LCD - Micro-Invasive Glaucoma Surgery (MIGS) (L38301)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
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
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
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Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
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Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
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LCD Information

Document Information

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LCD Title

Micro-Invasive Glaucoma Surgery (MIGS)

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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10/02/2021

Issue

Issue Description

Removed the statement regarding the MIGs Pivotal Trial as the hyperlink was no longer valid.

CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

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.

Section 1862(a)(1)(D) refers to limitations on items or devices that are investigational or experimental.

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 surgical procedures for glaucoma referred to as Micro-Invasive Glaucoma surgery (MIGS). Noridian considers up to two iStent aqueous drainage devices, or one 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. According to CPT®, in this setting a 'device' is a 'stent'. Therefore, 'two iStent aqueous drainage devices' means two (initial generation) iStents or one pair of stents that are contained in iStent Inject.

One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled Intraocular Pressure (IOP) on maximally tolerated medical therapy. 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 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 mm Hg 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. More 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 frequently performed using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast traditional filtration surgeries such as trabeculectomy and aqueous tube shunt, are typically performed from an external approach.

Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications, and 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 MIGS devices do not preclude subsequent trabeculectomy if needed. Therefore, health outcomes of interest are the IOP lowering achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are five Food and Drug Administration (FDA) approved/cleared micro-invasive surgical stents:

(Initial Generation) iStent Trabecular Micro-Bypass Stent (2011) a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into the Schlemm canal to augment the natural outflow system

CyPass Micro-Stent System (July, 2016) a 6.35 mm long fenestrated microstent made of bio compatible polypeptide inserted into the supraciliary space, thus using an alternative outflow system

XEN45 Glaucoma Treatment System (November 2016) a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system

Hydrus Microstent (August 2018) an 8 mm nitinol, crescent-shaped microstent with alternating spines of support and windows to provide outflow, also place into the Schlemm canal

iStent inject (June, 2018), two 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 instered into the Schlemm canal using a pre-loaded auto-injection trocar.

The (initial generation) iStent, iStent inject, Hydrus and CyPass were FDA approved (CyPass was recalled by FDA for safety concerns in September 2018, and remains so) 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.

Analysis of Evidence (Rationale for Determination)

According to the 2020 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]

In summary, Noridian considers up to two stents (either two initial generation iStents, or the pair of two stents included in iStent inject*, or one 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 the potential for 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 aqueous drainage implants. Therefore, all other indications are considered not reasonable and necessary at this time, including insertion of additional devices beyond what is stated, regardless of method, since a statistical benefit has not been demonstrated,[27] especially in conjunction with cataract surgery.

The XEN45 device received FDA 510(k) 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 as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP on maximally tolerated medical therapy. XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

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	REASONS FOR CHANGE
10/03/2021	R4	Under the Summary of Evidence - removed the statement regarding the MIGs Pivotal Trial as the hyperlink was no longer valid.	• Typographical Error
10/03/2021	R3	Typographical and verbiage changes were made throughout the document for clarification.	• Provider Education/Guidance
02/15/2021	R2	The LCD language in the Coverage paragraph was updated for clarity to show coverage for use of two iStent aqueous drainage devices per eye. Each injector is loaded with two devices and confusion was occurring as to whether the injector device was limited to one or if only one iStent was allowed.	• Provider Education/Guidance
03/23/2020	R1	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.	• Other (The LCD is revised to remove CPT/HCPCS codes in

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		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.	the Keyword Section of the LCD.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

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

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

LCDs

DL38301 - Micro-Invasive Glaucoma Surgery (MIGS)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
04/29/2022	10/03/2021 - N/A	Currently in Effect (This Version)
08/12/2021	10/03/2021 - N/A	Superseded
02/18/2021	02/15/2021 - 10/02/2021	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A