Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization

Title: Supersaturated Calcium Phosphate Rinse (Caphosol®, Mugard®, Episol®)

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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, revised, or archived.

Background Information:

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.
Background Information, continued:

Medication Summary

- Caphosol® is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, minimize friction, ulceration and corresponding pain and discomfort associated with mucositis. Caphosol® is indicated for dryness of the mouth or throat (hyposalivation, xerostomia) and is indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy.

- Mugard® is a viscous, mucoadhesive rinse which provides a protective coating to the oral mucosa. Mugard® is indicated for oral mucositis and stomatitis caused by radiation or chemotherapy and other oral wounds.

- Episil® is an oral liquid without preservatives given for relief of pain via mechanical barrier action by a protective film that forms in situ and adheres to the oromucosal surfaces.

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.

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.
Title: Supersaturated Calcium Phosphate Rinse (Caphosol®, Mugard®, Episil®)

Procedure:

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

1.1 Member is currently receiving high-dose chemotherapy or radiation;

1.2 Diagnosis of oral mucositis as evidenced by one (1) of the following:
   1.2.1 Redness or inflammation of the mucous membranes;
   1.2.2 Oral ulceration;
   1.2.3 Dry mouth with discomfort and/or pain;
   1.2.4 Difficulty with speech and/or swallowing;

1.3 Member has failed a trial of a formulation of ‘Magic Mouthwash’ (compound with numerous ingredients such as diphenhydramine, lidocaine, Maalox, nystatin, sucralfate) or viscous lidocaine or has a contraindication to such therapy;

1.4 If criteria is met, may approve Caphosol for a maximum of 120 units (total of 3600ml) per 30 days for three (3) months or less depending on the length of chemotherapy or radiation planned or Mugard for a maximum of 120 doses (total of 600ml) per 30 days for three (3) months or less depending on the length of chemotherapy or radiation planned or Episil for a maximum of 4 units (total of 40ml) per 30 days for three (3) months or less depending on the length of chemotherapy or radiation planned.

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 ALL of the following:

2.1 Member is still currently receiving high-dose chemotherapy or radiation;

2.2 Reductions in Member’s mucositis signs and symptoms;

2.3 If criteria are met, Caphosol, Mugard or Episil may be approved for three (3) additional months at the same dosage limitations as above.
Title: *Supersaturated Calcium Phosphate Rinse (Caphosol®, Mugard®, Episil®)*

**References:**


