Glaucoma Surgical Treatments

Policy Number: MCS041.07
Committee **Approval Date**: February 14, 2024
Effective Date: April 1, 2024

Instructions for Use

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Related Medicare Advantage Policy Guidelines

- Anterior Segment Aqueous Drainage Device
- Category III CPT Codes

Coverage Guidelines

Glaucoma surgical treatments are covered when the Medicare covered criteria are met.

Insertion of Aqueous Drainage Device

Hydrus® Microstent, iStent®, or iStent inject® (CPT Codes 66989 and 66991)

Medicare does not have a National Coverage Determination (NCD) for insertion of aqueous drainage device (Hydrus® Microstent, iStent®, or iStent inject®). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Hydrus® Microstent, iStent®, or iStent inject®.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Glaucoma Surgical Treatments.

Notes:

- After checking the Hydrus® Microstent, iStent®, or iStent inject® table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
- In September 2018, Alcon Research issued a voluntary market withdrawal of the CyPass® Micro-Stent from the global market.

(Accessed January 18, 2024)

Xen® Glaucoma Treatment System (CPT Codes 0449T and 0450T)

Medicare does not have a National Coverage Determination (NCD) for Xen® Glaucoma Treatment System). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Xen® Glaucoma Treatment System.

Implantation of Glaucoma Drainage Devices (e.g., ExPRESS™ Mini Glaucoma Shunt, Molteno Implant, Baerveldt Tube Shunt, Krupin Eye Valve, or the Ahmed Glaucoma Valve Implant) (CPT Codes 66179, 66180, and 66183 and HCPCS Codes C1783 and L8612)

Medicare does not have a National Coverage Determination (NCD) for the implantation of glaucoma drainage devices. Local Coverage Determinations (LCDs)/ Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Implantation of Glaucoma Drainage Devices.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Glaucoma Surgical Treatments.

Note: After checking the Implantation of Glaucoma Drainage Devices table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed January 18, 2024)

Dexamethasone Intracanalicular Ophthalmic Insert (e.g., Dextenza®) (CPT Code 68841)

Medicare does not have a National Coverage Determination (NCD) for dexamethasone intracanalicular ophthalmic insert. Local Coverage Determinations (LCDs)/ Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Dexamethasone Intracanalicular Ophthalmic Insert.

UnitedHealthcare considers the use of the Dextenza® dexamethasone insert reasonable and necessary for the treatment of ocular inflammation and pain following ophthalmic surgery.

Dextenza® is contraindicated in patients with the following conditions:

- Active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella
- Mycobacterial infections of the eye
- Fungal diseases of the eye
- Dacryocystitis

UnitedHealthcare uses the criteria above to supplement the general Medicare criteria regarding Dexamethasone Intracanalicular Ophthalmic Inserts. UnitedHealthcare uses the criteria noted above in order to ensure consistency in reviewing the conditions to be met for coverage of Dexamethasone Intracanalicular Ophthalmic Inserts, as well as reviewing when such services may be medically necessary. Use of this criteria to supplement the general provisions noted above provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services, because this additional criteria will provide greater consistency in determining when a patient's medical factors support Dexamethasone Intracanalicular Ophthalmic Inserts.

Note: After checking the Dexamethasone Intracanalicular Ophthalmic Insert table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the criteria referenced above for coverage guidelines.
(Accessed January 18, 2024)

Canaloplasty (CPT Codes 66174 and 66175)

Medicare does not have a National Coverage Determination (NCD) for canaloplasty. Local Coverage Determinations (LCDs)/ Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Glaucoma Surgical Treatments.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed January 18, 2024)

Viscocanalostomy

Medicare does not have a National Coverage Determination (NCD) for viscocanalostomy. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Glaucoma Surgical Treatments.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
(Accessed January 18, 2024)

Definitions

Glaucoma: Consists of a group of disease, frequently characterized by raised intraocular pressure which affects the optic nerve. It is the second leading cause of blindness in the world. Multiple LCDs for glaucoma treatment with aqueous drainage device.

Supporting Information

Implantation of Glaucoma Drainage Devices (e.g., Express™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant)

Accessed January 18, 2024

LCA ID	LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
A52432	Billing and Coding: Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (0192T 66183)	Part A and B MAC	CGS Administrators, LLC	KY, OH

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Dexamethasone Intracanalicular Ophthalmic Insert

Accessed January 18, 2024

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L38792 (A58392)	Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV

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Insertion of Aqueous Drainage Device (Xen® Glaucoma Treatment System)

Accessed January 18, 2024

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L37578 (A56491)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	CGS Administrators, LLC	KY, OH
L38233 (A56647)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI

Insertion of Aqueous Drainage Device (Xen® Glaucoma Treatment System) Accessed January 18, 2024				
LCD/LCA ID	**LCD/LCA Title**	**Contractor Type**	**Contractor Name**	**Applicable States/Territories**
L37244 (A56588)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
L38299 (A57863)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L38301 (A57864)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT, WY
L38223 (A56633)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L37531 (A56866)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L35490 (A56902)	Category III Codes	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
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Insertion of Aqueous Drainage Device (Hydrus® Microstent, iStent®, or iStent inject®) Accessed January 18, 2024				
LCD/LCA ID	**LCD/LCA Title**	**Contractor Type**	**Contractor Name**	**Applicable States/Territories**
L37578 (A56491)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	CGS Administrators, LLC	KY, OH
L38233 (A56647)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L37244 (A56588)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
L38301 (A57864)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT, WY
L38299 (A57863)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L38223 (A56633)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L37531 (A56866)	Micro-Invasive Glaucoma Surgery (MIGS)	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
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Clinical Evidence

An integrated assessment of Dextenza's® efficacy in ophthalmic surgery was demonstrated across 3 Phase 3 trials that included a total of 926 subjects (n = 541, Dextenza®, n = 385, placebo insert).1-3 An ad hoc pooled analysis of the 3 Phase 3 studies demonstrated patients receiving Dextenza® achieved statistically, significantly superior outcomes compared to patients receiving placebo vehicle in both primary efficacy endpoints, with 42.7% of Dextenza®-treated patients observed to have absence of anterior chamber cells (score of 0) at Day 14 (placebo: 27.5%; P < 0.0001), and 79.2% of Dextenza®-treated patients observed to have absence of ocular pain (score of 0) at Day 8 (placebo: 56.9%; P < 0.0001) with a favorable safety profile. Across all 3 studies, a greater proportion of subjects in the placebo group experienced at least 1 ocular adverse event in the study eye, as compared to patients receiving the Dextenza® insert. The most common Dextenza® ocular adverse events (> 1%) were increased (IOP), anterior chamber inflammation including iritis and iridocyclitis, eye inflammation, reduced visual acuity, corneal edema, and cystoid macular edema. There were no treatment-related serious adverse events.

Physician-administered Dextenza® delivers a 30-day tapered dose of dexamethasone to the eye (consistent with current standard of care tapered dosing regimen of patient-administered topical steroid drops).1,2 Physician administration of Dextenza® avoids risk of improper patient installation techniques with post-op topical eye drop therapy, complicated steroid tapering dosing regimens for patient administration, manual dexterity challenges associated with older age,5 and may reduce the potential for ophthalmic sequelae typically associated with poor patient adherence during the critical post-operative care period. Persistent ocular inflammation can potentially increase the risk for secondary ocular complications, such as increased IOP, cystoid macular edema (CME), posterior synechiae formation, posterior capsule opacification, secondary glaucoma, delayed recovery, ocular pain, and reduced visual outcomes, whereas untreated pain can affect overall patient surgical satisfaction.

Dexamethasone is a potent corticosteroid, and the Dextenza® Phase 3 data support the utility of a sustained-release intracanalicular insert delivery approach of dexamethasone to the ocular surface following ocular surgery. Relevant to IOP increases associated with ophthalmic surgery, the overall safety outcomes of an ad hoc pooled analysis of the Phase 3 Dextenza® studies showed IOP elevation with Dextenza® (6.3%) compared to placebo (3.4%);3 of all events, only 1 IOP increase in the dexamethasone insert arm (0.2%) out of 538 patients across 3 studies was considered by the investigator to be related to treatment.1-3 It is hypothesized the observed rates of IOP increase demonstrated with Dextenza® compared to placebo in the Phase 3 studies may potentially be associated with the reduced Cmax of sustained release preparations (e.g., Dextenza®), as compared to topical steroid therapy.

Additionally, the benefits of consistent tapered dosing with a dexamethasone-eluting intracanalicular insert is potentially clinically meaningful in the context of the demonstrated poor bioavailability of topical steroid eye drop preparations. The pharmacokinetic properties of the drug-eluting intracanalicular insert, in preclinical animal models, suggests sustained and tapered drug release into the tear film may minimize the potential of ocular rebound inflammation and demonstrate dexamethasone is eluted directionally and unilaterally towards the ocular surface, indicating limited systemic exposure and reduced wasted drug product.

By being physician-administered, Dextenza® eliminates the potential for improper drop installation techniques, including missing the eye, instilling an incorrect number of drops, bottle tip contamination with ocular surface contact, and failure to wash hands prior to patient-administered topical therapy; these challenges may be common amongst Medicare-aged patients. Researchers observed in an elderly (> 80 years) population with chronic ophthalmic pathologies, 61% scratched the eyedrop container along the conjunctiva or cornea upon administration, and 11% of patients in this cohort failed to successfully apply a drop to the ocular surface.

Finally, placement of Dextenza® into the intracanalicular space may afford the additional benefit of punctal occlusion. Available data indicate punctal occlusion following ophthalmic surgery is associated with improvement in postoperative healing and may prevent post-operative dry eye complications. In a study of refractive ocular surgery patients who received unilateral punctal occlusion following LASIK surgery, statistically significant ocular surface index score improvement was demonstrated, suggesting a decrease in dry eye disease severity.

Overall, results of the Phase 3 Dextenza® pooled studies support a greater proportion of patients treated with Dextenza® demonstrated an absence of ocular pain as early as the day after surgery (Day 2), and absence of inflammation as early as 3 days after surgery (Day 4). Additionally, there were consistently similar results with Dextenza® across all the evaluated time

points compared to placebo. Treatment with Dextenza® in the Phase 3 Clinical Trials demonstrated tolerability and efficacy during the post-operative period.

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Policy History/Revision Information

Effective Date	Summary of Changes

04/01/2024	**Coverage Guidelines**
	Insertion of Aqueous Drainage Device
	Hydrus® Microstent, iStent®, or iStent inject® (CPT Codes 66989 and 66991)
	• Modified service heading
	• Updated list of applicable CPT codes; removed 0253T
	• Reorganized and revised language to indicate:
	  ○ Medicare does not have a National Coverage Determination (NCD) for insertion of aqueous drainage device (Hydrus® Microstent, iStent®, or iStent inject®)
	  ○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the policy]

Effective Date	Summary of Changes
	○ For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled *Glaucoma Surgical Treatments* ○ After checking the table [in the policy] and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines ○ In Sep. 2018, Alcon Research issued a voluntary market withdrawal of the CyPass® Micro-Stent from the global market ***Implantation of Glaucoma Drainage Devices (e.g., ExPRESS™ Mini Glaucoma Shunt, Molteno Implant, Baerveldt Tube Shunt, Krupin Eye Valve, or the Ahmed Glaucoma Valve Implant) (CPT Codes 66179, 66180, and 66183 and HCPCS Codes C1783 and L8612)*** • Updated list of applicable codes; added: ○ CPT codes 66179 and 66180 ○ HCPCS code C1783 ***Dexamethasone Intracanalicular Ophthalmic Insert (e.g., Dextenza®) (CPT Code 68841)*** (new to policy) • Added language to indicate: ○ Medicare does not have a NCD for dexamethasone intracanalicular ophthalmic insert ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the policy] ○ UnitedHealthcare considers the use of the Dextenza® dexamethasone insert reasonable and necessary for the treatment of ocular inflammation and pain following ophthalmic surgery ○ Dextenza® is contraindicated in patients with the following conditions: ▪ Active corneal, conjunctival, or canalicular infections including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella ▪ Mycobacterial infections of the eye ▪ Fungal diseases of the eye ▪ Dacryocystitis ○ UnitedHealthcare uses the criteria above: ▪ To supplement the general Medicare criteria regarding Dexamethasone intracanalicular ophthalmic inserts ▪ In order to ensure consistency in reviewing the conditions to be met for coverage of Dexamethasone Intracanalicular Ophthalmic Inserts, as well as reviewing when such services may be medically necessary ○ Use of this criteria to supplement the general provisions noted above provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services, because this additional criteria will provide greater consistency in determining when a patient's medical factors support Dexamethasone intracanalicular ophthalmic inserts ○ After checking the table [in the policy] and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the criteria referenced above for coverage guidelines **Supporting Information** • Added *Clinical Evidence* and *References* sections • Updated list of available LCDs/LCAs to reflect the most current information • Archived previous policy version MCS041.06

Instructions for Use

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and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.