

Pharmacy Policy Bulletin: J-0869 Mucosal Agents – Commercial and Healthcare Reform	
Number: J-0869	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Other Managed Prior Authorization = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-0869-009	Original Date: 04/12/2019
Effective Date: 07/18/2025	Review Date: 06/25/2025

Drugs Product(s):	• Aquoral (oxidized glycerol triesters) • Caphosol (supersaturated calcium phosphate rinse) • Gelclair (bioadherent oral rinse gel) • GelX (mucosal coating gel) • MuGard (oral mucoadhesive) • SalivaMax (supersaturated calcium phosphate rinse)
FDA-Approved Indication(s):	• Aquoral ○ Relief from dry mouth due to certain diseases such as Sjogren's syndrome, medication use, inflammation, chemotherapy, radiotherapy, stress, or aging. • Caphosol ○ Dryness of the mouth and oropharynx (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent ○ Adjunct to standard oral care in the treatment of mucositis that may be caused by radiation or high-dose chemotherapy • Gelclair ○ Management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease ○ Diffuse aphthous ulcers • GelX ○ Alleviate induced radiotherapy and chemotherapy mouth lesions. • MuGard ○ Management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

	• SalivaMax ○ Treatment of oral mucositis, dryness of the oral mucosa, and xerostomia related to radiation therapy or chemotherapy, infection, dysfunction or obstruction of salivary glands, emotional factors such as fear or anxiety, medications, surgery, and Sjogren's syndrome
Background:	• Aquoral utilizes oxidized glycerol triesters (OGT) patented technology. OGTs are oily lipids that adhere to the surface of the oral cavity forming a protective film over the teeth, gums, and tongue. This protects the mouth from mechanical traumas and reduces moisture loss from the oral tissues. Aquoral spray is an artificial saliva. OGT is not a saliva substitute or a saliva stimulant and does not contain any pharmacological ingredients. • Caphosol is a preparation comprising two separately packaged aqueous solution, a phosphate solution (Caphosol A) and a calcium solution (Caphosol B) which, when both solutions are combined in equal volumes, forms a solution supersaturated with respect to both calcium and phosphate ions. Calcium phosphate solution resembles human saliva that is intended to replace the normal ionic and pH balance in the oral cavity. • Gelclair is a unique oral gel whose key ingredients are polyvinylpyrrolidone (PVP) and sodium hyaluronate (Hyaluronic Acid). Gelclair is easily applied, via an oral rinse, and provides rapid and effective relief from pain, by creating a protective coating over the oral mucosa. This coating, or barrier, alleviates irritation of exposed nerves in the ulcer areas, as well as moisturizing the tissue. • GelX consists of a polymer based on mineral salt and sulfonic acid. Once placed into the mouth, it coats the oral mucosa and begins to soothe oral lesions of various etiologies including oral mucositis/stomatitis radiotherapy and chemotherapy induced mouth lesions. • MuGard Oral Mucoadhesive is a mucoadhesive product. When swirled gently around the mouth, the mucoadhesive formulation results in the formation of a protective coating over the oral mucosa. • SalivaMax is available as a powder in a packet intended to be dissolved or dispersed in water (specifically, tap, distilled, or purified) before administration to form a solution supersaturated with respect to both calcium and phosphate ions. SalivaMax when dissolved or dispersed in water before use, forms an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. • The Mucositis Study Group of the Multinational Association for Supportive Care in Cancer and the International Society of Oral Oncology (MASCC/ISOO) guidelines recommend use of a standardized oral care protocol including brushing with a soft toothbrush, flossing and the use of non-medicated rinses (for example, saline or sodium bicarbonate rinses). • Magic Mouthwash is typically compounded by a pharmacy and most often contains anticholinergic agents, such as diphenhydramine; an anesthetic, such as viscous lidocaine; and an antacid or mucosal coating agent, such as magnesium or aluminum hydroxide. • Prescribing Considerations: ○ Patients and caregivers should be educated regarding the importance of effective oral hygiene. ○ Saliva substitutes and stimulants are not meant to be swallowed. ○ For oral rinses or other liquid saliva substitutes, swish a small amount in the mouth for 30 seconds, then spit out. ○ For oral powder, mix with about 1 ounce of water before using. Stir the mixture and use it right away. Do not save the mixture for later use. ○ For oral spray, shake gently before each use and spray directly onto the tongue.

- For oral tablets or lozenges, hold inside the mouth. They can be held in the mouth for long periods of time, even while sleeping.
- For gel, paste, or swabs, apply as instructed directly onto the gums, tongue, teeth, or sides of the mouth.

Approval Criteria

I. Approval Criteria

A. Aquoral

When a benefit, coverage of Aquoral may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using Aquoral for the treatment of xerostomia (ICD-10: R68.2, K11.7, M35.0) caused by one (1) of the following **(a. through e.)**:
 - a. Chemotherapy
 - b. Radiation
 - c. Sjögren's syndrome
 - d. Oral inflammation
 - e. Dry mouth associated with medication use
2. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(a., b., and c.)**:
 - a. A saliva substitute (for example, carboxymethylcellulose or hydroxyethyl cellulose solutions, Biotene, Mouth Kote, ACT Total Care)
 - b. A saliva stimulating agent (for example, XyliMelt, Natrol Dry Mouth Relief)
 - c. An alcohol-free mouth rinse (for example, Biotene Mouthwash, Crest Pro-Health Rinse, Eco-Dent Daily Rinse, Oasis Moisturizing Mouthwash)

B. Caphosol

When a benefit, coverage of Caphosol may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using Caphosol for one (1) of the following **(a. or b.)**:
 - a. The treatment of xerostomia (ICD-10: R68.2, K11.7)
 - b. The treatment of mucositis (ICD-10: K12.3) caused by radiotherapy or chemotherapy in adjunct to standard oral care
2. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. If Caphosol is being used for the treatment of xerostomia, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i., ii., and iii.)**:
 - i. A saliva substitute (for example, carboxymethylcellulose or hydroxyethyl cellulose solutions, Biotene, Mouth Kote, ACT Total Care)
 - ii. A saliva stimulating agent (for example, XyliMelt, Natrol Dry Mouth Relief)
 - iii. An alcohol-free mouth rinse (for example, Biotene Mouthwash, Crest Pro-Health Rinse, Eco-Dent Daily Rinse, Oasis Moisturizing Mouthwash)
 - b. If Caphosol is being used for the adjunct treatment of mucositis caused by radiotherapy or chemotherapy, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i., ii., and iii.)**:
 - i. An over the counter antacid agent (for example, aluminum hydroxide solution, Amphojel)
 - ii. An over the counter film forming agent or benzocaine product (for example, Zilactin, Anbesol)
 - iii. A viscous lidocaine containing product

C. Gelclair

When a benefit, coverage of Gelclair may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using Gelclair for one (1) of the following **(a. or b.)**:
 - a. The treatment of mucositis or stomatitis that may be caused by radiotherapy and chemotherapy (ICD-10: K12.3).
 - b. The treatment of oral wounds, mouth sores, and injuries (for example, ulcers and canker sores) (ICD-10: K12).
2. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(a., b., and c.)**:
 - a. An over the counter antacid agent (for example, aluminum hydroxide solution, Amphojel)
 - b. An over the counter film forming agent or benzocaine product (for example, Zilactin, Anbesol)
 - c. A viscous lidocaine containing product

D. GelX

When a benefit, coverage of GelX may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using GelX for one (1) of the following **(a. or b.)**:
 - a. The prevention or treatment of mucositis and stomatitis that may be caused by radiotherapy and chemotherapy (ICD-10: K12.3).
 - b. The treatment of oral wounds, mouth sores, and injuries (for example, ulcers and canker sores) (ICD-10: K12).
2. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(a., b., and c.)**:
 - a. An over the counter antacid agent (for example, aluminum hydroxide solution, Amphojel)
 - b. An over the counter film forming agent or benzocaine product (for example, Zilactin, Anbesol)
 - c. A viscous lidocaine containing product

E. Mugard

When a benefit, coverage of Mugard may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using Mugard for one (1) of the following **(a. or b.)**:
 - a. Prevention or treatment of mucositis and stomatitis that may be caused by radiotherapy or chemotherapy (ICD-10: K12.3).
 - b. The treatment of oral wounds, mouth sores, and injuries (for example, ulcers and canker sores) (ICD-10: K12).
2. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(a., b., and c.)**:
 - a. An over the counter antacid agent (for example, aluminum hydroxide solution, Amphojel)
 - b. An over the counter film forming agent or benzocaine product (for example, Zilactin, Anbesol)
 - c. A viscous lidocaine containing product

F. SalivaMax

When a benefit, coverage of SalivaMax may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is using SalivaMax for one (1) of the following **(a. or b.)**:
 - a. The treatment of xerostomia (ICD-10: R68.2, K11.7)
 - b. The adjunct treatment of mucositis caused by radiotherapy or chemotherapy (ICD-10: K12.3).
2. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. If SalivaMax is being use for the treatment of xerostomia, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i. through iv.)**:
 - i. A saliva substitute (for example, carboxymethylcellulose or hydroxyethyl cellulose solutions, Biotene, Mouth Kote, ACT Total Care)

- ii. A saliva stimulating agent (for example, XyliMelt, Natrol Dry Mouth Relief)
 - iii. An alcohol-free mouth rinse (for example, Biotene Mouthwash, Crest Pro-Health Rinse, Eco-Dent Daily Rinse, Oasis Moisturizing Mouthwash)
 - iv. Caphosol
 - b. If SalivaMax is being used for the adjunct treatment of mucositis caused by radiotherapy or chemotherapy, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products (**i. through iv.**):
 - i. An over the counter antacid agent (for example, aluminum hydroxide solution, Amphojel)
 - ii. An over the counter film forming agent or benzocaine product (for example, Zilactin, Anbesol)
 - iii. A viscous lidocaine containing product
 - iv. Caphosol
- II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

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3. Hester, Stacy. Prevention and treatment of oral mucositis. *Pharmacist's Letter.* November 2014.
4. Aquoral [package insert]. San Antonio, TX: Mission Pharmacal Company.
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6. Gelclair [package insert]. San Francisco, CA: Napo Pharmaceuticals, Inc.; May 2024.
7. GelX oral gel [package insert]. Louisville, KY: US WorldMeds, LLC; August 2019.
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9. SalivaMax. Available at: <https://forwardscience.com/salivamax>. Accessed May 12, 2025.
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11. Calcium Phosphate Mouth Rinse/Caphosol. ONS. Available at: <https://www.ons.org/education-hub/events/congress/blog/inside-look-get-know-nurses-behind-2024-ons-congressr>. Accessed May 12, 2025.
12. Saliva substitutes Uses, Side Effects & Warnings. Drugs.com. Available at: <https://www.drugs.com/mtm/saliva-substitutes.html>. Accessed May 12, 2025.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

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