MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy
Topical Ocular Hydrating Agents

Table of Contents

Policy Number: 426

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**3/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering prior authorization criteria and quantity limit requirements for topical ocular hydrating agents.

Policy

Length of Approval	12 months, unless otherwise specified below
Formulary Status	All requests must meet the Step Therapy requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Please refer to the chart below for the formulary and status of the medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Formulary, Preferred		
Cyclosporine Single Use Vials	PA, QCD	Prior authorization required. See criteria below.
Eysuvis ™ (loteprednol etabonate)	PA	
Verkazia ® (cyclosporine)	PA	
Xiidra ™ (lifitegrast)	PA, QCD	
Formulary, Non-Preferred		
Miebo ® (perfluorohexyloctane)	PA, QCD	Prior authorization required. See criteria below.
Restasis ® (cyclosporine) **Single Use Vials**	PA, QCD	
Non-Formulary, Non-Covered		
Cequa ™ (cyclosporine)	NFNC, PA, QCD	Prior authorization required. See criteria below.
Restasis ® (cyclosporine) **Multidose**	NFNC, PA, QCD	
Tyrvaya nasal spray ™ (varenicline)	NFNC, PA, QCD	
Vevye ® (cyclosporine)	NFNC, PA, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior authorization; NFNC – Non-formulary, Non-formulary, Non-Covered

Cyclosporine Single Use Vials

Cyclosporine Single Use Vials may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of moderate or severe keratoconjunctivitis sicca; **AND**

2. Age 16 years of age or older; **AND**

3. Prescribed by a board-certified ophthalmologist, board eligible ophthalmologist, board-certified optometrist, or board eligible optometrist.

Xiidra™

Xiidra ™ (lifitegrast, ophthalmic) may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of moderate or severe dry eye disease (DED); **AND**
2. Age 17 years of age or older; **AND**
3. Prescribed by a board-certified ophthalmologist, board eligible ophthalmologist, board-certified optometrist, or board eligible optometrist.

Cequa™, Restasis® Multidose, Restasis® Single Use Vials, Tyrvaya™ & Vevye

Cequa ™ (cyclosporine, ophthalmic), **Restasis** ® **Multidose** (cyclosporine, ophthalmic), **Restasis** ® **Single use vials** (cyclosporine, ophthalmic), **Tyrvaya** ® nasal spray (varenicline) or **Vevye** ®(cyclosporine, ophthalmic) may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of moderate or severe keratoconjunctivitis sicca; **AND**
2. Age 18# years of age or older; **AND**
3. Prescribed by a board-certified ophthalmologist, board eligible ophthalmologist, board-certified optometrist, or board eligible optometrist; **AND**
4. Previous use of, or evidence of BCBSMA paid claims for BOTH **Xiidra**™ (lifitegrast) AND **Cyclosporine** (including all formulations).

#Restasis® (cyclosporine, ophthalmic) has safety data to include ages 16 and older.

Eysuvis ™

Eysuvis ™ (loteprednol etabonate, ophthalmic) may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of moderate or severe dry eye disease (DED); **AND**
2. Age 18 years of age or older; **AND**
3. Prescribed by a board-certified ophthalmologist, board eligible ophthalmologist, board-certified optometrist, or board eligible optometrist; **AND**
4. The patient does NOT have glaucoma or any other eye issues, such as infection.

Note: If approved, the Prior Authorization for **Eysuvis** ™ will be granted for tow (2) weeks.

Miebo ®

Miebo ® (perfluorohexyloctane) may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of severe dry eye disease (DED); **AND**

2. Age 18 years of age or older.

Note: If approved, the Prior Authorization for **Miebo** ® will be granted for up to six (6) months.

Verkazia ®

Verkazia ® (cyclosporine) may be covered and considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Definite diagnosis of moderate or severe vernal keratoconjunctivitis (VKC); **AND**

2. Age 4 years of age or older.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and

specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
3/2023	Updated to add Vevye ®(cyclosporine) to the policy as non-covered.
10/2023	Updated to add Miebo ® **(**perfluorohexyloctane) to the policy. Reformatted policy.
9/2023	Clarified FE criteria when using cyclosporin and updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
6/2023	Updated Criteria for Cyclosporine, Xiidra ™, and Eysuvis ™ and added Auth lengths for the drug groupings.
7/2022	Updated to include Verkazia to the policy.
4/2022	Updated to add Generic Restasis ® and move Restasis ® to a non-preferred status.
2/2022	updated to add Tyrvaya nasal spray™ to the policy.
4/2021	Clarified age for Xiidra ™.
1/2021	Updated to add Eysuvis™ to the policy.
1/2020	Updated criteria for Restasis ® Multidose to not covered.
10/2019	Updated to clarify Cequa ™ coverage
2/2019	Updated to add Cequa ™ to the policy.
6/2017	Updated address for Pharmacy Operations.
11/2016	Updated to add Xiidra ™ to the policy.
7/2014	Updated policy to include prior use of over the counter preparations, requiring a diagnosis of moderate or severe keratoconjunctivitis sicca, and requiring prescription by a board/eligible ophthalmologist or board/eligible optometrist. Also to remove Blue Value from policy.
8/2013	Reviewed and updated drug sample exclusion language.
1/2013	New policy effective 1/1/13.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome –Limited Revision. San Francisco, CA:American Academy of Ophthalmology; 2011.
2. American Academy of Ophthalomology/External Disease Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Franciso, CA; American Academy of Ophthalmology; 2013.
3. Gumas, K. et al, The role of inflammation and anti-inflammation therapies in keratoconjunctivitis sicca. Clinical Ophthalmology 2009:3 57–67
4. Restasis ® [package insert]. Irvine, CA: Allergan, Inc.: 2010.
5. Xiidra ™ [package insert]. Lexington, MA: Shire US, Inc.: 2016.
6. Cequa ™ [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.: Aug 2018.
7. Eysuvis ™ [package insert]. Watertown, MA: Kala Pharmaceuticals, Inc.: Nov 2020.
8. Miebo ® [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.: May 2023.
9. Vevye ® [package insert]. Nashville, TN: Harrow, Inc.: November 2023.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf