Pharmacy Policy Bulletin: J-0220 Evoxac (cevimeline) – Commercial and Healthcare Reform	
Number: J-0220	**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-0220-009	**Original Date:** 05/01/2019
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Evoxac (cevimeline)
FDA-Approved Indication(s):	• Treatment of symptoms of dry mouth in patients with Sjögren's Syndrome.

Background:	• Cevimeline is a cholinergic agonist acting at the muscarinic receptor. It increases secretion of exocrine glands such as salivary and sweat glands. Cevimeline also increases smooth muscle tone in the gastrointestinal and urinary tract.
	• Sjögren syndrome is a chronic autoimmune disorder. It causes exocrine gland dysfunction and dryness of mucosal surfaces (also known as sicca symptoms). Sjögren syndrome primarily affects the eyes and mouth.
	• Cevimeline is FDA approved for xerostomia associated with Sjögren's Syndrome. The safety and efficacy of the product in treatment of other conditions has not been established.
	• Cevimeline has been studied in the treatment of xerostomia due to radiation therapy for head and neck cancer, but it is not FDA approved. The National Comprehensive Cancer Network (NCCN) guidelines for head and neck cancer recommend the following for pre-radiation dental and oral care:
	  ○ Increased hydration
	  ○ Minimize ingestion of caffeinated products and alcohol
	  ○ Salivary substitutes (for example, calcium phosphate-containing solutions; gels containing lysozyme, lactoferrin, and peroxidase)
	  ○ Alcohol-free mouthwash
	  ○ Salivary stimulation
	  ▪ Gustatory stimulants (for example, xylitol chewing gum, sorbitol/malic acid lozenges, xylitol lozenges)
	  ▪ Cholinergic agonists (for example, pilocarpine, cevimeline)
	• Prescribing Considerations:

	○ Standard dosing for cevimeline in patients with dry mouth due to radiation therapy for the head and neck cancer is 30 mg three times daily. ○ Drugs with parasympathomimetic effects administered concurrently with cevimeline can be expected to have additive effects. Cevimeline may interfere with desirable antimuscarinic effects of drugs used concomitantly.

Approval Criteria

I. Initial Authorization

A. Dry mouth in Patients with Sjögren's Syndrome
When a benefit, coverage of Evoxac (cevimeline) may be approved when all of the following criteria are met **(1., 2., and 3.)**:
1. The member has a diagnosis of Sjögren's Syndrome (Sicca Syndrome) (ICD-10: M35.0).
2. The member is experiencing symptoms of dry mouth.
3. If the request is for brand Evoxac, the member meets all of the following criteria **(a. and b.)**:
a. The member has experienced therapeutic failure or intolerance to generic cevimeline.
b. The member has experienced therapeutic failure, intolerance, or contraindication to the plan-preferred generic pilocarpine.

B. Dry Mouth due to Radiation Therapy for Head and Neck Cancer (No ICD-10 Codes)
When a benefit, coverage of Evoxac (cevimeline) may be approved when all of the following criteria are met **(1., 2., and 3.)**:
1. The member has a diagnosis of head and neck cancer.
2. The member is experiencing symptoms of dry mouth associated with radiation therapy.
3. If the request is for brand Evoxac, the member meets all of the following criteria **(a. and b.)**:
a. The member has experienced therapeutic failure or intolerance to generic cevimeline.
b. The member has experienced therapeutic failure, contraindication, or intolerance to the plan-preferred generic pilocarpine.

II. Reauthorization
When a benefit, reauthorization of Evoxac (cevimeline) may be approved when the following criterion is met **(A. and B.)**:
A. The prescriber attests that the member has experienced positive clinical response to therapy.
B. If the request is for brand Evoxac, the member has experienced therapeutic failure or intolerance to generic cevimeline.

III. 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. Evoxac (cevimeline) is contraindicated in patients with uncontrolled asthma and when miosis is undesirable (for example, in acute iritis and in narrow-angle glaucoma).
II. 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.
III. 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:

1. Evoxac [package insert]. South Plainfield, NJ: Cosette Pharmaceuticals Inc.; September 2022.
2. NCCN Guidelines Version 2.2025 Head and Neck Cancers. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed April 30, 2025.
3. DynaMed. Sjögren's Syndrome. Available at: https://www.dynamed.com/condition/sjogren-syndrome. Accessed May 7, 2024.