Restasis_Cequa (cyclosporine ophthalmic), Xiidra (lifitegrast)
Policy Number: C4728-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
06/2013	07/31/2019	07/31/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q4 2020 20201028C4728-A

PRODUCTS AFFECTED:
Restasis, Cequa (cyclosporine ophthalmic emulsion), Xiidra (lifitegrast)

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 member self-administered

AVAILABLE DOSAGE FORMS:
Restasis Multidose EMUL 0.05%0.05% (30), (60), Cequa SOLN 0.09% (60), cycloSPORINE in Klarity EMUL 0.1%., Xiidra SOLN 5% (60 single use containers)

FDA-APPROVED USES:
Restasis (cyclosporine ophthalmic emulsion)- indicated to increase tear production in members 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 members currently taking topical anti-inflammatory drugs or using punctal plugs.

Xiidra (lifitegrast ophthalmic solution) 5% - indicated for the treatment of the signs and symptoms of dry eye disease

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 members with keratoconjunctivitis sicca or dry eye syndrome (also known as dry eye)

AND
2. Member 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
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

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

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, Cequa (cyclosporine ophthalmic emulsion) or Xiidra (lifitegrast) is contraindicated. All other uses of, Restasis, Cequa (cyclosporine ophthalmic emulsion) or Xiidra (lifitegrast) that 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:
None

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 member s whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (KCS). Increased tear production was not seen in member s 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 member s < 16 years of age.

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

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