PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Durysta Prior Authorization Policy
- Durysta® (bimatoprost implant, for intracameral administration – Allergan)

REVIEW DATE: 02/21/2024

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 (e.g., bimatoprost, latanoprost), beta-blockers (e.g., levobunolol, timolol), alpha-agonist (brimonidine), carbonic anhydrase inhibitors (brizolamide, dorzolamide), 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 prescription benefit coverage of Durysta. 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

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 (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 (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), and 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 other 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 (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 administered by or under the supervision of an ophthalmologist.

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 (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 (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 other 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 (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 administered by or under the supervision of an ophthalmologist.

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. **Concurrent use of Durysta with iDose TR (travoprost intracameral implant).** iDose TR is another intracameral implant and should not be used with Durysta.

3. 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 February 15, 2024.
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 February 15, 2024.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on February 15, 2024. Search terms: ophthalmic beta blockers, alpha agonists, prostaglandins, netarsudil.