University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-46 Ophthalmic Specialty agents

Effective Date: 10/22/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by UM Health Plan and may not be covered by all UM Health Plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact UM Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Tepezza is a specialty drug used to treat Thyroid Eye Disease (TED) and Oxervate is a drug to treat Neurotrophic Keratitis. These criteria were developed and implemented to ensure appropriate use for the intended diagnosis, severity of disease and place in therapy.

3.0 Clinical Determination Guidelines:

I. General Considerations:

A. Appropriate medication use [must meet all listed below]

1. Diagnosis: meets standard diagnostic criteria that designate signs, symptoms, and test results to support specific diagnosis.

2. Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved use: Compendium support (Lexicomp®) for use of a drug for a non-FDA approved indication or dosage regimen.

3. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

B. Dose Rounding: medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturers strength of the requested medication for patients weighing more than 10 kg (see DDP-21 Dose Rounding and Wastage).

C. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

D. Adherence to requested medication required for re-approval [must meet one listed below]:

1. Medications processed on the medical benefit: consistent utilization history documented in claims history or chart notes.

2. Medications processed on the pharmacy benefit: consistent fill history electronically or verbally from pharmacy.

II. Thyroid Eye Disease: Tepezza [must meet all listed below]:

A. Age: at least 18 years.

B. Prescriber: prescribed by or in consultation with a specialist in the treatment of Graves' disease associated with thyroid eye disease (endocrinologist, ophthalmologist).

C. Diagnosis and severity [must meet all listed below]:

1. Active moderate-to severe thyroid eye disease related to Graves' disease (also known as Graves orbitopathy).

2. Clinical Activity Score: at least 4 in the more severely affected eye (see Appendix 1).

3. Treated Thyroid disease: euthyroid OR has mild hypo-or hyperthyroidism.

4. Surgical ophthalmological intervention is NOT required.

D. Other therapies: Trial of the methylprednisolone IV regimen below is required unless contraindicated. Trial must result in an inadequate response after 12 consecutive weeks of use or severe adverse reaction.

1. Methylprednisolone intravenous: 500 mg weekly for six weeks, then 250mg weekly for six weeks.

E. Dosage regimen:

1. Tepezza intravenous (teprotumumab IV): 10 mg per kg initial dose, then three weeks later 20 mg per kg every three weeks for seven doses.

2. Not in combination with other biological immunomodulators (e.g., rituximab and biosimilars, Actemra, Kevzara).

F. Approval:

1. Initial: seven months.

2. Reapproval: not indicated, limited to one course of eight infusions per lifetime.

III. Neurotrophic keratitis: Oxervate [must meet all listed below]

A. Age: at least two years.

B. Prescriber: ophthalmologist, optometrist, corneal specialist, neurologist.

C. Diagnosis and severity [must meet one listed below]:

1. Stage 2 neurotrophic keratitis (refer to Appendix II).

2. Stage 3 neurotrophic keratitis (refer to Appendix II).

D. Other therapies:

1. Stage 2 neurotrophic keratitis: Trial of both products below is required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use or severe adverse reaction.

a. Preservative-free artificial tears/ointments.

b. Antibiotic eye drops.

2. Stage 3 neurotrophic keratitis: Trial of one drug below is required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or severe adverse reaction.

a. N-acetylcysteine

b. Tetracycline

c. Medroxyprogesterone.

E. Dosage and administration.

1. Dosage regimen: instill one drop into affected eye(s) every two hours for six doses daily.

a. Documented patient education regarding administration with contact lenses and other topical ophthalmic products such as eye ointment, gel, or other viscous eye drops.

2. Members must agree to case management by the Health Plan.

F. Approval.

1. Initial: eight weeks.

2. Re-approval: not indicated.

4.0 Coding:

COVERED CODES – MEDICAL BENEFIT				
Code	**Brand Name**	**Generic Name**	**Billing Units (1 unit)**	**Prior Approval**
J3241	Tepezza	Teprotumumab-trbw	10 mg	Y

COVERED PRODUCTS – PHARMACY BENEFIT			
NDC	**Brand Name**	**Generic Name**	**Prior Approval**
All	Oxervate	cenegermin-bkbj	Y

5.0 References, Citations & Resources:

1. Lexi comp, Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Tepezza, Oxervate accessed August 2025.
2. UpToDate Treatment of Grave's orbitopathy (ophthalmopathy) accessed June 2020.
3. Randomized, single blind trial of intravenous versus oral steroid monotherapy in Graves Orbitopathy J. Clin. Endocrininol. Metab. 2005;90:5234.
4. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. Thyroid 2016; 26:1343.
5. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. Eur Thyroid J 2016; 5:9.
6. ATA/ETA, "Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association," December 2022
7. EUGOGO, "The 2021 European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the Medical Management of Graves' Orbitopathy," August 2021
8. Topical Recombinant Human Nerve Growth Factor (Cenegermin) for Neurotrophic Keratopathy. Ophthalmology. 2020; 127(1):14-26.
9. Neurotrophic keratopathy. Prog Retin Eye Resin. 2018; 66:107-131.
10. Neurotrophic Keratitis American Academy of Ophthalmology EyeWiki https://eyewiki.org/Neurotrophic_Keratitis accessed August 2024.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 10/29/2025

Next Review Date: 07/2021

Revision Date	Reason for Revision
8/21	Annual review: clarified criteria instructions, added appropriate use section; updated HCPCS code for drug
10/22	Annual Review; added references
8/23	Annual review: added sections to appropriate use, added 2 references, reformatted; added Oxervate and renamed the policy Ophthalmic Specialty agents

Revision Date	Reason for Revision
8/24	Annual review, Deleted Monitoring and patient safety table; updated and added reference
8/25	Annual review, update references, correct appendix I citation

Appendix I: Thyroid Eye Disease Clinical Activity Score (CAS)

Clinical Activity Score

- Add 1 point for each finding
- Symptoms
  - Pain or pressure in a periorbital or retroorbital distribution
  - Pain with upward, downward, or lateral eye movement
- Signs
  - Swelling of the eyelids
  - Redness of the eyelids
  - Conjunctival injection
  - Chemosis
  - Inflammation of the caruncle or plica
- Changes
  - Increase in measured proptosis $\geq$ 2 mm over 1-3 months
  - Decrease in eye movement limit of $\geq$ 8° over 1-3 months
  - Decrease in visual acuity (2 Snellen chart lines) over 1-3 months

Mourits MP, Koornneef L, Wiersinga WM, Prummel MF, Berghout A, van der Gaag R. Br J Ophthalmol. 1989 Aug;73(8):639-44.

Appendix II: Neurotrophic Keratitis Staging

Stages of Neurotrophic Keratitis	Signs and Symptoms
Stage 1	• Dry and opaque corneal epithelium • Superficial punctuate keratopathy • Corneal edema • Stromal scarring • Corneal neovascularization
Stage 2	• Persistent epithelial defect (PED) • Stromal swelling • Loose corneal epithelium
Stage 3	• Corneal ulcer • Corneal perforation • Stromal lysis/melting