

PHARMACY POLICY – 5.01.661


Dry Eye Disease Medications

Effective Date: May 1, 2026
Last Revised: Apr. 14, 2026
Replaces: N/A

RELATED MEDICAL POLICIES:
None

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Introduction

Dry eye disease is a common long-lasting condition that affects both the amount and quality of tears needed to keep the eyes healthy and comfortable. Tears play an important role in protecting the surface of the eye, keeping it moist, and allowing for clear vision. When the eyes do not make enough tears, or when tears evaporate too quickly or do not function properly, the surface of the eye can become dry and irritated. People with dry eye disease may experience a range of symptoms, including stinging or burning sensations, a gritty or scratchy feeling, itching, redness, sensitivity to light, and blurred or fluctuating vision. Treatment for dry eye disease focuses on improving comfort, protecting the surface of the eye, and restoring a healthy tear balance. This may be done by increasing moisture in the eyes, helping the eyes produce more tears, improving the quality of existing tears, keeping tears on the eye longer, or reducing inflammation that can cause redness and swelling. Treatments can include artificial tears, prescription eye drops, or other therapies based on the severity and cause of the condition. This policy describes when dry eye disease medications may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
<p>Cequa (cyclosporine ophthalmic solution)</p>	<p>Cequa (cyclosporine ophthalmic solution) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> • Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> • Cequa (cyclosporine ophthalmic solution) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Restasis or Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution) <p>AND</p> <ul style="list-style-type: none"> • The prescribed quantity is limited to 60 single-use vials per 30 days
<p>Eysuvis (loteprednol etabonate ophthalmic suspension)</p>	<p>Eysuvis (loteprednol etabonate ophthalmic suspension) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> • Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> • Has tried and failed two of the following ophthalmic drugs for dry eye disease: <ul style="list-style-type: none"> ○ Dexamethasone eye drops ○ Loteprednol etabonate eye drops ○ Fluorometholone eye drops



Drug	Medical Necessity
	<ul style="list-style-type: none"> ○ Prednisolone eye drops
<p>Miebo (perfluorohexyloctane ophthalmic solution)</p>	<p>Miebo (perfluorohexyloctane ophthalmic solution) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> • Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> • Miebo (perfluorohexyloctane ophthalmic solution) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution) <p>AND</p> <ul style="list-style-type: none"> • The prescribed quantity is limited to one 3 ml bottle per 30 days
<p>Restasis (cyclosporine ophthalmic emulsion)</p>	<p>Restasis (cyclosporine ophthalmic emulsion) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> • Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> • Restasis (cyclosporine ophthalmic emulsion) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Cequa or Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), Tyrvaya



Drug	Medical Necessity
	<p>(varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution)</p> <p>AND</p> <ul style="list-style-type: none"> The prescribed quantity is limited to 60 single-use vials per 30 days OR one 5.5 ml bottle per 30 days
<p>Tryptyr (acoltremon ophthalmic solution)</p>	<p>Tryptyr (acoltremon ophthalmic solution) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> Tryptyr (acoltremon ophthalmic solution) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution) <p>AND</p> <ul style="list-style-type: none"> The prescribed quantity is limited to 60 single-use vials per 30 days
<p>Tyrvaya (varenicline solution nasal spray)</p>	<p>Tyrvaya (varenicline solution nasal spray) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> Tyrvaya (varenicline solution nasal spray) is not being used concurrently with an ophthalmic cyclosporine product (e.g.,



Drug	Medical Necessity
	<p>Cequa, Restasis, Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution)</p>
<p>Verkazia (cyclosporine ophthalmic emulsion)</p>	<p>Verkazia (cyclosporine ophthalmic emulsion) may be considered medically necessary for the treatment of vernal keratoconjunctivitis when all the following are met:</p> <ul style="list-style-type: none"> • The individual is aged 4 years or older <p>AND</p> <ul style="list-style-type: none"> • Has moderate-to-severe vernal keratoconjunctivitis <p>AND</p> <ul style="list-style-type: none"> • Has tried two ophthalmic medications to treat this condition (e.g., cromolyn, Alomide, Zerviate, azelastine, bepotastine, epinastine, ketotifen, Lastacaft, and olopatadine) <p>AND</p> <ul style="list-style-type: none"> • Verkazia (cyclosporine ophthalmic emulsion) is prescribed by or in consultation with an optometrist or ophthalmologist <p>AND</p> <ul style="list-style-type: none"> • The prescribed quantity is limited to 120 single-use vials per 30 days
<p>Vevye (cyclosporine ophthalmic solution)</p>	<p>Vevye (cyclosporine ophthalmic solution) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> • Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% <p>AND</p> <ul style="list-style-type: none"> • Vevye (cyclosporine ophthalmic solution) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Cequa or Restasis), Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution) <p>AND</p>



Drug	Medical Necessity
	<ul style="list-style-type: none"> The prescribed quantity is limited to one 2 ml bottle per 30 days
Xiidra (generic)	<p>Xiidra (lifitegrast ophthalmic solution) may be considered medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> The individual is being treated for the signs and symptoms of dry eye disease <p>AND</p> <ul style="list-style-type: none"> Is aged 18 years or older <p>AND</p> <ul style="list-style-type: none"> Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic <p>AND</p> <ul style="list-style-type: none"> Xiidra (lifitegrast ophthalmic solution) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tryptyr (acoltremon ophthalmic solution), or Tyrvaya (varenicline solution nasal spray) <p>AND</p> <ul style="list-style-type: none"> The prescribed quantity is limited to 60 single-use containers per 30 days

Drug	Investigational
As listed	All other uses of the drugs for conditions not outlined in this policy are considered investigational.

Length of Approval	
Approval	Criteria
Initial authorization	All drugs in this policy may be approved up to 12 months.
Re-authorization criteria	All drugs in this policy may be approved up to 12 months as long as the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.



Documentation Requirements

The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

N/A

Related Information

Consideration of Age

Age limits specified in this policy are determined according to FDA-approved indications where applicable.

Benefit Application

This policy is managed through the pharmacy benefit.

Evidence Review

Background

Dry eye disease (DED) or keratoconjunctivitis sicca is a chronic condition caused by reduced tear production (aqueous deficient dry eye) or excessive tear evaporation (evaporative dry eye). Those with aqueous deficient dry eye disease can be further subdivided into Sjögren syndrome



dry eye or non-Sjögren syndrome while evaporative dry eye includes intrinsic and extrinsic disease.

Risk factors for DED include certain medications (diuretics, antihistamines, antidepressants, anxiolytics, hormone replacement therapy, and isotretinoin), sedentary lifestyle, chronic pain, diabetes, metabolic syndrome, fibromyalgia, anxiety or depression, increased age, female gender, use of electronic devices, androgen deficiency, low intake of omega-3 fatty acids, connective tissue disease, irritable bowel disease, radiation, stem cell transplantation, thyroid disease, migraines, Parkinson's disease, psoriasis, sleep disorders, contact lenses, and vitamin A deficiency. Ophthalmic preservatives can also worsen DED as can environmental factors such as low humidity, increased airflow over the eye, dust, smoke, and air pollution.

Common symptoms include ocular erythema, excessive tearing, visual disturbance, burning, dryness, gritty sensation, pruritus, and photophobia. Damage to the ocular surface may occur with severe DED including conjunctival scarring with severe or late-stage disease. Diagnosis is based on patient history and tests such as ocular surface staining, lipid layer analysis, tear breakup time, tear osmolarity, and others. Referral to an eye specialist is often required.

DED is common, affecting an estimated 16.4 million adults in the United States. In the overall population, the prevalence of DED is estimated at 5.3%-14.5% with a summary estimate of 8.1% (95% CI 4.9-13.1). The prevalence is increased in Asians (16%-23.7%) and with increasing age. Overall, an estimated 4.88 million people >50 years of age have DED.

Meibomian gland dysfunction, a cause of DED, is present in 30%-35% of Whites and 33%-50% of East Asians. The pooled estimate prevalence of Meibomian gland dysfunction is 21.2%. Of patients over 65 years of age, Meibomian gland dysfunction is present in 52%-61%. However, an estimated two-thirds of those with Meibomian gland dysfunction are asymptomatic.

DED occurs because of decreased tear film or increased evaporation of tears. Tears are secreted by the lacrimal glands, Meibomian glands, and conjunctival goblet cells. The trigeminal and facial nerves are involved in tear stimulation. Decreased tear film production leads to hyperosmolality, tear film instability, inflammation, damage to the ocular surface and ocular irritation. This can occur due to dysfunction of lacrimal glands, Meibomian glands, cornea, or conjunctiva which together impact electrolytes, water, mucin, and lipids in tears. Additionally, decreased blinking leads to decreased release of tears from the lacrimal glands. Decreased tear film causes an inflammatory reaction on the ocular surface which includes changes in T-cell infiltration. Inflammation leads to an influx of cytokines and induces injury to the cornea, conjunctiva, and lacrimal and Meibomian glands.



Transient receptor potential cation channels sense irritation and temperature changes. Ion channels also influence DED with dysfunction in sodium channels leading to increased sensitivity, pain, and ocular discomfort, dysfunction in potassium channels leading to altered tear secretion, and dysfunction in calcium channels decreasing tear secretion. Prolonged immune response alters the function of ion channels, worsening DED.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

The American Academy of Ophthalmology (AAO) published a preferred practice guideline for dry eye syndrome in 2024. Recommended therapies are categorized by treatment step (see Table I). Step 1 includes ocular lubricants, eyelid hygiene, and warm compresses; prescription drugs are recommended in step 2. The guidelines do not recommend one prescription treatment over another. Other step 2 treatments include non-preserved ocular lubricants, ointment and moisture chamber devices, artificial tear substitutes, and tear conservation.

Table I. AAO Guidelines for Dry Eye Syndrome Treatment (2024)

Disease Severity	Recommended Treatment of Dry Eye Syndrome
Step 1	<ul style="list-style-type: none"> • Patient education • Modification of the environment • Treatment or elimination of any causative factors • Evaluation of topical and systemic medications • Eyelid hygiene and warm compresses • Ocular lubricants
Step 2	<p>If Step 1 is inadequate, consider:</p> <ul style="list-style-type: none"> • Non-preserved ocular lubricants • Overnight treatments (ointment or moisture chamber devices) • Prescription drugs: <ul style="list-style-type: none"> ○ Topical corticosteroids (limited duration) ○ Topical secretagogues



Disease Severity	Recommended Treatment of Dry Eye Syndrome
	<ul style="list-style-type: none"> ○ Topical nonglucocorticoid immunomodulatory drugs (i.e., cyclosporine) ○ Topical lymphocyte function-associated antigen-1 antagonist (i.e., lifitegrast) ○ Topical water-free lipophilic liquid (perfluorohexyloctane) ○ Nasal spray, chronic neuro-activation via the trigeminal parasympathetic pathway (varenicline) ○ Oral macrolide or tetracycline antibiotics • Artificial tear substitutes, gels, or ointments (non-preserved preferred) • Tear conservation via punctal occlusion or moisture chamber spectacles or goggles • In office treatments for Meibomian glands • Treatment of Demodex if present • Treatment of anterior blepharitis if present
Step 3	<p>If above options are inadequate, consider:</p> <ul style="list-style-type: none"> • Oral secretagogues • Autologous/allogeneic serum eye drops • Platelet rich plasma eye drops • Blood-based products • Therapeutic contact lenses (soft bandage, rigid scleral lenses)
Step 4	<p>If above options are inadequate, consider:</p> <ul style="list-style-type: none"> • Topical corticosteroid for a longer duration • Amniotic membrane grafts • Surgical punctal occlusion and other surgical approaches

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History

Date	Comments
05/01/26	New policy, approved April 14, 2026. Add to Prescription Drug section. Moved Cequa (lifitegrast ophthalmic solution), Eysuvis (loteprednol etabonate ophthalmic suspension), Miebo (perfluorohexyloctane ophthalmic solution), Restasis (cyclosporine ophthalmic emulsion), Tryptyr (acoltremon ophthalmic solution), Tyrvaya (varenicline solution nasal spray), Verkazia (cyclosporine ophthalmic emulsion), Vevye



Date	Comments
	(cyclosporine ophthalmic solution), and Xiidra (lifitegrast ophthalmic solution) from policy 5.01.605 Medical Necessity Criteria for Pharmacy Edits to 5.01.661 Dry Eye Disease Medications with no changes to the coverage criteria.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

