Drug Coverage Policy

Effective Date 6/1/2024
Coverage Policy Number.....IP0218
Policy Title.....Durysta

Ophthalmology – Durysta

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

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policies

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.

Medical Necessity Criteria

Durysta is considered medically necessary when ONE of the following is met:

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), 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.

   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 (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 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 administered by or under the supervision of an ophthalmologist.

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

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.

Coding / Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7351	Injection, bimatoprost, intracameral implant, 1 microgram

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	**Updated policy title**: from Bimatoprost Ophthalmic Implant **All covered uses (Ocular Hypertension, Open-Angle Glaucoma):** Added is <u>not</u> receiving re-treatment of eye(s) previously treated with Durysta **Conditions Not Covered:** Added Concurrent use of Durysta with iDose TR (travoprost intracameral implant)	6/1/2024

The policy effective date is in force until updated or retired.