



Drug Coverage Policy

Effective Date7/15/2025

Coverage Policy Number.....IP0644

Policy Title.....Xiidra

Ophthalmology – Dry Eye Disease – Xiidra for Individual and Family Plans

- Xiidra® (lifitegrast ophthalmic solution - Novartis)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Xiidra, a lymphocyte function-associated antigen-1 (LFA-1) antagonist, is indicated for the treatment of the signs and symptoms of **dry eye disease**.¹ The safety and efficacy of Xiidra in pediatric patients have not been established.

Guidelines

The American Academy of Ophthalmology (AAO) Dry Eye Syndrome Preferred Practice Pattern® (2024) notes dry eye syndrome is also known as dry eye disease or keratoconjunctivitis sicca.² Dry eye is generally classified according to both symptoms and signs (i.e., mild, moderate, or severe); however, there is an emphasis on symptoms over signs. Management of dry eye is listed as a four-step staged approach, but specific therapies may be chosen from any step, regardless of the level of disease severity, depending on provider experience and patient preference. Xiidra, as well as other FDA-approved therapies for dry eye disease (cyclosporine ophthalmic products, Miebo™ [perfluorohexyloctane ophthalmic solution], and Tyrvaya® [varenicline nasal spray]), and are noted as Step 2 options in the Preferred Practice Pattern. The AAO notes use of any of these FDA-approved products may lead to improvement of patient symptoms and/or signs but none has been proven more effective than the other in head-to-head trials; there are no direct comparisons in a prospective clinical trial in the literature.

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POLICY STATEMENT

Prior Authorization is required for benefit coverage of Xiidra. All approvals are provided for the duration noted below.

Xiidra is considered medically necessary when the following are met:

FDA-Approved Indication

- 1. Dry Eye Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B)
Note: Examples of dry eye disease include dry eye syndrome and keratoconjunctivitis sicca.
A. Patient is ≥ 18 years of age; AND
B. Preferred product criteria is met for the product as listed in the below table

Individual and Family Plans:

Product	Criteria
Xiidra (lifitegrast ophthalmic solution)	ONE of the following (1 <u>or</u> 2): 1. The patient has tried, and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with cyclosporine ophthalmic 0.05% emulsion; OR 2. The patient is currently receiving therapy with Xiidra.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Xiidra for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concomitant Use with an Ophthalmic Cyclosporine Product or Tyrvaya (varenicline nasal solution).** There are no data to support the concomitant use of Xiidra with an ophthalmic cyclosporine product or Tyrvaya.

Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.

References

1. Xiidra® ophthalmic solution [prescribing information]. East Hanover, NJ: Novartis; June 2020.
2. Amescua G, Ahmad S, Cheung AY, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4);P1-P49.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	New policy	7/15/2024
Annual Revision	No criteria changes.	7/15/2025

The policy effective date is in force until updated or retired.

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