Restasis_Cequa (cyclosporine ophthalmic)
Policy Number: C4728-A

CRITERIA EFFECTIVE DATES:

<table>
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<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
<th>NEXT REVIEW DATE</th>
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<tr>
<td>06/2013</td>
<td>07/31/2019</td>
<td>07/31/2020</td>
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J CODE | TYPE OF CRITERIA | LAST P&T APPROVAL/VERSION
---|-----------------|--------------------------|
NA | RxPA | Q3 2019 20190828C4728-A |

PRODUCTS AFFECTED:
Restasis (cyclosporine ophthalmic emulsion)

DRUG CLASS:
Ophthalmic Immunomodulators

ROUTE OF ADMINISTRATION:
Ocular instillation

PLACE OF SERVICE:
Retail Pharmacy

The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

AVAILABLE DOSAGE FORMS:
Restasis MultiDose EMUL 0.05%0.05% (30), (60), Cequa SOLN 0.09% (60)

FDA-APPROVED USES:
indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (DRY EYE).

***Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: keratoconjunctivitis sicca (DRY EYE)

REQUIRED MEDICAL INFORMATION:

A. KERATOCONJUNCTIVITIS SICCA (DRY EYE):
   1. Documented clinical diagnosis of tear deficiency due to ocular inflammation in patients with keratoconjunctivitis sicca or dry eye syndrome (also known as dry eye)
   AND
   2. Patient must have a functioning lacrimal gland
   AND
   3. Documentation that member currently uses artificial tears at least 4 times a day
   AND
   4. Documentation of trial and failure or intolerant to TWO different OTC and/or RX artificial tear products
DURATION OF APPROVAL:
Initial: 12 months, Continuation of therapy: 12 months

QUANTITY:
up to 60 units per 30 days OR (1) 5.5ML multi dose bottle per 30 days

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with optometrist or ophthalmologist

AGE RESTRICTIONS:
16 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. KERATOCONJUNCTIVITIS SICCA (DRY EYE):
   1. Documentation of positive clinical response to therapy as evidenced by an improvement in symptoms of chronic eye irritation, such as eye dryness, red eyes, and burning

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
If a Member has a current ocular infection, Restasis® (cyclosporine ophthalmic emulsion) is contraindicated. All other uses of , Restasis® (cyclosporine ophthalmic emulsion) hat are not an FDA-approved indication or not included in the ‘Coverage Criteria’ section of this policy are considered experimental/ investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND:
Restasis is a topical emulsion which contains cyclosporine, an immunosuppressive agent when administered systemically. It also has anti-inflammatory effects with some evidence suggesting that it is a disease-modifying agent rather than being a merely palliative treatment for dry eye syndrome. Restasis is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (KCS). Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. Though its exact mechanism to alleviate ocular inflammation and to increase tear production is unknown, it is thought to act as a partial immunomodulator. The safety and efficacy of Restasis have not been established in pediatric patients < 16 years of age.

APPENDIX:

REFERENCES:


