CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**			**POLICY NO**	**600.04**		
POLICY TITLE	**DURYSTA™ (Bimatoprost Implant) IMPLANT**								
POLICY DATE	**01/01/2022**	**REVISION DATE**	**08/08/2022**	**APPROVAL DATE**	**08/10/2022**				
DISCLAIMER LANGUAGE	- **Policy content and application may have state specific variance and considerations** - **Health Plan specific 'Indications and Limitations of Coverage' may apply as specified** - **Line of Business considerations (i.e., Medicaid, Medicare, Commercial) may apply as specified**								
EXCLUSIONS	- **This policy is not applicable to Medicaid in the state(s) of Delaware and Louisiana, as DURYSTA™ is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as DURYSTA™ does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section IV.**								

I. POLICY STATEMENT

Coverage of DURYSTA™ (Bimatoprost implant) will be provided only when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity for this service, Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO). The AAO incorporates evidence based best practice and FDA approval and/or recommendations[1]. Avēsis Medical Directors and clinical staff are licensed medical professionals that review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Coverage is limited to membership eligible at the time of the date of service and in accordance with continuity requirements, as applicable.

1.1 New enrollee ninety (90) day continuity applies.

2.0 DURYSTA™ (Bimatoprost implant) is a biodegradable sustained-release implant that continuously delivers the prostaglandin analog Bimatoprost within the eye to reduce and maintain intraocular pressure (IOP).

2.1 The implant contains ten (10) micrograms of Bimatoprost administered via bicameral implant, and absorbs naturally over time.

3.0 DURYSTA™ (Bimatoprost implant) will be considered for coverage in the following:

3.1 For enrollees with established diagnosis of:

3.1.1 open angle glaucoma

3.1.2 ocular hypertension;

3.2 For enrollees who:

3.2.1 demonstrate an inability to use eyedrops for the treatment of glaucoma; or,

3.2.2 have a significant medical condition that would prevent the instillation of eye drops for the treatment of glaucoma.

4.0 Coverage for DURYSTA™ (Bimatoprost implant) is limited to a frequency of one implant per eye per lifetime.

5.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for DURYSTA™ (Bimatoprost implant).

[1]American Academy of Ophthalmology https://www.aao.org

III. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J7351

1.0 To establish medical necessity all criterion points referenced below must be clearly & legibly documented in the medical record and made available to Avēsis upon submission of request.
- 1.1 Areas where 'white out' is used are not accepted.
- 1.2 Areas with 'black out' or 'scribble' will not be accepted.
  - 1.2.1 A single line through text where the text will remain readable is acceptable with provider initials and date.

2.0 Physician signature must be present on chart and procedural notes, orders, and testing interpretations.

3.0 The submitted documentation must clearly support medical necessity as outlined in Section II Indications and Limitations of Coverage.

4.0 Medical documentation must clearly evidence that enrollee has been screened for the following medical conditions that would contraindicate the use of DURYSTA™ including but are not limited to:
- 4.1 Active or suspected ocular infection
- 4.2 Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs Dystrophy)
- 4.3 History of corneal transplantation or endothelial cell transplant
- 4.4 Absent or posterior lens capsule
- 4.5 Hypersensitivity to Bimatoprost or any other component of DURYSTA™.

5.0 Medical documentation must clearly evidence that the following tests have been conducted and interpreted to firmly establish supporting diagnosis:
- 5.1 Visual field testing
- 5.2 Optical Coherence Tomography (OCT)
- 5.3 Intraocular Pressure
- 5.4 Gonioscopy and evaluation of the optic nerve

6.0 Procedure note must include:
- 6.1 Actual administered dosage of DURYSTA™ given
- 6.2 Site of injection
- 6.3 Route of administration
- 6.4 Injection Lot #
- 6.5 Injection expiration date
- 6.6 Post-injection vision ≥ CF

7.0 Medical documentation must evidence number 7.0 above along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 7.1 Date
- 7.2 Consent to perform
- 7.3 Consent to waive
- 7.4 Patient or Representative Signature
- 7.5 Surgeon/Physician Signature
- 7.6 Witness Signature

IV. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

1.0 For any code not listed below, please supply proper documentation with your prior authorization request, and Avēsis will review and make a determination based on medical necessity.

ICD-10 Code	Description
H40.051 – H40.059	Ocular hypertension
H40.10X0 – H40.10X4	Unspecified open-angle glaucoma
H40.1110 – H40.1194	Primary open-angle glaucoma, right eye – unspecified eye
H40.1310 – H40.1394	Pigmentary glaucoma, right eye – unspecified eye
H40.1410 – H40.1494	Capsular glaucoma with pseudoexfoliation of lens, right eye – unspecified eye