Local Coverage Determination (LCD): Micro-Invasive Glaucoma Surgery (MIGS) (L37531)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information

Document Information

LCD ID
L37531

LCD Title
Micro-Invasive Glaucoma Surgery (MIGS)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL37531

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For services performed on or after 12/24/2018

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For services performed on or after 08/15/2019

Revision Ending Date
N/A

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N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Notice Period Start Date
11/08/2018

Notice Period End Date
12/23/2018

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862 (a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862 (a)(1)(D) indicates no payment may be made in the case of clinical care where items and services provided are in research and experimentation.

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 14, §10 Coverage of Medical Devices

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 23, §30 Services Paid Under the Medicare Physician's Fee Schedule

CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.1 Reasonable and Necessary Provisions in LCDs and §13.7.1 Evidence Supporting LCDs

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Background

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's 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's 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. Aqueous drainage implants use silicone/plastic tubing and large plates to shunt aqueous humor 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 two Food and Drug Administration (FDA) approved/cleared micro-invasive surgical stents, the iStent® Trabecular Micro-Bypass Stent (2011) and the XEN® Glaucoma Treatment System (November, 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. The XEN45® is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space bypassing the natural outflow system.

The iStent® was FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate open angle glaucoma (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 pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. The pivotal trial data for each, constituting the main evidentiary support, is summarized in the table below.

Pivotal Trials for FDA Approved Micro-Invasive Glaucoma Surgery*

Study	**Year**	**Journal**	**FDA**	**Study Design**	**No. of Eyes**	**Follow-up (yrs)**	**IOP ≤ 21mm Hg no Meds**	**☐ IOP 20% no meds**	**Mean # meds**	**Mean IOP reducti (mm H**
Samuelson, iStent® Study Group (2)	2011	Ophthalmology	PMA	RCT	111/122	1 yr. (233)	72%/50% (p>0.001)	66%/48% (p=0.003)	0.2/0.4 (p=0.011)	8.4/8. (p=NS
Craven, iStent® Study	2012	J Cataract Refract Surg	PMA	RCT	98/101	2 yr. (199)	61%/50% (p=0.036)	53%/44% (p=0.09)	0.3/0.5 (p=NS)	8.4/7. (p=NS

Group 2 yr. follow-up (3)										
Stalmans, (APEX) XEN® Study Group (5)	2016	Abstract presented at European Glaucoma Society Congress	510K	Case series	111 (stent alone)	1 yr. (81)	-	55.6%	0.7 (p<0.001) c/w preop 2.6	8.0 (p<0.0

*all results are depicted in the format (study group/control group)

According to the 2015 American Academy of Ophthalmology (AAO) POAG Preferred Practice Pattern (PPP), the "potential benefits of a combined procedure (cataract extraction with intraocular lens (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)."

Indications and Limitations of Coverage

In summary, Palmetto GBA considers one iStent® or Xen® 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. Therefore, all other indications are considered not reasonable and necessary at this time.

Palmetto GBA 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.

Summary of Evidence

Review of Relevant Literature

Technology Assessments:

American Academy of Ophthalmology (AAO): AAO (Minckler, et al., 2008) conducted a technology assessment on aqueous shunts for the treatment of Glaucoma. Following a systematic review of the literature, AAO made the following conclusions:

• Aqueous shunts are comparable to trabeculectomy for IOP control and duration of benefit.

• Larger explant surface area is related to better IOP control.

• Although primary indication for aqueous shunts is when prior medical or surgical therapy has failed, they may be used as primary surgical therapy for selected conditions such as trauma, chemical burns or pemphigoid.

• There is sufficient level I evidence that demonstrates no benefit in using antifibrotic agents as adjuncts to aqueous shunt procedures.

• There is sufficient level I evidence that demonstrates no benefit of systemic corticosteroids as adjuncts to aqueous shunt procedures.

• There are insufficient published data to draw any definitive conclusions about the relative likelihood of early postoperative hypotony with implantation of valved or nonvalved devices.

The assessment concluded that "based on level I evidence, aqueous shunts offer a valuable alternative to standard filtering surgery or to cyclodestructive therapy for many refractory glaucomas. The failure rate is approximately the same rate for trabeculectomy with adjunctive antifibrotic agents and in favorable cases shunts may continue to function to control IOP for more than two decades."

In a prospective randomized controlled multi-center (29 sites) clinical trial, Craven et al (2012) evaluated the long-term safety and effectiveness of a single trabecular micro-bypass stent with concomitant cataract surgery versus cataract surgery alone for mild-to-moderate open-angle glaucoma. 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 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 ($p = 0.036$). Overall, the mean IOP was stable between 12 months and 24 months (17.0 mm Hg ± 2.8 [SD] and 17.1 ± 2.9 mm Hg, respectively) in the stent group but increased (17.0 ± 3.1 mm Hg to 17.8 ± 3.3 mm Hg, 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.

On June 25, 2012, the FDA approved the iStent® Trabecular Micro-Bypass Stent System, Model GTS100R/L. This is the first device approved for use in combination with cataract surgery to reduce IOP in adult patients with mild or moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce IOP. The safety and effectiveness of the iStent® Trabecular Micro-Bypass Stent has not been established as an alternative to the primary treatment of glaucoma with medications. The effectiveness of this device has been demonstrated only in patients with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and who are undergoing concurrent cataract surgery for visually significant cataract.

In a retrospective, cohort study, Jea and colleagues (2012) compared the effect of ab interno trabeculectomy with trabeculectomy. A total of 115 patients who underwent ab interno trabeculectomy (study group) were compared with 102 patients who underwent trabeculectomy with intra-operative mitomycin as an initial surgical procedure (trabeculectomy group). Inclusion criteria were open-angle glaucoma, aged greater than or equal to 40 years and uncontrolled on maximally tolerated medical therapy. Exclusion criterion was concurrent surgery. Clinical variables were collected from patient medical records. Main outcome measures included IOP and Cox proportional hazard ratio (HR) and Kaplan-Meier survival analyses with failure defined as IOP greater than 21 mmHg or less than 20 % reduction below baseline on 2 consecutive follow-up visits after 1 month; IOP less than or equal to 5 mmHg on 2 consecutive follow-up visits after 1 month; additional glaucoma surgery or loss of light perception vision. Secondary outcome measures included number of glaucoma medications and occurrence of complications. Mean follow-up was 27.3 and 25.5 months for the study and trabeculectomy groups, respectively. Intra-ocular pressure decreased from 28.1 +/- 8.6 mmHg at baseline to 15.9 +/- 4.5 mmHg (43.5 % reduction) at month 24 in

the study group and from 26.3 +/- 10.9 mmHg at baseline to 10.2 +/- 4.1 mmHg (61.3 % reduction) at month 24 in the trabeculectomy group. The success rates at 2 years were 22.4 % and 76.1 % in the study and trabeculectomy groups, respectively ($p < 0.001$). Younger age ($p = 0.037$; adjusted HR, 0.98 per year; 95 % CI: 0.97 to 0.99) and lower baseline IOP ($p = 0.016$; adjusted HR, 0.96 per 1 mmHg; 95 % CI: 0.92 to 0.99) were significant risk factors for failure in the multi-variate analysis of the study group. With the exception of hyphema, the occurrence of postoperative complications was more frequent in the trabeculectomy group ($p < 0.001$). More additional glaucoma procedures were performed after ab interno trabeculectomy (43.5 %) than after trabeculectomy (10.8 %, $p < 0.001$). The authors concluded that ab interno trabeculectomy has a lower success rate than trabeculectomy.

In 2016, the XEN® Glaucoma Treatment System (Allergan, Inc. Aliso Viejo, CA) was FDA 510(k) approved as a Class II aqueous shunt indicated "for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy".

The XEN® Glaucoma Treatment System consists of the XEN®45 Gel Stent preloaded into the XEN® Injector. The XEN®45 Gel Stent is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde.

Ab Interno Gel Stent (i.e., XEN® Glaucoma Treatment System): Clinical trials evaluating the safety and effectiveness of the XEN® system with phacoemulsification are lacking. Studies have primarily been in the form of case series with small patient populations (n=30) with short-term follow-ups (12 months) (Pérez-Torregrosa, et al., 2016).

After receiving FDA approval in July 2016 based on the two-year safety and efficacy results of the COMPASS study, Alcon announced a voluntary worldwide market withdrawal of the CyPass Micro-Stent® on August 29, 2018, after 5-year postoperative data from the COMPASS-XT safety study indicated a statistically significant corneal endothelial cell loss associated with this device.

Several additional devices are under development/investigation but have not yet received FDA approval.

Analysis of Evidence
(Rationale for Determination)

Glaucoma is a disease of the eye associated with IOP. The majority (about 90%) of patients with glaucoma have POAG, a chronic condition in which the IOP is elevated beyond a level compatible with the continued health and function of the eye, with a gonioscopically open angle and a decreased facility of outflow.

Traditionally, POAG has been treated with topical ophthalmic medications which include timolol (a non-specific beta blocker) and latanoprost (a prostaglandin F2a agonist). Brimonidine (an alpha agonist) and dorzolamide (a topical carbonic anhydrase inhibitor) have been employed as second line drugs when there is suboptimal control of IOP with first line agents. Third-line drugs may include apraclonidine (an alpha agonist), pilocarpine (a cholinergic agonist), acetazolamide (an oral carbonic anhydrase inhibitor) and epinephrine (a non-specific adrenergic agonist). In some patients, the treatment of POAG may involve

multiple topical medications administered at frequent intervals during the day which is a significant factor in overall medication compliance.

When medications regimens fail to produce a reduction in IOP to a level significant enough to slow or arrest the progression of optic nerve damage, surgical interventions may be employed as a next step in the management of IOP. These interventions include laser trabeculoplasty and/or filtering procedures such as (a) full-thickness fistulas (e.g., thermal sclerostomy), (b) partial-thickness fistulas (e.g., trabeculectomy), (3) tubes and setons (e.g., Molteno implant, Krupin-Denver valve implant, or Ahmed glaucoma implant) and (4) cyclodestructive procedures (e.g., cyclophotocoagulation or cyclocryotherapy).

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.

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.

N/A

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:

N/A

Group 1 Codes:

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

Group 1 Codes: N/A

Additional ICD-10 Information

N/A

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 Local Coverage Determination (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.

Micro-Invasive Glaucoma Surgery (MIGS) using the iStent® device must be performed in conjunction with cataract surgery on the same date of service and documented in the medical record. The Xen® device is FDA approved for both stand alone insertion or insertion in conjunction with cataract surgery.

Sources of Information

N/A

Bibliography

1. American Academy of Ophthalmology (AAO), Glaucoma Panel. Preferred Practice Pattern. San Francisco, CA: AAO; 2015. Available at: Primary Open-Angle Glaucoma Accessed 8/11/17

2. Craven ER, Katz LJ, Wells JM, et al. iStent Study Group. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: Two-year follow-up. *J Cataract Refract Surg*. 2012;38(8):1339-45.

3. 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.

4. Stalmans I, Vera, V. Evaluation of the XEN Implant in Patients With Moderate Primary Open-Angle Glaucoma: 1-Year Results. Abstract presented at the European Glaucoma Society 2016 Congress (EGS), June 19-22, 2016, Prague, Czech Republic.

Other Contractor's LCDs:

Anthem policy SURG.00103. Intraocular Anterior Segment Aqueous Drainage Devices (without extraocular reservoir).

UnitedHealthcare policy 2017T0443T. Glaucoma Surgical Treatments.

BCBSMA policy 223. Aqueous Shunts and Stents for Glaucoma.

Aetna policy 0484. Glaucoma Surgery.

BCBS policy A.9.03.21. Aqueous Shunts and Stents for Glaucoma.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/15/2019	R1	All coding located in the **Coding Information** section has been moved into the related Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) A56866 article and removed from the LCD. Under **CMS National Coverage Policy** removed verbiage, "CMS National Coverage Policy Language quoted from the Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy." Formatting, punctuation, and typographical errors were corrected throughout the LCD. Acronyms were inserted where appropriate throughout the LCD. *At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A56866 - Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS)
A56172 - Response to Comments: Micro-Invasive Glaucoma Surgery (MIGS)
LCD(s)
DL37531 - Micro-Invasive Glaucoma Surgery (MIGS)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 08/09/2019 with effective dates 08/15/2019 - N/A
Updated on 11/02/2018 with effective dates 12/24/2018 - N/A

Keywords

- MIGS
- Micro-Invasive Glaucoma Surgery