

Local Coverage Determination (LCD): Micro-Invasive Glaucoma Surgery (MIGS) (L38301)

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Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
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Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
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Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
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LCD Information

Document Information

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Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Publications:

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 14,

10 Coverage of Medical Devices

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 23,

30 Services paid under the Medicare Physicians Fee Schedule

CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13,

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 new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery (MIGS). Noridian considers one iStent, iStent inject, or Hydrus 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. One XEN45 device per eye is covered for the management of refractory glaucoma, defined 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

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 five FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July, 2016), the XEN Glaucoma Treatment System (Nov., 2016), the Hydrus

Microstent (Aug., 2018), and the iStent inject (Jun, 2018). 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 iStent inject system comprises 2 heparin-coated titanium stents (each having 0.23 mm diameter x 0.36 mm height, 0.08 mm central lumen diameter, and four 0.05 mm side outlets to allow for multidirectional outflow), both inserted into Schlemm's canal using a pre-loaded auto-injection trocar. Hydrus is a 8 mm nitinol, crescent-shaped microstent with alternating spines for support and windows to provide outflow, also placed into Schlemm's canal. 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.

iStent, iStent inject, Hydrus and CyPass were FDA approved (Cypass recalled by FDA for safety concerns Sept., 2018) 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 pseudoexfoliative 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 attached table. [MIGS Pivotal Trials](#)

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

In summary, Noridian considers one iStent, iStent inject*, or Hydrus 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. There is no additional payment for multiple devices (so-called "dosing"), regardless of method, since a statistical benefit has not been demonstrated,²⁷ especially in conjunction with cataract surgery.

The XEN45 device received 510K clearance based on having a similar mechanism (subconjunctival pathway) as "gold standard" filtration procedures (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), the New York State Ophthalmological Society (NYSOS), and numerous glaucoma experts wrote Noridian 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."

Noridian 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.

*The iStent inject device consists of the 2-stent system. There is no coverage for placement of part of the device (i.e., only one of the two stents).

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
03/23/2020	R1	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. At this time 21st Century Cures Act will apply to new	<ul style="list-style-type: none"> • Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		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.	the LCD.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57864 - Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS)

A57908 - Response to Comments: Micro-Invasive Glaucoma Surgery (MIGS)

LCD(s)

DL38301 - Micro-Invasive Glaucoma Surgery (MIGS)

Related National Coverage Documents

N/A

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