Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization          Number: 07.060

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| Approval: Robert Bonnell, M.D., Med. Dir. | DATES - Origination: 02/25/09 |
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|                                            | Annual Review: 11/16/16       |

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

Background Information:

Medication Summary

- Restatis® (cyclosporine ophthalmic emulsion) 0.05% contains a topical immunomodulatory with anti-inflammatory effects. Cyclosporine emulsion is used for the treatment of xerophthalmia (dry eyes) in Members whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The exact mechanism of action is unknown.
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Background Information, continued:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Coverage Guidelines

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- If a Member has a current ocular infection, Restasis® (cyclosporine ophthalmic emulsion) is contraindicated.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.0 Request for initial therapy requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying ALL of the following:

1.1 Member has a diagnosis of dry eye disease (keratoconjunctivitis sicca); AND

1.2 Member has tried and failed an ocular lubricant (i.e., artificial tears, Akwa Tears, Refresh, Systane); AND

1.3 Provider is an ophthalmologist, optometrist, or rheumatologist or mid-level practitioner under one (1) of these respective specialists;

1.4 If criteria are met, may approve Restasis® 60 units per 30 days for up to 12 months.
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Procedure, continued:

2.0 Request for continuation therapy beyond the initial authorization period requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying that the Member has shown a favorable response such as reduction in signs and symptoms of dry eyes:

2.1 If criterion is met, may approve Restasis® 60 units per 30 days for up to 12 months.

References:


