Local Coverage Determination (LCD):
Micro-Invasive Glaucoma Surgery (MIGS) (L37578)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

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Coverage of Medical Devices

30 Services paid under the Medicare Physicians Fee Schedule

5.1 Reasonable and necessary provisions in LCDs

7.1 Evidence supporting LCDs.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This LCD addresses use of a group of a group of new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery (MIGS). CGS considers one iStent or CyPass device per eye medically reasonable and necessary 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. CGS considers one XEN45 device per eye medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).
Summary of Evidence

Primary open-angle glaucoma (POAG) has a prevalence in the US of 2% of adults over 40 years old, or about 2.2 million people, and is expected to increase to 3.3 million in 2020 as the population ages (1). 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. It is associated with an 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. Nearly 40% of those with otherwise characteristic POAG may not have elevated IOP measurements (1).

In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork or the inner wall of the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

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. IOP above 21 mmHg has been shown to increase rates of visual field loss. However, because of the differences in susceptibility to pressure-related disc damage among POAG patients, pressure-lowering treatments are aimed at achieving a lower “target” pressure individualized to each patient’s baseline IOP in which glaucomatous damage occurred.

When the maximum tolerated medical therapy fails to control progression of glaucomatous optic neuropathy, surgical care is considered the next treatment option. Traditional filtration surgery includes trabeculectomy (including ExPress shunt) and aqueous drainage implants (Ahmed, Baerveldt, Molteno). 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.

While IOP outcomes are generally worse with aqueous drainage implants compared with trabeculectomy, complications such as hypotony (low pressure), and postoperative infection are reduced. However, failure rates are similar (approximately 10% of devices fail annually), and shunts still have complications, including corneal endothelial failure and erosion of the overlying conjunctiva.

The term micro-invasive or minimally invasive glaucoma surgery (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.

It is this potentially improved safety profile that opened up the indications for MIGS to include patients with early-stage glaucoma to reduce the burden of medications and problems with compliance (due to eye drop application difficulty, cost, cosmetic effects, and frequency). Another area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are three FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July, 2016), and the XEN Glaucoma Treatment System (Nov, 2016). The iStent is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into Schlemm’s canal to augment the natural outflow system. CyPass is a 6.35 mm long fenestrated microstent made of biocompatible polyimide inserted into the supraciliary space, thus using an alternative outflow system. The XEN45 is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system.

Both iStent and CyPass were FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and a cataract that are currently being treated with medication to reduce IOP. XEN45 was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoxfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. The published pivotal trial data for each, constituting the main evidentiary support, is summarized in the table below.
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<th>Study</th>
<th>Year</th>
<th>Journal</th>
<th>FDA</th>
<th>Study Design</th>
<th>No. of Eyes</th>
<th>Follow-up (yrs)</th>
<th>IOP ≤ 21mm Hg no Meds</th>
<th>IOP 20% no meds</th>
<th>Mean # meds</th>
<th>Mean IOP reduction (mm Hg)</th>
<th>Conclusions</th>
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<td>Samuelson, iStent Study Group (2)</td>
<td>2011</td>
<td>Ophthalmology</td>
<td>PMA</td>
<td>RCT</td>
<td>111/122</td>
<td>1 yr. (233)</td>
<td>72%/50% (p&gt;0.001)</td>
<td>66%/48% (p=0.003)</td>
<td>0.2/0.4</td>
<td>8.4/8.2 (p=NS)</td>
<td>Pressure reduction on fewer medication 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.</td>
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<td>Craven, iStent Study Group 2 yr. follow-up (3)</td>
<td>2012</td>
<td>J Cataract Refract Surg</td>
<td>PMA</td>
<td>RCT</td>
<td>98/101</td>
<td>2 yr. (199)</td>
<td>61%/50% (p=0.036)</td>
<td>53%/44% (p=0.09)</td>
<td>0.3/0.5</td>
<td>8.4/7.5 (p=NS)</td>
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<tr>
<td>Study</td>
<td>Year</td>
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<td>FDA</td>
<td>Design</td>
<td>No. of Eyes</td>
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<td>Conclusions</td>
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<td>Vold, COMPASS Cypass Study Group (4)</td>
<td>2016</td>
<td>Ophthalmology</td>
<td>PMA</td>
<td>RCT</td>
<td>374/131</td>
<td>2yr. (480)</td>
<td>-</td>
<td>77%/60% (p=0.001)</td>
<td>0.2/0.6 (p&lt;0.001)</td>
<td>7.4/5.3 (p&lt;0.001)</td>
<td>This RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication. 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.</td>
</tr>
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Analysis of Evidence  
(Rationale for Determination)

According to the 2015 AAO POAG Preferred Practice Pattern (PPP), the “potential benefits of a combined procedure (cataract extraction with IOL implantation and glaucoma surgery) 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 (1).”

The XEN45 device received 510K 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 (17). 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” (11). In addition, the American Glaucoma Society (AGS), and numerous glaucoma experts wrote CGS to support XEN45 as a minimally invasive method that, “would improve the access of older patients with refractory glaucoma to surgical care with reduction in post-operative discomfort, shorter post-operative disability, equivalent efficacy and safety.”

In summary, CGS considers one iStent or CyPass device per eye medically reasonable and necessary 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. CGS considers one XEN45 device per eye medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management. Therefore, all other indications are considered not reasonable and necessary at this time.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)  
012x Hospital Inpatient (Medicare Part B only)  
013x Hospital Outpatient  
014x Hospital - Laboratory Services Provided to Non-patients  
018x Hospital - Swing Beds  
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

**Group 1 Paragraph:**
The CPT codes in Group 1 are considered medically necessary when the Indications of Coverage are met.

**Group 1 Codes:**

0191T INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE TRABECULAR MESHWORK; INITIAL INSERTION

0449T INSERTION OF AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUBCONJUNCTIVAL SPACE; INITIAL DEVICE

0450T APPROACH, INTO THE SUBCONJUNCTIVAL SPACE; EACH ADDITIONAL DEVICE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

0474T INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITH CREATION OF INTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE SUPRACILIARY SPACE

**Group 2 Paragraph:**
The CPT codes in Group 2 are considered not medically necessary.

**Group 2 Codes:**

INSERTION OF ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE, WITHOUT EXTRAOCULAR RESERVOIR, INTERNAL APPROACH, INTO THE TRABECULAR MESHWORK; EACH ADDITIONAL DEVICE INSERTION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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<td>H40.1112</td>
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<td>H40.1114</td>
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<td>Primary open-angle glaucoma, bilateral, indeterminate stage</td>
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ICD-10 Codes | Description
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H40.1211 | Low-tension glaucoma, right eye, mild stage
H40.1212 | Low-tension glaucoma, right eye, moderate stage
H40.1213 | Low-tension glaucoma, right eye, severe stage
H40.1214 | Low-tension glaucoma, right eye, indeterminate stage
H40.1221 | Low-tension glaucoma, left eye, mild stage
H40.1222 | Low-tension glaucoma, left eye, moderate stage
H40.1223 | Low-tension glaucoma, left eye, severe stage
H40.1224 | Low-tension glaucoma, left eye, indeterminate stage
H40.1231 | Low-tension glaucoma, bilateral, mild stage
H40.1232 | Low-tension glaucoma, bilateral, moderate stage
H40.1233 | Low-tension glaucoma, bilateral, severe stage
H40.1234 | Low-tension glaucoma, bilateral, indeterminate stage
H40.1311 | Pigmentary glaucoma, right eye, mild stage
H40.1312 | Pigmentary glaucoma, right eye, moderate stage
H40.1313 | Pigmentary glaucoma, right eye, severe stage
H40.1314 | Pigmentary glaucoma, right eye, indeterminate stage
H40.1321 | Pigmentary glaucoma, left eye, mild stage
H40.1322 | Pigmentary glaucoma, left eye, moderate stage
H40.1323 | Pigmentary glaucoma, left eye, severe stage
H40.1324 | Pigmentary glaucoma, left eye, indeterminate stage
H40.1331 | Pigmentary glaucoma, bilateral, mild stage
H40.1332 | Pigmentary glaucoma, bilateral, moderate stage
H40.1333 | Pigmentary glaucoma, bilateral, severe stage
H40.1334 | Pigmentary glaucoma, bilateral, indeterminate stage
H40.1411 | Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412 | Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413 | Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414 | Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1421 | Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422 | Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1423 | Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424 | Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1431 | Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432 | Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433 | Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434 | Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage

ICD-10 Codes that DO NOT Support Medical Necessity

**Group 1 Paragraph:**

Any ICD-10-CM code not listed in Group 1 "ICD-10 Codes that Support Medical Necessity" section

**Group 1 Codes:** N/A

ICD-10 Additional Information [Back to Top]

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**General Information**

**Associated Information**

**Documentation Requirements:**
The patient’s medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. The medical record and/or test results documenting medical necessity should be maintained and made available on request.

The iStent and CyPass Micro-Invasive Glaucoma Surgery (MIGS) must be performed in conjunction with cataract surgery on the same date of service and documented in the medical record. The XEN45 is allowed one device per eye when medically reasonable and necessary for the management of refractory glaucoma documented in the medical record and must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Sources of Information
N/A

Bibliography


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**Associated Documents**

- Attachments N/A
- Related Local Coverage Documents LCD(s) DL37578 - Micro-Invasive Glaucoma Surgery (MIGS)
- Related National Coverage Documents N/A
- Public Version(s) Updated on 01/26/2018 with effective dates 03/19/2018 - N/A Updated on 01/24/2018 with effective dates 03/19/2018 - N/A

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**Keywords**

N/A Read the LCD Disclaimer