Inveltys™ (loteprednol ophthalmic suspension)

Policy # 00669
Original Effective Date: 04/24/2019
Current Effective Date: 05/11/2020

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 Inveltys™‡ (loteprednol ophthalmic suspension) for the treatment of post-operative inflammation and pain following ocular surgery to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Inveltys (loteprednol ophthalmic suspension) will be considered when the following criteria are met:

- Patient will use the requested drug for post-operative inflammation and pain following ocular surgery; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) a generic ophthalmic corticosteroid (e.g., dexamethasone, fluorometholone, prednisolone) 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; AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g., intolerance or inadequate response) one of the following: Durezol®‡ (difluprednate) or Lotemax®‡ (loteprednol), unless there is clinical evidence or patient history that suggests the use of the two mentioned 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).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Inveltys (loteprednol ophthalmic suspension) when the alternative products have not been tried and failed 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.

Based on review of available data, the Company considers the use of Inveltys (loteprednol ophthalmic suspension) for any indication other than for post-operative inflammation and pain following ocular surgery to be **investigational.***

Background/Overview

Inveltys is an ophthalmic corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery. The American Academy of Ophthalmology's (AAO) preferred practice pattern (PPP) from 2016 for cataracts in the adult eye notes that clinically significant cystoid macular edema (CME) occurs infrequently after routine uncomplicated small-incision cataract surgery (1% to 3%). CME is generally associated with postsurgical inflammation and topical anti-inflammatories are used to prevent CME and to treat established CME. The report concludes that there is no firmly-established specific protocol for preventing cystoid macular edema (CME) following cataract surgery. All of the older ophthalmic corticosteroids (generics) are approved for steroid responsive inflammatory conditions of the eye. These include generic ophthalmic products such as dexamethasone, fluorometholone, and prednisolone. The generic products have been a mainstay for use in various conditions. Ophthalmic non-steroidal anti-inflammatory drugs are often co-administered with the ophthalmic steroids following ocular surgery (as they are approved for the treatment of post-operative pain). Brand name products approved for the same indication as Inveltys (pain and inflammation following ocular surgery) include Durezol and Lotemax gel/ointment. Dosing among the brand name products varies. Inveltys is dosed twice daily, while Durezol is dosed 4 times daily for the first two weeks, then two times daily for a week. Lotemax is dosed four times daily. Besides the dosing interval component advantage, there have been no head to head studies versus the other available products for the condition that would suggest superiority of Inveltys.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Inveltys is an ophthalmic corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Rationale/Source

The clinical efficacy of Inveltys was evaluated in 2 multi-centered, randomized, double-masked, placebo-controlled trials in which patients with an anterior cell grade greater than or equal to "2" (a cell count of 6 or higher using a slit-lamp biomicroscope) after cataract surgery were assigned to Inveltys or placebo (vehicle) following surgery. One to two drops of Inveltys or vehicle was self-administered twice a day for 14 days, beginning the day after surgery. Complete resolution of inflammation (a cell count of 0 maintained through day 15 without rescue medication) and complete resolution of pain (a patient-reported pain grade of 0 maintained through day 15 without rescue medication) was assessed 4, 8, and 15 days post-surgery. In the intent-to-treat analysis of both studies, a significant benefit was seen in the Inveltys-treated group for complete resolution of ocular inflammation at days 8 and 15, and complete resolution of pain at days 4, 8, and 15, when compared with placebo. In terms of complete resolution of inflammation at day 8, 24% of Inveltys subjects reached this endpoint vs. 13% in the vehicle group. At day 15, 50% of Inveltys subjects had a complete resolution of inflammation vs. 27% in the vehicle group. In terms of those who were pain free, 43%, 56%, and 69% of Inveltys subjects were pain free at days 4, 8, and 15, respectively. In the vehicle group, 25%, 36%, and 48% of subjects were pain free at days 4, 8, and 15, respectively.

The intent of this policy is to maintain usage to Invelty's FDA approved indication as well as ensuring use of the preferred products in this class.

References

1. Inveltys [package insert]. Kala Pharmaceuticals, Inc. Waltham, Massachusetts. Updated 8/2018.
2. Ophthalmic Corticosteroids Therapy Class Summary. Express Scripts. Updated September 2018.

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Policy History

Original Effective Date: 04/24/2019
Current Effective Date: 05/11/2020
04/04/2019 Medical Policy Committee review
04/24/2019 Medical Policy Implementation Committee approval. New policy.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2021

*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:

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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
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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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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