Restasis® (cyclosporine ophthalmic emulsion)
Restasis® MultiDose™ (cyclosporine ophthalmic emulsion) 0.05%
Prior Approval
April 2017

OVERVIEW
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.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Restasis is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indication

1. Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca (KCS) [e.g., dry eye syndrome or dry eye disease]. Approve for one year if the patient meets the following criteria (A, B, C, D and E):
   A. The patient is ≥ 16 years of age; AND
   B. The medication is prescribed by an ophthalmologist or optometrist; AND
   C. The patient has a 6 or greater score for the DEQ-5 or 13 or greater for OSDI [documentation required]; AND
   D. Provider has administered testing for one of the following homeostasis markers with corresponding results: non-invasive tear breakup time (< 10s), osmolarity (≥ 308 mOsm/L in either eye or interocular difference of > 8 mOsm/L), ocular surface staining (> 5 corneal spots, > 9 conjunctival spots, or lid margin [≥ 2mm length & ≥ 25% width]; AND
   E. If diagnosis is mild dry eye disease, patient has tried and failed preservative free artificial tears.

Other Uses with Supportive Evidence

1. Dry Eye Conditions due to Systemic Inflammatory Diseases (e.g., Sjögren syndrome, rheumatoid arthritis [RA], systemic lupus erythematosus [SLE]). Approve for one year if the patient meets BOTH of the following criteria (A and B):
   A. The patient is ≥ 16 years of age; AND
B. The medication is prescribed by an ophthalmologist or optometrist

**Approval Duration:** 365 days (1 year)

**References**