Subject: Durysta (bimatoprost implant)	Original Effective Date: Q3 2020
Policy Number: MCP-370	Revision Date(s):
P&T Approval Date: Q3 2020	

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP document and provide the directive for all Medicare members.

Contents

SUMMARY OF EVIDENCE/POSITION

This policy addresses Durysta (bimatoprost implant) for the treatment of adults with open-angle glaucoma (OAG) or ocular hypertension (OHT) when appropriate criteria are met.

The intent of this policy, Durysta (bimatoprost implant), is to ensure appropriate selection of patients for therapy based on product labeling, clinical studies, nationally recognized authoritative references and current peer-reviewed scientific literature. The information outlined in the Molina Clinical Policy includes but is not limited to a review of evidence-based information obtained from the following sources Evaluation of New and Existing Technologies (UM 10). This policy is intended to address coverage criteria that are appropriate for the majority of individuals/members with a particular disease, illness, or condition. Each member's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

Molina Healthcare reserves the right to update this policy and revise coverage criteria to include or omit any off-label condition(s) as necessary based on medical literature and clinical studies that may become available.

Ocular Hypertension (OHT) can be used as a generic term referring to any situation in which intraocular pressure (IOP) is greater than 21 mm Hg, the widely accepted upper limit of normal intraocular pressure in the general population.

- A clinical management strategy that targets a 20% reduction in IOP in people with ocular hypertension has been shown to delay or prevent the onset of glaucoma.

Open-Angle Glaucoma (OAG) is an optic neuropathy characterized by progressive peripheral visual field loss followed by central field loss in a typical pattern. It is usually but not always in the presence of elevated IOP. Increased aqueous production and/or decreased outflow are possible mechanisms for elevation of intraocular pressure.

- Lowering IOP is the primary goal of therapy, which has been shown to reduce the progression of visual field loss. The target IOP and subsequent monitoring intervals depends on several factors, including the extent of optic nerve damage, whether or not there is recent progression of damage, the stability of IOP, and the level of patient adherence. A target IOP ≥ 25 to 30 percent below initial IOP is a reasonable initial target. [Early Manifest Glaucoma Trial (EMGT); Collaborative Initial Glaucoma Treatment Study (CIGTS)]
- Pharmacologic therapy, laser therapy (trabeculoplasty), and/or surgery (trabeculectomy) have been shown to lower IOP
    - For most patients, pharmacologic or laser therapy is the first-line treatment. Surgical therapy a first-line approach only for patients with severe visual field loss at baseline, and a second-line approach for patients with advanced open-angle glaucoma who do not respond to medications or laser therapy
    - If pharmacologic therapy is chosen, topical prostaglandins are generally recommended as first-line pharmacologic therapy rather than other topical medications. Meta-analyses have found prostaglandins to be more effective at lowering IOP than beta blockers, carbonic anhydrase inhibitors, and alpha adrenergic agonists for the treatment of open-angle glaucoma. (Li T, et al. 2016; van der VR, et al. 2005; Fung AT et al. 2007) Prostaglandins have lower rates of systemic side effects and may have somewhat better efficacy than beta blockers.
    - Combining drops from different classes (i.e., beta blocker plus prostaglandin or beta blocker plus carbonic anhydrase inhibitor) can cause a greater reduction in the IOP than monotherapy. Adding a second medication is reasonable if initial monotherapy is not effective.

Durysta (bimatoprost implant)

The first intracameral, biodegradable sustained-release implant indicated to reduce intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT)

- **Prostaglandin analog.** Lowers IOP by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional). Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

- The implant's efficacy was tested in two 20-month-long multicenter, randomized, controlled clinical trials involving 1,122 patients with open-angle glaucoma (OAG) or ocular hypertension (OHT), with an eight-month-long follow-up period. (Subjects' mean baseline IOP was 24.5 mmHg.) The implant's efficacy was compared to that of twice-daily topical timolol 0.5% drops.
    - In both ARTEMIS studies, the Durysta implant reduced IOP by approximately 30% from baseline over the 12-week primary efficacy period, meeting the predefined criteria for non-inferiority to the study comparator timolol.
    - Durysta demonstrated an IOP reduction of approximately 5-8 mmHg in patients with a mean baseline IOP of 24.5 mmHg.

- The device, implanted intracamerally at 4-month intervals for 1 year in an office-based procedure to continuously deliver bimatoprost, proved to have about the same IOP-lowering effects as timolol administered as an eye drop twice a day. In addition, Durysta showed evidence of being able to slow glaucoma progression, as evidenced on visual fields.
- The FDA approval states that the implant should not be re-administered to an eye that has previously had one.

⌘ **The Efficacy and Safety of Bimatoprost SR in Patients with Open-angle Glaucoma or Ocular Hypertension**

- Efficacy and Safety Study of Bimatoprost Sustained-Release (SR) in Participants With Open-angle Glaucoma or Ocular Hypertension: https://clinicaltrials.gov/ct2/show/results/NCT02247804

- The Efficacy and Safety of Bimatoprost SR in Patients with Open-angle Glaucoma or Ocular Hypertension. ClinicalTrials.gov Identifier: NCT02250651 Available at: https://clinicaltrials.gov/ct2/show/NCT02250651
  As of this writing in June 2020: No Study Results Posted on ClinicalTrials.gov for this study

⌘ The 2015 Primary Open-Angle Glaucoma practice guidance from the American Academy of Ophthalmology recommends switching eye-drop agents or adding on for combination therapy when target IOP is not achieved with one drug alone. **The practice guidance has not been updated to include the use of Durysta in its recommendations at the time of this review.**

FDA Indications

Open angle glaucoma (OAG) or ocular hypertension (OHT) To reduce elevated intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension

Available as: Intracameral implant containing 10 mcg of bimatoprost; single-use applicator

Approved by the FDA: March 5, 2020

CLASSIFICATION: Antiglaucoma, Prostaglandin analog

Coverage Criteria for Initial Authorization

Durysta (bimatoprost implant) may be authorized for members who meet **ALL** of the following criteria **[ALL]**

1. Prescriber specialty [ONE]

❑ Prescribed by, or in consultation with, a board-certified specialist in glaucoma and/or neuro-ophthalmology, or ophthalmologist experienced in the administration of intracameral biodegradable implant. Submit consultation notes if applicable.

2. Diagnosis/Indication [ALL]

Documentation of ALL of the following criteria are required. May include chart notes from the member's medical records, relevant labs and/or tests, and other relevant clinical information supporting the diagnosis.

- ❑ Diagnosis of open angle glaucoma (OAG) (i.e., primary OAG, pseudoexfoliation glaucoma, pigmentary glaucoma) **OR** ocular hypertension requiring intraocular pressure-lowering treatment

3. Age/Gender/Other restrictions [ALL]

- ❑ 18 years of age
  - *Safety and effectiveness have not been established in pediatric patients.*

- ❑ Member does not have ANY of the following conditions (exclusions): [ANY]
  - ❍ Previous eye surgery (including cataract surgery) and/or any eye laser surgery within the past 6 months in the affected eye, or
  - ❍ History of glaucoma surgery
  - ❍ Anticipated need for laser eye surgery within one year

4. Step/Conservative Therapy/Other condition Requirements [ALL]

- ❑ Member has a documented inability to manage regular glaucoma eye drop use (e.g., due to age, dexterity, or comorbidities including visual impairment). Documentation required.

- ❑ Affected eye has not received prior treatment with Durysta

- ❑ Failure of an adequate trial of ALL formulary anti-glaucoma medications (at least ONE drug from each class), unless contraindicated or clinically significant adverse effects are experienced: prostaglandins, topical beta blockers (e.g., timolol, carteolol, levobunolol), carbonic anhydrase inhibitors (e.g. bimatoprost, latanoprost) and alpha-2-agonists (brimonidine). Prescriber submit documentation of ALL therapy with dates and doses of tried and failed antiglaucoma and/or contraindications

  MOLINA REVIEWER: Review profile for anti-glaucoma drug claims and enter an authorization if applicable. Notify Prescriber if an authorization is entered.

  - *Informational Note: The topical prostaglandins are increasingly chosen as initial monotherapy in open-angle glaucoma and have been consistently shown to be effective at lowering IOP and well tolerated. Prostaglandins have the advantage of once-daily dosing and do not have the risk of systemic side effects seen with topical beta blockers (UpToDate 2020).*

5. *Contraindications/Exclusions/Discontinuations to Durysta (bimatoprost implant) therapy

**There are no contraindications listed in the manufacturer's labeling*

Authorization will not be granted if ANY of the following conditions apply [ANY]

- ❒ Non-FDA approved indications
- ❒ Hypersensitivity to bimatoprost or any of the other components of the therapy
- ❒ Active or suspected ocular or periocular infection
- ❒ Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs endothelial dystrophy)
- ❒ Prior corneal transplantation or endothelial cell transplants (e.g., Descemet stripping automated endothelial keratoplasty [DSAEK])
- ❒ Absence or rupture of posterior lens capsule owing to the risk of implant migration into the posterior segment
  NOTE: Laser posterior capsulotomy in pseudophakia (not contraindicated if the intraocular lens fully covers the posterior capsule opening)

Exclusions

- ❍ Eye surgery (including cataract surgery) and/or any eye laser surgery within the past 6 months in the affected eye
- ❍ History of glaucoma surgery
- ❍ Anticipated need for laser eye surgery within one year

Warnings and precautions for Durysta include corneal adverse reactions, iridocorneal angle, macular edema, intraocular inflammation, pigmentation, and endophthalmitis.

6. Labs/Reports/Documentation required [ALL]

All documentation for determination of medical necessity must be submitted for review. Prescriber to submit documentation as indicated in the criteria above, including but not limited to chart notes, applicable lab values and/or tests, adverse outcomes, treatment failures, or any other additional clinical information or clinical notes from the member's medical records supporting the diagnosis. Letters of support and/or explanation are often useful but are not sufficient documentation unless ALL specific information required by this MCP are included.

- ❑ Member's current weight (to authorize the appropriate amount of drug per the labeling)

NOTE: *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.*

REAUTHORIZATION /CONTINUATION OF THERAPY

Retreatment will not be authorized due to insufficient evidence of therapeutic value since clinical benefit beyond 24 weeks has not been established.

There is no published literature available at this time to support the use of Durysta (bimatoprost implant) in patients who have already received a 24-week treatment (up to a total of 8 infusions over a 24-week period).

WARNINGS AND PRECAUTIONS
Endothelial cell loss: Due to possible corneal endothelial cell loss, administration of Durysta should be limited to a single implant per eye without retreatment. (5.1)

Corneal Adverse Reactions: 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.

ADMINISTRATION, QUANTITY LIMITATIONS, AND AUTHORIZATION PERIOD

Consult the manufacturer's labeling for more detailed information on dosage and administration of this drug, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and monitoring.

1. **Recommended Dosage [ALL]**

   Implant (Durysta)
   - ❑ Insert 1 implant (10 mcg) 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

2. **Authorization Limit [ALL]**

   - ❑ Quantity limit: One implant (10 mcg) per eye (lifetime total)

   - ❒ Continuation of treatment: Will not be authorized

3. **Route of Administration [ALL]**
   - ❑ May be authorized in an **ophthalmologist's office or at a surgicenter center** only. Routine administration in a hospital or outpatient setting will not be authorized

   - ❑ Refer to MHI Policy & Procedure (P&P): Specialty Medication Administration Site of Care Policy: MHI Pharm 11

   - ❑ If member meets all criteria and approval for therapy is granted, medication will be dispensed by a specialty pharmacy vendor at the discretion of Molina Healthcare.

COVERAGE EXCLUSIONS

This policy addresses Durysta (bimatoprost implant) for the treatment of adults with thyroid eye disease when appropriate criteria are met.

All other uses of Durysta (bimatoprost implant) that are not an FDA-approved indication or not included in the 'Coverage Criteria' section of this policy are considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

**FDA-approved indication does not, in itself, dictate coverage. Molina Clinical Policy may not recommend coverage for all FDA-approved indications. Please review this Policy in its entirety for indications covered by Molina Healthcare.*

BACKGROUND/SUMMARY

Durysta (bimatoprost implant) is the first intracameral (eye chamber), biodegradable, sustained-release implant that is FDA approved to reduce IOP in those with open-angle glaucoma or ocular hypertension.

Prior to this approval, pharmacologic therapy consisted of topical eye-drops with varying mechanisms of action. Durysta is delivered via a disposable single-use applicator that is inserted into the anterior chamber of the affected eye. Insertion is performed under magnification in an office or ambulatory surgery center. Due to an increased risk of corneal endothelial cell loss, patients should receive only one implant per eye and no retreatment.

Phase 3

Phase 3 ARTEMIS studies FDA approval of the bimatoprost implant is supported by the results of two 20-month studies (including 8-month extended follow up) studies evaluating 1,122 subjects on the efficacy and safety of Durysta compared to twice daily topical timolol drops in patients with OAG or OHT.

- Bimatoprost intracameral implant was compared with twice daily topical timolol 0.5% drops in two, 20-month, randomized trials of patients with open angle glaucoma or ocular hypertension.
    - In Study 1, mean intraocular pressure (IOP) was significantly lower with the bimatoprost implant at week 2 (hour 0 mean difference, -0.8 mmHg; hour 2 mean difference, -0.9 mmHg) and week 6 (hour 0 mean difference, -0.8 mmHg; hour 2 mean difference, -0.7 mmHg) with no significant difference at week 12; at week 15, mean IOP was significant higher with the bimatoprost implant (hour 0 mean difference, +1.1 mmHg; hour 2 mean difference, +0.9 mmHg).
    - In Study 2, mean IOP was significantly lower with the bimatoprost implant at week 2, hour 2 (mean difference, -0.7 mmHg) but not at week 2, hour 0 or at weeks 6 or 12; at week 15, mean IOP was significantly higher with the bimatoprost implant (hour 0 mean difference, +1 mmHg; hour 2 mean difference, +1.2 mmHg). The bimatoprost intracameral implant reduced IOP approximately 5 to 8 mmHg in patients with a mean baseline IOP of 24.5 mmHg.

Results

- **The device, implanted intracamerally at 4-month intervals for 1 year in an office-based procedure to continuously deliver bimatoprost, proved to have about the same IOP-lowering effects as timolol administered as an eye drop twice a day.**
- **Results of the trials indicated the bimatoprost implant reduced IOP by approximately 30% from baseline over the 12-week primary efficacy period, meeting the predefined criteria for non-inferiority to the study comparator.** Reduction in IOP was similar with the bimatoprost intracameral insert compared with twice daily topical timolol 0.5% drops at weeks 2, 6, and 12 in two 20-month, randomized trials of patients with open angle glaucoma or ocular hypertension. At 15 weeks, IOP was significantly higher with the bimatoprost insert.
- Durysta demonstrated an IOP reduction of approximately 5-8 mmHg in patients with a mean baseline IOP of 24.5 mmHg.
- Among 1,122 study subjects, more than 80% remained treatment-free and did not require additional treatment for at least a year.
- The most common ocular adverse reaction (in 27%) with Durysta use was conjunctival hyperemia. Other common adverse reactions (5% to 10%) with Durysta use were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, increased IOP, corneal endothelial cell loss, blurred vision, iritis, and headache.

The most common ocular adverse reaction observed in two randomized, active-controlled clinical trials with DURYSTA in patients with OAG or OHT was conjunctival hyperemia, which was reported in 27% of patients. Other common ocular adverse reactions reported in 5-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, and iritis. Ocular adverse reactions occurring in 1-5% of patients were anterior chamber cell, lacrimation increased, corneal edema, aqueous humor leakage, iris adhesions, ocular discomfort, corneal touch, iris hyperpigmentation, anterior chamber flare, anterior chamber inflammation, and macular edema. The following additional adverse drug reactions occurred in less than 1% of patients: hyphema, iridocyclitis, uveitis, corneal opacity, product administered at inappropriate site, corneal decompensation, cystoid macular edema, and drug hypersensitivity.

PRACTICE GUIDELINES AND POSITION STATEMENTS

At the time of this writing, no guidelines were identified that addressed the use of Tepezza to treat TED. Furthermore, there have been no U.S. guidelines published within the past 10 years identified that addressed the treatment of TED.

<u>European Thyroid Association/European Group on Graves' Orbitopathy</u>

The Guidelines for the Management of Graves' Orbitopathy addressing the treatment of TED was updated in 2016. The guidelines recommended high-dose systemic glucocorticoids for first-line treatment for moderate-to-severe and active TED with off-label rituximab listed as an option among second-line recommended therapies (EUGOGO, 2016).

DEFINITIONS

Glaucoma: A group of eye diseases traditionally characterized by elevated intraocular pressure (IOP) and more accurately defined as an optic neuropathy than a disease of high pressure. After cataracts, glaucoma is the second leading cause of blindness in the world.

IOP: A measurement of the fluid pressure inside the eye. When eye pressure increases and damages the optic nerve, glaucoma results. This damage reduces vision and if not treated can lead to total blindness.

APPENDIX

N/A

CODING INFORMATION: THE CODES LISTED IN THIS CLINICAL POLICY ARE FOR INFORMATIONAL PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE AND INCLUSION OR EXCLUSION OF ANY CODES DOES NOT GUARANTEE COVERAGE. PROVIDERS SHOULD REFERENCE THE MOST UP-TO-DATE SOURCES OF PROFESSIONAL CODING GUIDANCE PRIOR TO THE SUBMISSION OF CLAIMS FOR REIMBURSEMENT OF COVERED SERVICES.

CPT	Description

HCPCS	Description
J3490, J3590	Unclassified drugs (when specified as [Durysta])
C9399	Unclassified drugs or biologicals (when specified as [Durysta])

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Package Insert, FDA, Drug Compendia

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Policy History	Approval
Policy Developed Peer Review: AMR Peer Review Network. 6/11/2020. Practicing Physician. Board certified in Ophthalmology	P&T Q3 2020