POLICY: Ophthalmology – Durysta™ (bimatoprost implant, for intracameral administration – Allergan)

DATE REVIEWED: 04/22/2020

OVERVIEW

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

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 diagnosis provided.

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. 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).

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Reduction of Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or 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)** The patient is ≥ 18 years of age; AND
   - **B)** The patient is not receiving re-treatment of eye(s) previously treated with Durysta; AND
   - **C)** The patient meets the following criteria (i and ii):

i. The 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.
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 Zioptan® (tafluprost 0.0015% ophthalmic solution); AND

ii. The 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.
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); AND

D) For each of the ophthalmic medications that were tried, the patient meets ONE of the following criteria (i or ii):

i. The patient has had inadequate efficacy to the previously-tried ophthalmic products, according to the prescriber; OR

ii. The patient has experienced adverse event(s) severe enough to warrant discontinuation of the previously-tried ophthalmic products, according to the prescriber; AND

E) Durysta 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

Durysta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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 Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Durysta™ [prescribing information]. Madison, NJ: Allergan USA, Inc; March 2020.
2. Boyd K. Glaucoma. Available at: https://www.aao.org/eye-health/diseases/what-is-glaucoma. Accessed on March 23, 2020.
3. Prum BE, Rosenberg LF, Gedde SJ, et al. Preferred practice pattern: primary open-angle glaucoma. The American Academy of Ophthalmology. 2015. Available at: http://www.aao.org/guidelines-browse?filter=preferredpracticepatterns. Accessed on March 23, 2020.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2020. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on March 23, 2020. Search term: netarsudil.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	--	04/22/2020