BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Sustained-Release Intracameral Glaucoma Therapy

Policy #: 735
Latest Review Date: June 2024
Category: Vision

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **sustained-release intracameral glaucoma therapies** (e.g. Durysta®, iDose® TR) as a **covered benefit** for indications approved by the FDA, including the following: open-angle glaucoma or ocular hypertension.

Blue Advantage will treat **sustained-release intracameral glaucoma therapies** (e.g. Durysta®, iDose® TR) as a **non-covered benefit** and **investigational** for ALL other indications.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE

Durysta® (bimatoprost intracameral implant) is an intracameral biodegradable, sustained-release implant designed to lower intraocular pressure (IOP) in individuals with conditions such as open angle glaucoma or ocular hypertension. The active ingredient involved is bimatoprost, which is a prostaglandin analog medication used to treat glaucoma and lower high eye pressure. Durysta is composed of biodegradable polymers designed to release bimatoprost in a non-pulsatile, steady-state manner over a 90-day period.

Durysta is delivered via a disposable single-use applicator that is inserted into the anterior chamber of the affected eye. Insertion is performed under magnification in an office or ambulatory surgery center. The presence of Durysta implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Per the FDA recommendation, administration of Durysta should be limited to a single implant per eye without retreatment. Caution should be used when prescribing Durysta in individuals with limited corneal endothelial cell reserve.

iDose®TR (travoprost intracameral implant) delivers continuous long-term prostaglandin analog therapy directly into the anterior chamber for the reduction of intraocular pressure in individuals with open-angle glaucoma or ocular hypertension.

Open-angle glaucoma is an optic neuropathy characterized by progressive peripheral visual loss. The peripheral vision loss is often followed by central field loss. Open-angle glaucoma is typically accompanied by intraocular pressure increases caused by increased aqueous production and/or decreased aqueous outflow. Elevated intraocular pressure presents a major risk factor for glaucomatous field loss. The higher the level of intraocular pressure, the greater the likelihood of optic nerve damage and visual field loss.

Ocular hypertension is distinguished from glaucoma in that there are no detectable changes in vision, no evidence of visual field loss, and no damage to the optic nerve. Individuals diagnosed with ocular hypertension are at an increased risk of developing glaucoma. Typical treatments for open-angle glaucoma and ocular hypertension include drug classes such as ophthalmic prostaglandins (e.g., latanoprost) and ophthalmic beta blockers (e.g., timolol), both of which have generic products available in their respective classes.

Lowering of IOP is the only proven method to decrease risk of development and/or worsening glaucomatous optic neuropathy. Topical medical therapy is an effective strategy, but many individuals are non-adherent to medications. Barriers to adherence are multifold and include forgetfulness, difficulty with drop instillation, need for frequent administration.

KEY POINTS:

This policy was developed with medical literature review through June 15, 2024.

Summary of Evidence

The FDA approval of Durysta is based on results from two prospective, randomized, multicenter, double-masked, 20-month (including eight-month extended follow up) Phase 3 ARTEMIS studies evaluating the efficacy and safety of Durysta versus twice daily topical timolol drops, an FDA accepted comparator for registrational clinical trials, in individuals with OAG or OHT. In the two Phase 3 ARTEMIS studies, Durysta reduced IOP by approximately 30 percent from baseline over the 12-week primary efficacy period, meeting the predefined criteria for non-inferiority to the study comparator. Noted risks to using Durysta include, eye pain, eye irritation, lacrimation, and conjunctival hemorrhage. Studies have shown that Durysta is an effective treatment for glaucoma, but not superior to the standard of care.

The FDA approval of Glaukos' iDose TR in December 2023, was based on Phase 3 clinical program consisting of two pivotal studies that randomized 1,150 subjects across 89 clinical sites. Based on these outcomes, the FDA concluded in the prescribing information that iDose TR demonstrated non-inferiority to timolol ophthalmic solution in IOP reduction during the first 3 months. The FDA also noted that subsequently iDose TR did not demonstrate non-inferiority over the next 9 months. At 12 months, 81% of iDose TR subjects were completely free of IOP-lowering topical medications across both trials. Studies have shown that iDose TR is an effective treatment for glaucoma, but not superior to the standard of care.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

The 2020 American Academy of Ophthalmology (AAO) preferred practice guidelines for the treatment of primary open-angle glaucoma note that the initial therapy choice may be influenced by cost, adverse event profile, and dosing schedules. The guidelines note prostaglandins as the most frequently used initial eye drops for lowering intraocular pressure in patients with glaucoma. The AAO does not prefer one prostaglandin over another.

In 2020, a bimatoprost intracameral implant (Allergan, Irvine, CA) received Food and Drug Administration (FDA) approval for use in patients with ocular hypertension and POAG. This biodegradable implant, which is injected with a 28-gauge delivery system, demonstrated noninferiority to twice daily timolol in phase III clinical trials. In phase I/II studies, a single bimatoprost sustained-release (SR) implant showed similar efficacy to topical bimatoprost 0.03% through 4 months of follow-up, and 68% of patients had a persistent effect at 6 months. At 24 months, central endothelial cell density was comparable between eyes that received the bimatoprost implant and those treated topically.

The practice guidelines do not mention the use of iDose TR in its recommendations.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Durysta®, bimatoprost, biodegradable implant, ocular implant, Allergan, OAG, open angle glaucoma, OHT, ocular hypertension, intracameral administration, iDose, iDose TR

APPROVED BY GOVERNING BODIES:
Durysta
On March 4, 2020, the FDA approved Allergan's Durysta (bimatoprost implant) 10 mcg for intracameral administration to treat open-angle glaucoma (OAG) or ocular hypertension (OHT). Durysta (bimatoprost implant) is a biodegradable implant intended for a single administration and should not be re-administered to an eye that received a prior Durysta (bimatoprost implant).

iDose TR
December 14, 2023, Glaukos announces the FDA approval of iDose TR (travoprost intracameral implant). FDA approval was based on Phase 3 clinical program consisting of two pivotal studies that randomized 1,150 subjects across 89 clinical sites.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

66030	Injection, anterior chamber of eye (separate procedure); medication

0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant

HCPCS Codes:

J3490	Unclassified Drugs
J7351	Injection, bimatoprost, intracameral implant, 1 microgram
J7355	Injection, travoprost, intracameral implant, 1 microgram (effective 07/01/2024)

REFERENCES:

1. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel, Hospkins Center for Quality Eye Care. Primary Open-Angle Glaucoma 2022. Available online at: www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-suspect-ppp.
2. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel, Hospkins. Center for Quality Eye Care(2020) Primary Open-Angle Glaucoma 2020. https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp.
3. Aref, Ahmad A. Durysta (Bimatoprost Implant) Available online at: eyewiki.aao.org/Durysta_(Bimatoprost_Implant).
4. Craven ER, Walters T, Christie WC, Day DG, Lewis RA, Goodkin ML, Chen M, Wangsadipura V, Robinson MR, Bejanian M; Bimatoprost SR Study Group. 24-Month Phase I/II Clinical Trial of Bimatoprost Sustained-Release Implant (Bimatoprost SR) in Glaucoma Patients. Drugs. 2020 Feb; 80(2):167-179. doi: 10.1007/s40265-019-01248-0.
5. Gedden SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma PPP 2020. AAO PPP Glaucoma Committee, Hoskins Center for Quality Eye Care. Nov 2020. Available online at: www.aao.org/education/preferred-practice-pattern/primary-open-angle-glaucoma-ppp.
6. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
7. Huang AS, Meyer JJ. Bimatoprost Ophthalmic Solution. 2022 Nov 14. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–.
8. Kolomeyer, Natasha N. Top 7 Things to Know About First Sustained-Release Glaucoma Medication. aao.org/young-ophthalmologists/yo-info/article/top-7-things-to-know-about-first-sustained-release.

9. Lewis RA, Christie WC, Day DG, Craven ER, Walters T, Bejanian M, Lee SS, Goodkin ML, Zhang J, Whitcup SM, Robinson MR; Bimatoprost SR Study Group. Bimatoprost Sustained-Release Implants for Glaucoma Therapy: 6-Month Results From a Phase I/II Clinical Trial. Am J Ophthalmol. 2017 Mar;175:137-147. doi: 10.1016/j.ajo.2016.11.020. Epub 2016 Dec 22.
10. Medeiros FA, Walters TR, Kolko M, et al.(2020) Phase 3, Randomized, 20-Month Study of Bimatoprost Implant in Open-Angle Glaucoma and Ocular Hypertension (ARTEMIS 1). Ophthalmology. 2020 Jun 13:S0161-6420(20)30555-8. doi: 10.1016/j.ophtha.2020.06.018. Epub ahead of print.
11. Rajan, K. Biodegradable bimatoprost implant gains FDA approval. Available online at: www.aao.org/headline/biodegradable-bimatoprost-implant-gains-fad-approv.
12. Sarkisian SR, Ang RE, Lee AM, et al. Travoprost Intracameral Implant for Open-Angle Glaucoma or Ocular Hypertension: 12-Month Results of a Randomized, Double-Masked Trial. Ophthalmol Ther. 2024;13(4):995-1014. doi:10.1007/s40123-024-00898-y
13. Sarkisian SR Jr, Ang RE, Lee AM, et al. Phase 3 Randomized Clinical Trial of the Safety and Efficacy of Travoprost Intraocular Implant in Patients with Open-Angle Glaucoma or Ocular Hypertension. Ophthalmology. Published online February 27, 2024. doi:10.1016/j.ophtha.2024.02.022
14. U.S. Food and Drug Administration (FDA).(2020) Durysta. Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211911s000lbl.pdf
15. U.S. Food and Drug Administration (FDA).(2023) iDose®TR. Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/218010s000lbl.pdf

POLICY HISTORY

Medical Policy Panel, July 2020: New policy created.
Medical Policy Group, April 2021
Medical Policy Group, June 2022
Medical Policy Group, June 2023: Reviewed by consensus. No new published peer-reviewed literature identified that would alter the coverage statement at this time.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, June 2024: Updated the policy title to "Sustained-Release Intracameral Glaucoma Therapy." Policy statement updated to include iDose TR as a covered benefit. Added codes 0060T, 0661T, J3590 and J7355 to Current Coding section. Removed Previous Coding section.
On draft August 1, 2024, through September 1, 2024.
UM Committee, June 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.