PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

XIIDRA
(lifitegrast)

Status: CVS Caremark Criteria ***Ref # 1505-C***
Type: Initial Prior Authorization with Quantity Limit ***Ref # MMT 2259-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for dry eye disease
  AND
- The patient has experienced an inadequate treatment response to an artificial tears product
  OR
- The patient has experienced an intolerance to an artificial tears product
  OR
- The patient has a contraindication that would prohibit a trial of an artificial tears product

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease.[1]

The Preferred Practice Pattern (PPP) for Dry Eye Syndrome by the American Academy of Ophthalmology classifies dry eye as mild, moderate, and severe based on both symptoms and signs, but with an emphasis on symptoms over signs. The PPP notes that this classification is imprecise because characteristics at each level overlap due to the nature of dry eye disease. Dry eye syndrome is also categorized into one of two forms, aqueous tear deficiency and evaporative dry eye, which coexist in the majority of the patients with the disease. Ocular lubricants, such as artificial tear substitutes, are a Step-1 treatment option for dry eye. Artificial tear substitutes have been found to be a safe and effective treatment for dry eye. Topical lifitegrast is a Step-2 treatment option.[4] Therefore, coverage for Xiidra will be provided for patients with dry eye disease and who have experienced an inadequate treatment response or intolerance to, or who have a contraindication that would prohibit a trial of an artificial tears product.

Dosage for Xiidra is one drop in each eye twice a day, 4 drops per day total. Xiidra is available as single-use container. Each container contains enough solution to deliver one drop in each eye.[1] Therefore, the limit for Xiidra containers will be set at 60 containers per month.

REFERENCES

1. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; June 2020.

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed October 5, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed October 5, 2021.
4. Preferred Practice Pattern. Dry Eye Syndrome. American Academy of Ophthalmology. November 2018.

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for dry eye disease? [If no, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to an artificial tears product? [If yes, then skip to question 5.]	Yes	No
3	Has the patient experienced an intolerance to an artificial tears product? [If yes, then skip to question 5.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of an artificial tears product? [If no, then no further questions.]	Yes	No
5	Does the patient require more than the plan allowance of 4 drops per day of the requested drug? [RPh Note: If yes, then deny and enter a partial approval for 60 containers per 25 days or 180 containers per 75 days of Xiidra.]	Yes	No

Mapping Instructions (1505-C)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have dry eye disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an artificial tears product and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or contraindication to artificial tears]

5.	Deny	Approve, 36 months, 60 containers/25 days* or 180 containers/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 60 containers/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 36 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Mapping Instructions (MMT 2259-C)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have dry eye disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried an artificial tears product and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate treatment response, intolerance or contraindication to artificial tears]
5.	Deny	Approve, 12 months, 60 containers/25 days* or 180 containers/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 60 containers/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*