Original Effective Date: 06/11/2020
Current Effective Date: 12/09/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C19830-A

Durysta (bimatoprost implant)

PRODUCTS AFFECTED

Durysta (bimatoprost implant)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Open-Angle Glaucoma, Ocular Hypertension

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. OPEN-ANGLE GLAUCOMA (OAG) OR OCULAR HYPERTENSION (OHT):
   1. Documented diagnosis of open angle glaucoma (OAG) (i.e., primary OAG, pseudoexfoliation glaucoma, pigmentary glaucoma) OR ocular hypertension (OHT) requiring intraocular pressure-lowering treatment.
      AND

2. Documented inadequate response, serious side effects, contraindication, or clinical rationale supporting the inappropriateness to ALL of the following anti-glaucoma medications [DOCUMENTATION REQUIRED of ALL therapy with dates of failed therapy or clinical events]:
   a) ONE Ophthalmic prostaglandin (e.g., lantanoprost, bimatoprost, travoprost)
      AND
   b) ONE Beta-adrenergic blocker or combination product (e.g., carteolol, levobunolol, metipranolol, timolol, betaxolol, dorzolamide plus timolol)
      AND
   c) ONE Alpha-2-agonist (brimonidine)

   AND
3. Documentation member has an inability to manage regular glaucoma eye drop use (e.g., due to age, dexterity, or comorbidities including visual impairment)
   AND
4. Prescriber attests or clinical reviewer has found member has not received prior Durysta administration to the affected eye
   NOTE: Durysta should not be re-administered to an eye that received a prior Durysta implant
   AND
5. Prescriber attests or clinical reviewer has found member does not have ANY of the following conditions (exclusions):
   i. Previous eye surgery (including cataract surgery) and/or any eye laser surgery within the past 6 months in the affected eye(s)
      OR
   ii. History of glaucoma surgery
      OR
   iii. Anticipated need for laser eye surgery within one year

   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Durysta (bimatoprost intracameral implant) include: ocular or periocular infections, corneal endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior lens capsule, hypersensitivity]

CONTINUATION OF THERAPY:
N/A Retreatment will not be authorized due to insufficient evidence of therapeutic value since clinical benefit beyond one implant for the same eye has not been established.

DURATION OF APPROVAL:
Initial authorization: 3 months, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified ophthalmologist, specialist in neuro-ophthalmology, or glaucoma specialist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
ONE implant (10 µg) per eye per lifetime

PLACE OF ADMINISTRATION:
The recommendation is that intracameral implant medications in this policy will be for pharmacy or medical benefit coverage and the intracameral implant products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intracameral implant

DRUG CLASS:
Prostaglandin ophthalmic

FDA-APPROVED USES:
Indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
FDA approval of Durysta is based on results from two Phase 3 multicenter, randomized, parallel-group, controlled, 20-month (including an 8-month extended follow-up) studies of Durysta compared to twice-daily topical timolol 0.5% drops in patients with OAG or OHT. ARTEMIS 1 and 2 were two identical, multicenter, randomized, parallel-group, controlled, 20-month studies with an extended follow-up of 8 months. The ARTEMIS studies compared the efficacy of Durysta was compared to topical timolol 0.5% drops administered twice daily in 1,122 patients with OAG or OHT. In the ARTEMIS trials, the Durysta implant reduced IOP by approximately 30% from a baseline mean of 24.5 mmHg (lowering IOP by 5 to 8 mmHg) over a 12-week period, meeting the specified criteria for non-inferiority to the study comparator. Durysta reduced mean IOP more than timolol at all time points (hours 0 and 2, weeks 2, 6, and 12) and was found to be non-inferior to timolol at all time points.

The most commonly reported adverse event (AE) is conjunctival hyperemia (27%). Other adverse events (5% to 10%) include foreign body sensation, eye pain, photophobia, conjunctival hemorrhage dry eye, eye irritation, increased IOP, corneal endothelial cell loss, blurred vision, iritis, and headache.

ARTEMIS 1 assessed the IOP-lowering efficacy and safety of 10- and 15-µg bimatoprost implants in patients with OAG and OHT following initial and recurring doses. Participants were assigned to one of three treatment groups: 10-µg bimatoprost implant (n=198), 15-µg bimatoprost implant (n = 198) or BID timolol drops (n = 198). The mean age of the participants in the study was 62.5 years. Primary OAG was detected in the majority of the studied eyes (78.1%). The mean IOP in the study eyes was comparable across treatment groups. 90.4 % (10 µg), 79.3 % (15 µg), and 86.9% completed the study (timolol groups). There were 3 administration cycles: week 1, week 16, and week 32. The primary endpoints were IOP and the change in IOP from baseline to week 12. After the last bimatoprost implant or sham administration, participants were to be followed for at least 12 months, or until month 20. Corneal endothelial cell loss and corneal edema were the most common treatment-emergent adverse events (TEAE) that led to early withdrawal from the bimatoprost implant treatment groups. TEAEs, primarily corneal endothelial cell loss and edema, resulted in the removal of implants in 7 participants (3.6%) in the 10 µg bimatoprost implant group and 16 patients (8.3%) in the 15-µg bimatoprost implant group.

Bimatoprost implants (10- and 15-µg) were shown to be noninferior to timolol in decreasing IOP through

week 12. IOP was controlled in most participants after 3 administrations and no further treatment was required after a year. The risk-benefit analysis indicated that the 10 µg implant was preferable to the 15-µg implant. Durysta is an effective treatment for glaucoma, however it is not superior to standard of care. Durysta was implanted every four months for a year.

ARTEMIS 2. This phase 3 study included 528 participants with OAG or OHT and an open iridocorneal angle inferiorly (NCT02250651). Participants received 10 or 15 µg bimatoprost implanted or twice-daily topical timolol maleate 0.5% in the study eye. The primary endpoints were IOP and the change in IOP from baseline to week 12. TEAEs and corneal endothelial cell density were used as safety measures. Results supported the prior phase 3 bimatoprost implant research. The bimatoprost implant met the primary goal of lowering IOP. After the third dosage, most patients required no more treatment for 12 months. Benefit-risk assessment favored the 10g implant over the 15g implant. Other administration regimens with lower risk of corneal events are being studied.

ARGOS, a phase IV, prospective, 18-month study to assess the effectiveness and safety of bimatoprost intracameral implant (DURYSTA) in clinical practice is currently recruiting participants as of April 2023 (NCT04647214). This prospective observational study to collect data on the efficacy and safety of a bimatoprost intracameral implant in individuals with OAG or OHT is noted to be completed by June 30, 2023.

National and Specialty Organizations

American Academy of Ophthalmology (AAO)

The preferred practice guidelines (2015) for the treatment of primary OAG note that there are many considerations when choosing a target IOP, including the stage of the overall glaucoma damage as determined by the degree of structural optic nerve damage and/or functional visual field loss, the baseline IOP at which damage occurred, the age of the patient, and additional risk factors. The initial treatment choice may be influenced by potential cost, AE profile, and dosing schedule. The guidelines note prostaglandins as the most frequently used initial eye drops for lowering IOP in patients with glaucoma. The AAO does not prefer one prostaglandin over another. (Prum, 2015). Lowering the pretreatment IOP by ≥ 25% has been shown to slow the progression of primary OAG. If the target IOP is not achieved by one medication, switching, or adding medications should be considered, depending on whether the patient has responded to the first medication. The guideline recommends switching eye-drop agents or adding on for combination therapy when target IOP is not achieved with one drug alone. A more aggressive target (i.e., a lower target IOP) can be justified if there is more severe nerve damage or the damage is progressing rapidly; a less aggressive target IOP may be reasonable if the risks of treatment outweigh the benefits. The practice guidance has not been updated to include the use of Durysta in its recommendations at the time of this review. Note: The Primary OAG guideline was corrected as of May 2021; however, the intent of the guideline remains unchanged by the corrections.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Durysta (bimatoprost intracameral implant) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Durysta (bimatoprost intracameral implant) include: ocular or periocular infections, corneal endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior lens capsule, hypersensitivity.

OTHER SPECIAL CONSIDERATIONS:

Insert 1 implant (10 µg) intracamerally in anterior chamber of affected eye. Limit to a single implant per eye; do not re-administer to an eye that has received a prior implant

Warnings and Precautions: Due to possible corneal endothelial cell loss, administration of Durysta should be limited to a single implant per eye without retreatment. Durysta has been associated with corneal

adverse reactions and risks are increased with multiple implants. Use caution in patients with limited corneal endothelial cell reserve.

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

HCPCS CODE	DESCRIPTION
J7351	Injection, bimatoprost, intracameral implant, 1 mcg

AVAILABLE DOSAGE FORMS:
Durysta IMPL 10MCG single-use applicator

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SUMMARY OF REVIEW/REVISIONS	DATE
MCP Conversion	Q4 2023
Policy reviewed and updated. No changes in coverage criteria. Updated References and Summary of Medical Evidence sections.	06/14/2023
Policy reviewed and updated. No changes in coverage criteria. Updated References.	06/08/2022
Policy reviewed and revised. Updated references. IRO Peer Review. 5/12/2021. Practicing Physician. Board certified in Ophthalmology. Content update includes: •In initial coverage criteria section 'Step/Conservative Therapy/Other Condition Requirements' added 'or combination product' to beta-adrenergic blocker [updated criterion: beta-adrenergic blocker or combination product (e.g., carteolol, levobunolol, metipranolol, timolol, betaxolol, dorzolamide plus timolol)] •Reviewed and updated ongoing clinical trials	06/09/2021
New policy. IRO Peer Review. 6/11/2020. Practicing Physician. Board certified in Ophthalmology.	Q3 2020 P&T