CYCLOSPORINE OPHTHALMICS
Restasis (cyclosporine ophthalmic emulsion), Cequa (cyclosporine ophthalmic solution)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Cyclosporine ophthalmics are 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 ophthalmics increase tear production and are thought to act as partial immunomodulators (1-3).

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).

Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye) (2).

The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16. The safety and efficacy of Cequa ophthalmic solution have not been established in pediatric patients below the age of 18 (1-2).

Summary
Cyclosporine ophthalmics are 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 ophthalmics increase tear production and are thought to act as partial immunomodulators. The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16. The safety and efficacy of Cequa ophthalmic solution have not been established in pediatric patients below the age of 18 (1-3).

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

References