Restasis
(cyclosporine ophthalmic solution)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Restasis ophthalmic emulsion is used to treat chronic dry eye as a result of keratoconjunctivitis sicca. Restasis contains cyclosporine ophthalmic emulsion packaged in sterile, preservative-free single-use vials and is administered every 12 hours. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine emulsion increases tear production and is thought to act as a partial immunomodulator (1-2).

Regulatory Status
FDA-approved indication: Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs (1).

The safety and efficacy of Restasis has not been established in pediatric patients below the age of 16 (1).

Summary
Restasis ophthalmic emulsion is used to treat chronic dry eye as a result of keratoconjunctivitis sicca. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine emulsion increases tear production and is thought to act as a partial immunomodulator. The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16 (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Restasis while maintaining optimal therapeutic outcomes.

References