LCD - Micro-Invasive Glaucoma Surgery (MIGS) (L37578)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

LCD Information

Document Information

LCD ID
L37578

LCD Title
Micro-Invasive Glaucoma Surgery (MIGS)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL37578

Original Effective Date
For services performed on or after 03/19/2018

Revision Effective Date
For services performed on or after 03/23/2023

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date

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Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under Coverage Indications, Limitations and/or Medical Necessity.

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 new surgical procedures for glaucoma referred to as micro-invasive glaucoma

surgery (MIGS). CGS 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, CGS 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 stents (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 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."

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.

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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.

iStent, iStent inject, and Hydrus must be performed in conjunction with cataract surgery on the same date of service and documented in the medical record.

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
03/23/2023	R10	R10 Revision Effective: 03/23/2023 Revision Explanation: Annual review, no changes were made.	• Other (Annual Review)
05/05/2022	R9	R9 Revision Effective: 05/05/2022 Revision Explanation: Updated link for MIGS pivotal table in summary of evidence section.	• Provider Education/Guidance
03/31/2022	R8	R8 Revision Effective: 03/31/2022 Revision Explanation: Annual Review, no changes were made.	• Other (Annual Review)
04/01/2021	R7	R7 Revision Effective: 04/01/2021 Revision Explanation: Annual Review, no changes made.	• Other (Annual review)
12/30/2019	R6	R6 Revision Effective: n/a Revision Explanation: Annual Review, no changes made.	• Other (Annual Review)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
12/30/2019	R5	R5 Revision Effective: 12/30/2019 Revision Explanation: Released draft revision to final.	• Provider Education/Guidance
11/08/2018	R4	R4 Revision Effective: N/A Revision Explanation: Annual Review, no changes made.	• Other (Annual Review)
11/08/2018	R3	R3 Revision Effective: 11/08/2018 Revision Explanation: Based on a reconsideration request received in October 2018, coverage has been added for Hydrus Microstent with the use of CPT code 0191T, effective for services rendered on or after 11/8/2018	• Reconsideration Request
08/29/2018	R2	R2 Revision Effective: 08/29/2018 Revision Explanation: The following was added to the policy due to a voluntary recall: Due to recall of the CYPASS stent by the manufacturer on 8/29/2018, claims submitted for services rendered on or after 8/29/2018 for CPT code 0474T will be automatically denied.	• Provider Education/Guidance
03/19/2018	R1	R1 Revision Effective: 03/19/2018 Revision Explanation: Adding coverage for XEN to policy as was left out in finalizing of draft policy.	• Typographical Error

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A56491 - Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS)

A57285 - Response to Comments: Micro Invasive Glaucome Surgery (MIGS)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
03/15/2023	03/23/2023 - N/A	Currently in Effect (This Version)
04/28/2022	05/05/2022 - 03/22/2023	Superseded
03/21/2022	03/31/2022 - 05/04/2022	Superseded
03/22/2021	04/01/2021 - 03/30/2022	Superseded
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Keywords

N/A