Products For Dry Eye Disease (Restasis®, Xiidra™)

Policy #  00535
Original Effective Date:  01/01/2017
Current Effective Date:  01/01/2017

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 products for dry eye diseases including, but not limited to Restasis® (cyclosporine ophthalmic) and Xiidra™ (lifitegrast ophthalmic) to be eligible for coverage when the patient selection criteria for the requested drug are met.

Patient Selection Criteria
Coverage eligibility for Restasis (cyclosporine ophthalmic) or Xiidra (lifitegrast ophthalmic) will be considered when the following criteria are met for the selected drug:

- For Restasis requests:
  o Restasis is NOT used in combination with Xiidra; AND
  o One of the following:
    ▪ Patient has a Dry Eye Condition due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca (KCS); OR
    ▪ Patient has a Dry Eye Condition due to Systemic Inflammatory Diseases (e.g., Sjögren syndrome, rheumatoid arthritis [RA], systemic lupus erythematosus [SLE]); OR
    ▪ Patient has a Dry Eye Condition due to Ocular Surface Diseases (e.g., ocular rosacea, atopic keratoconjunctivitis, acute corneal graft rejection, blepharitis, herpetic stromal keratitis, conjunctival graft versus host disease [GVHD]).

- For Xiidra requests:
  o Patient has a diagnosis of Dry Eye Disease; AND
  o Xiidra is NOT used in combination with Restasis

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 Restasis (cyclosporine ophthalmic) or Xiidra (lifitegrast ophthalmic) when patient selection criteria are not met to be investigational.*

Background/Overview
Xiidra is a lymphocyte function associated antigen (LFA-1) antagonist indicated for the treatment of the signs and symptoms of dry eye disease. It is dosed one drop twice daily in each eye (approximately 12 hours apart). Restasis contains the active ingredient, cyclosporine, and is indicated to increase tear
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Production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Restasis is dosed one drop twice a day in each eye (approximately 12 hours apart). Even though dry eye diseases due to systemic inflammatory disease or ocular surface diseases are not technically FDA approved indications for Restasis, the American Academy of Ophthalmology gives recommendations for Restasis in these conditions.

**FDA or Other Governmental Regulatory Approval**
U.S. Food and Drug Administration (FDA)
Restasis was approved in 2003. Xiidra was approved in 2016. See indications in the Background/Overview section.

**Rationale/Source**
The rationale behind this policy is to ensure that Restasis and Xiidra are being utilized for their labeled indication as well as medically necessary uses.

**References**

**Policy History**
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017
10/06/2016 Medical Policy Committee review
10/19/2016 Medical Policy Implementation Committee approval. New Policy.
Next Scheduled Review Date: 10/2017

*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. 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.