XEN Glaucoma Implant with Mitomycin C 1-Year Follow-Up: Result and Complications. *Journal of Ophthalmology*. 2017;2017:1-5. doi:10.1155/2017/5457246
20. Gedde SJ, Herndon LW, Brandt JD, Budenz DL, Feuer WJ, Schiffman JC. Surgical Complications in the Tube Versus Trabeculectomy Study During the First Year of Follow-up. *American Journal of Ophthalmology*. 2007;143(1). doi:10.1016/j.ajo.2006.07.022
21. Bashford KP. Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months. *American Journal of Ophthalmology*. 2017;183:25-36. doi:10.1016/j.ajo.2017.01.031
22. Hengerer FH, Kohnen T, Mueller M, Conrad-Hengerer I. Ab Interno Gel Implant for the Treatment of Glaucoma Patients With or Without Prior Glaucoma Surgery. *Journal of Glaucoma*. 2017;26(12):1130-1136. doi:10.1097/ijg.0000000000000803
23. Giamporcaro JE, Katz LJ, Erb C, et al. Prospective, randomized study of one, two, or three trabecular bypass stents in open-angle glaucoma subjects on topical hypotensive medication. *Clinical Ophthalmology*. 2015:2313-2320. doi:10.2147/opth.s96695
24. Mansouri K, Guidotti J, Rao HL, et al. Prospective Evaluation of Standalone XEN Gel Implant And Combined Phacoemulsification-XEN Gel Implant Surgery: 1 year results. *Journal of Glaucoma*. 2018:140-147. doi:10.1097/ijg.0000000000000858
25. NIH U.S. National Library of Medicine. Clinical Trials.gov NCT01461291. Multicenter Study Using Glaukos® Trabecular Micro-Bypass Stent Model GTS400 Using the G2-M-IS Injector System in Conjunction With Cataract Surgery.
26. Ozal SA, Kaplaner O, Basar BB, Guclu H, Ozal E. An innovation in glaucoma surgery: XEN45 gel stent implantation. *Arquivos Brasileiros de Oftalmologia*. 2017;80(6):382-385. doi:10.5935/0004-2749.20170093
27. Pérez-Torregrosa V, Olate-Pérez Á, Cerdà-Ibáñez M, et al. Combined phacoemulsification and XEN45 surgery

- from a temporal approach and 2 incisions. *Archivos de la Sociedad Española de Oftalmología (English Edition)*. 2016;91(9):415-421. doi:10.1016/j.oftale.2016.05.004
28. Pillunat LE, Erb C, Jünemann AG, Kimmich F. Micro-invasive glaucoma surgery (MIGS): a review of surgical procedures using stents. *Clinical Ophthalmology*. 2017;Volume 11:1583-1600. doi:10.2147/opth.s160409
29. Tielsch JM. Racial Variations in the Prevalence of Primary Open-angle Glaucoma. *Jama*. 1991;266(3):369-374. doi:10.1001/jama.1991.03470030069026
30. UnitedHealthcare Medical Policy 2018T0443U. Glaucoma Surgical Treatments. Effective March 1, 2018.
31. U.S. Food and Drug Administration (FDA) approval/clearance letters and summaries. Devices@FDA located at: <https://www.accessdata.fda.gov/SCRIPTS/cdrh/devicesatfda/index.cfm>
32. Voskanyan L, García-Feijó J, Belda JI, Fea A, Jünemann A, Baudouin C. Prospective, Unmasked Evaluation of the iStent® Inject System for Open-Angle Glaucoma: Synergy Trial. *Advances in Therapy*. 2014;31(2):189-201. doi:10.1007/s12325-014-0095-y
33. Wellik S, Dale E. A review of the iStent® trabecular micro-bypass stent: safety and efficacy. *Clinical Ophthalmology*. 2015:677-684. doi:10.2147/opth.s57217
34. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract: The HORIZON Study. *Ophthalmology*. 2018.
35. Samuelson TW, Sarkisian Jr. SR, Lubeck DM, Stiles MC, Duh Y-J, Romo EA, Giamporcaro JE, Hornbeak DM, Katz LJ, for the iStent inject Study Group, Prospective, Randomized, Controlled Pivotal Trial of iStent inject Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract: Two-Year Results, *Ophthalmology* (2019), doi: <https://doi.org/10.1016/j.opthta.2019.03.006>.
36. Tseng VL, Coleman AL, Chang MY, Caprioli J. Aqueous shunts for glaucoma. Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD004918. DOI: 10.1002/14651858.CD004918.pub3.
37. Ahmed, Iqbal I.K., Fea, Antonioo, Au, Leon, Ang, R.E, Harasymowycz, Paul, Jampel, Henry, Samuelson, T.W., Chang, D.F., Rhee, D.J., COMPARE Investigators. A prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of open-Angle Glaucoma: The COMPARE Study. *Ophthalmology* (2019), doi: <http://doi.org/10.1016/j.opthta.2019.04.034>
38. de Jong L, Lafuma A, Aguadé AS, et al. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. *Clin Ophthalmology*. 2011; 5: 527-533.
39. De Gregorio A, Pedrotti E, Russo L, et al. Minimally invasive combined glaucoma and cataract surgery: clinical results of the smallest ab interno gel stent. *Int Ophthalmology*. 2018 Jun;38(3):1129-1134.
40. Netland PA, et al. Randomized, prospective, comparative trial of EX-PRESS glaucoma filtration device versus trabeculectomy (XVT study) *Am. J. Ophthalmology*. 2014;157:433-440. doi: 10.1016/j.ajo.2013.09.014.
41. Chansangpetch S, Lau K, Perez CI, Nguyen N, Porco TC, Lin SC. Efficacy of cataract surgery with trabecular microbypass stent implantation in combined-mechanism angle closure glaucoma patients. *AM J Ophthalmology* . 2018; 195:191-8.

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Associated Documents

Attachments

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Related Local Coverage Documents

Article(s)

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