



Louisiana

Ophthalmic Prostaglandins

Policy # 00363

Original Effective Date: 09/18/2013

Current Effective Date: 05/16/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand or generic ophthalmic prostaglandins (including, but not limited to Lumigan[®] [bimatoprost], Xalatan[®] [latanoprost], Travatan Z[®] [travoprost], Rescula[®] [unoprostone], Zioptan[®] [tafluprost], and Vyzulta[™] [latanoprostene bunod])[†] to be **eligible for coverage** when the below patient selection criteria are met for the selected drug.

Patient Selection Criteria

Coverage eligibility for brand or generic ophthalmic prostaglandins (EXCEPT Vyzulta [latanoprostene bunod]) will be considered for patients under 60 years of age when the following criterion is met:

- Patient is using the requested medication to lower intraocular pressure caused by open-angle glaucoma or ocular hypertension.

Coverage eligibility for Vyzulta (latanoprostene bunod) will be considered when the following criteria are met:

- Patient is using the requested medication to lower intraocular pressure caused by open-angle glaucoma or ocular hypertension; AND
- Patient has tried and failed (e.g. intolerance or inadequate response) TWO generic ophthalmic prostaglandins (e.g. latanoprost, bimatoprost) after at least one month of therapy with EACH product unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vyzulta (latanoprostene bunod) when the patient has NOT tried and failed (e.g. intolerance or inadequate response) TWO generic ophthalmic prostaglandins (e.g. latanoprost, bimatoprost) after at least one month of therapy with EACH product to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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Based on review of available data, the Company considers the use of brand or generic ophthalmic prostaglandins for indications other than to lower intraocular pressure caused by open-angle glaucoma or ocular hypertension to be **investigational**.*

Background/Overview

The ophthalmic prostaglandins referred to in this policy are only indicated to lower intraocular pressure caused by open angle glaucoma or ocular hypertension.

Open angle glaucoma typically results in peripheral visual field loss followed by central field loss. This condition is typically accompanied by an elevation of intraocular pressure. Increased pressure can be present without glaucoma (ocular hypertension). The causes are typically due to increased aqueous production and/or decreased outflow of fluid. Pharmacologic therapy for these conditions can include drugs such as topical prostaglandins and topical beta blockers. Both of these drug classes contain generic medications for use in treatment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The ophthalmic prostaglandins referred to in this policy are only indicated to lower intraocular pressure caused by open angle glaucoma or ocular hypertension. Some of these products may be marketed under different trade names for treatment of hypotrichosis of the eyelashes.

Rationale/Source

Ophthalmic prostaglandins have the potential to be used off label for their cosmetic side effects (e.g. eyelash growth). None of the ophthalmic prostaglandins mentioned above are indicated for cosmetic treatment.

The purpose of this policy is to limit the use of the ophthalmic prostaglandins to those patients with open angle glaucoma or ocular hypertension as well as to limit use to the most cost effective products available in this class (generic products).

In clinical studies up to 12 months duration, patients with open-angle glaucoma or ocular hypertension with average baseline intraocular pressures of 26.7 mmHg, the intraocular pressure-lowering effect of Vyzulta once daily was up to 7 to 9 mmHg.

To note, the American Academy of Ophthalmology guidelines do not prefer one prostaglandin analogue over another.

References

1. Xalatan 0.005% ophthalmic solution [prescribing information]. New York, NY: Pfizer Inc; April 2014.
2. Lumigan 0.03% ophthalmic solution [prescribing information]. Irvine, CA: Allergan, Inc.; February 2013.
3. Travoprost 0.004% ophthalmic solution [prescribing information]. Spring Valley, NY: Par Pharmaceutical Companies, Inc.; April 2013.

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4. Travatan Z 0.004% ophthalmic solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc.; September 2011.
5. Zioptan 0.0015% ophthalmic solution [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc.; February 2013.
6. Rescula 0.15% ophthalmic solution [prescribing information]. Bethesda, MD: Sucampo Pharma Americas, LLC; November 2012.
7. Latisse[®] [prescribing information]. Irvine, CA: Allergan, Inc.; November 2013.
8. Vyzulta [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America. November 2017.
9. Vyzulta Drug Evaluation. Express Scripts. Updated December 2017.
10. UpToDate. Open Angle Glaucoma. Accessed 4/2018.

Policy History

Original Effective Date: 09/18/2013

Current Effective Date: 05/16/2018

09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. New policy.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Added a new drug, Vyzulta, with new criteria to this policy. Updated background and rationale section. Added FDA approval section.

Next Scheduled Review Date: 05/2019

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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