Restasis®, Cequa™ (cyclosporine ophthalmic)

Policy # 00640
Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

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 Restasis®‡, Restasis Multidose™‡, and Cequa™‡ (cyclosporine ophthalmic) to be **eligible for coverage**** when the patient selection criteria are met**.**

Patient Selection Criteria

Coverage eligibility for Restasis, Restasis Multidose, and Cequa (cyclosporine ophthalmic) will be considered when the following criteria are met:

- Requested drug will NOT be used in combination with Xiidra®‡ (lifitegrast ophthalmic); AND
- Patient has one of the following conditions:
    - Dry eye condition due to ocular inflammation associated with keratoconjunctivitis sicca (KCS); OR
    - Dry eye condition due to systemic inflammatory diseases (e.g. Sjögren syndrome, rheumatoid arthritis [RA], systemic lupus erythematosus [SLE]); OR
    - 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]); AND
- Patient has tried and failed (e.g. intolerance or inadequate response) Xiidra after at least 3 months of therapy unless there is clinical evidence or patient history that suggests the use of Xiidra will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Restasis®, Cequa™ (cyclosporine ophthalmic)

Policy # 00640
Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

When Services Are Considered Not Medically Necessary

The use of Restasis, Restasis Multidose, or Cequa (cyclosporine ophthalmic) when the patient has not tried and failed Xiidra after at least 3 months of therapy is considered 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 Restasis, Restasis Multidose, or Cequa (cyclosporine ophthalmic) when the patient selection criteria are not met (other than those considered to be **not medically necessary****) to be **investigational.***

Background/Overview

Restasis and Cequa contain the active ingredient, cyclosporine, and both are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Cequa is a novel formulation of cyclosporine in which the hydrophobic cyclosporine molecules are encased in nanomicelles to facilitate the crossing of the corneal barrier. However, no head to head studies have been conducted to establish any benefit of Cequa over Restasis. In pivotal studies of Restasis, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. Both products are 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 these products, the American Academy of Ophthalmology gives recommendations for Restasis in these conditions. Other options for the treatment of dry eye diseases include Xiidra (lifitegrast ophthalmic) and artificial tears. Guidelines have not been updated since Xiidra and Cequa received FDA approval.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Restasis®, Cequa™ (cyclosporine ophthalmic)

Policy # 00640
Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

Restasis was approved in 2003 and is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Cequa was approved in 2018 and is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

Rationale/Source

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the alternative treatment agent for dry eye disease, Xiidra (lifitegrast ophthalmic), is contraindicated, ineffective, or will cause an adverse reaction to the patient. Based on review of the data, if these factors are not present, there is no advantage of using Restasis or Cequa over Xiidra.

References

1. Restasis [package insert]. Allergan. Irvine, California. Updated July 2017.
2. Xiidra [package insert]. Shire. Lexington, Massachusetts. Updated December 2017.
3. Cequa [package insert]. Sun Pharmaceutical. Cranbury, NJ. Updated August 2018.
4. Ophthalmic Dry Eye Medications Therapy Class Summary. Express Scripts. September 2018.

Policy History

Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

10/04/2018	Medical Policy Committee review
10/17/2019	Medical Policy Implementation Committee approval. New policy.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Added new drug, Cequa, to policy with relevant background information.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2021

Restasis®, Cequa™ (cyclosporine ophthalmic)

Policy # 00640
Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

*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
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.

Restasis®, Cequa™ (cyclosporine ophthalmic)

Policy # 00640
Original Effective Date: 01/01/2019
Current Effective Date: 07/13/2020

‡ 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.