

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Ophthalmology – Durysta Utilization Management Medical Policy

- Durysta® (bimatoprost implant, for intracameral administration – Allergan)

REVIEW DATE: 04/19/2023

OVERVIEW

Durysta, a prostaglandin analog, is indicated for the reduction of intraocular pressure (IOP) in patients with **open-angle glaucoma** or **ocular hypertension**.¹

Disease Overview

Glaucoma, a disease that damages the eye's optic nerve, is the leading cause of blindness in people > 60 years of age.² Reduction of IOP, regardless of the pretreatment IOP, reduces the risk of disease progression.³ In addition, IOP reduction may prevent the onset of early glaucoma in patients with ocular hypertension.

Ophthalmic prostaglandins, beta-blockers, alpha-agonist (brimonidine), carbonic anhydrase inhibitors, rho kinase inhibitor (netarsudil), and fixed combination products are used to treat glaucoma.^{3,4} The choice of product is influenced by potential cost, adverse event profile, dosing schedule, and the degree of pressure lowering needed.³

Dosing Considerations

Durysta, a biodegradable implant, is given as a single intracameral administration.¹ Durysta should not be re-administered to an eye that was previously treated with Durysta.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Durysta. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for one implant per treated eye (i.e., one implant per treated eye; maximum of two implants per patient). Note that a 1-month (30 days) approval duration is applied to allow for the one-time treatment of one or both eye(s). Because of the specialized skills required for evaluation and diagnosis of patients treated with Durysta as well as the monitoring required for adverse events and long-term efficacy, approval requires Durysta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Durysta is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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- 1. Ocular Hypertension.** Approve for a one-time use in each treated eye (i.e., one implant per treated eye; a total of two implants per patient) if the patient meets ALL of the following criteria (A, B, C, D, and E):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient is not receiving re-treatment of eye(s) previously treated with Durysta; AND
 - C) Patient meets BOTH of the following criteria (i and ii):
 - i. Patient has tried at least two ophthalmic prostaglandins (either as monotherapy or as concomitant therapy) for the treatment of open-angle glaucoma or ocular hypertension; AND
Note: Examples of ophthalmic prostaglandins include bimatoprost 0.03% ophthalmic solution, latanoprost 0.005% ophthalmic solution, travoprost 0.004% ophthalmic solution; Lumigan (bimatoprost 0.01% ophthalmic solution), Vyzulta (latanoprostene bunod 0.024% ophthalmic solution), Xelpros (latanoprost 0.005% ophthalmic emulsion), tafluprost 0.0015% ophthalmic solution, Iyuzeh (latanoprost 0.005% ophthalmic solution), and Omlonti (omidenepag isopropyl 0.002% ophthalmic solution).
 - ii. Patient has tried at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes for the treatment of open-angle glaucoma or ocular hypertension; AND
Note: Examples of pharmacological classes of ophthalmic products for the treatment of open-angle glaucoma or ocular hypertension include beta-blockers, alpha-agonist (brimonidine), carbonic anhydrase inhibitors, and rho kinase inhibitor (netarsudil).
 - D) For each of the ophthalmic medications that were tried, the patient meets ONE of the following criteria (i or ii):
 - i. Patient has had inadequate efficacy to the previously tried ophthalmic products, according to the prescriber; OR
 - ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of the previously tried ophthalmic products, according to the prescriber; AND
 - E) The medication is prescribed by or in consultation with an ophthalmologist.

Dosing. Approve up to one Durysta implant per treated eye(s) [two implants per patient].

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- 2. Open-Angle Glaucoma.** Approve for a one-time use in each treated eye (i.e., one implant per treated eye; a total of two implants per patient) if the patient meets ALL of the following criteria (A, B, C, D, and E):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient is not receiving re-treatment of eye(s) previously treated with Durysta; AND
 - C) Patient meets BOTH of the following criteria (i and ii):
 - i. Patient has tried at least two ophthalmic prostaglandins (either as monotherapy or as concomitant therapy) for the treatment of open-angle glaucoma or ocular hypertension; AND
Note: Examples of ophthalmic prostaglandins include bimatoprost 0.03% ophthalmic solution, latanoprost 0.005% ophthalmic solution, travoprost 0.004% ophthalmic solution; Lumigan (bimatoprost 0.01% ophthalmic solution), Vyzulta (latanoprostene bunod 0.024% ophthalmic solution), Xelpros (latanoprost 0.005% ophthalmic emulsion), tafluprost 0.0015% ophthalmic solution, Iyuzeh (latanoprost 0.005% ophthalmic solution), and Omlonti (omidenepag isopropyl 0.002% ophthalmic solution).
 - ii. Patient has tried at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes for the treatment of open-angle glaucoma or ocular hypertension; AND

Note: Examples of pharmacological classes of ophthalmic products for the treatment of open-angle glaucoma or ocular hypertension include beta-blockers, alpha-agonist (brimonidine), carbonic anhydrase inhibitors, and rho kinase inhibitor (netarsudil).

- D) For each of the ophthalmic medications that were tried, the patient meets ONE of the following criteria (i or ii):
 - i. Patient has had inadequate efficacy to the previously tried ophthalmic products, according to the prescriber; OR
 - ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of the previously tried ophthalmic products, according to the prescriber; AND
- E) The medication is prescribed by or in consultation with an ophthalmologist.

Dosing. Approve up to one Durysta implant per treated eye(s) [two implants per patient].

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Durysta is not recommended in the following situations:

1. **Re-Treatment of Previously-Treated Eye(s).** Durysta is approved for a one-time use in each treated eye. Repeat administration in previously treated eye(s) is not approvable.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Durysta® [prescribing information]. Madison, NJ: Allergan; November 2020.
2. Boyd K. Glaucoma. Available at: <https://www.aao.org/eye-health/diseases/what-is-glaucoma>. Last reviewed, December 6, 2022. Accessed on April 6, 2023.
3. Gedde SJ, Vinod K, Wright MW, et al. Primary open-angle glaucoma Preferred Practice Pattern® guidelines. The American Academy of Ophthalmology. 2020. Available at: <https://www.aao.org/education/preferred-practice-pattern/primary-open-angle-glaucoma-ppp>. Accessed on April 6, 2023.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on April 6, 2023. Search terms: ophthalmic beta blockers, alpha agonists, prostaglandins, netarsudil.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	The indication “Reduction of Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension” was separated into two indications for approval: Ocular Hypertension and Open-angle glaucoma. The criteria for approval were not changed.	04/27/2022
Annual Revision	Ocular Hypertension. The Note for examples of ophthalmic prostaglandins was revised to include Iyuzeh (latanoprost 0.005% ophthalmic solution) and Omlonti (omidenepag isopropyl 0.002% ophthalmic solution). Open-Angle Glaucoma. The Note for examples of ophthalmic prostaglandins was revised to include Iyuzeh (latanoprost 0.005% ophthalmic solution) and Omlonti (omidenepag isopropyl 0.002% ophthalmic solution).	04/19/2023