

PA CHECKLIST

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Help your appropriate patients gain access to Xiidra*
 Use this checklist to help ensure necessary information is documented to facilitate the processing of a PA request

AVOID COMMON ERRORS
 Incomplete or missing information in any of these designated categories may result in a PA denial

DESIRED MEDICATION

Medication name (eg, Xiidra)	Quantity (eg, 60 each per 30 days)
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PATIENT'S CLINICAL RECORDS (including medical history)

Patient-reported dry eye symptoms, such as the following¹:

- Dryness
- Watery eyes
- Itchiness
- Stinging
- Burning
- Irritation
- Grittiness
- Redness
- Blurry vision
- Feeling like something is in the eye

Clinician-observed signs and symptoms, such as the following¹:

- Inflammatory conditions
- Tear production
- Severity of disease

Clinical diagnosis of dry eye disease (DED),[†] such as the following:

- Date of diagnosis
- Valid ICD-10 diagnosis code with the full 7 characters and description
- Diagnostic testing and results, which may include at least 1 of the following¹:

○ External eye examination	○ Corneal and conjunctival staining	○ Matrix metalloproteinase-9 (MMP-9) test	○ Corneal sensitivity
○ Tear film breakup time (TBUT)	○ Blink rate	○ Tear osmolarity	○ Slit-lamp exam
○ Aqueous tear production (Schirmer's test)	○ Validated questionnaire		

Prior treatment history for DED

- Drugs tried and failed (failure may require inadequate response to at least 1 formulary alternative or over-the-counter medication [eg, artificial tears, lubricants, gels, or ointments]), including the following information:

○ Product name	○ Frequency of use	○ Response to treatment
○ Dose	○ Dates of treatment	○ Outcome

Functional impact of DED on work and home life, if any, like the ability to perform daily tasks, such as the following¹:

- Reading
- Using a computer
- Driving at night
- Productivity at work

Attach a copy of your patient's medical records, including chart notes, when required by the plan

CHECK TO ENSURE YOUR SIGNATURE IS INCLUDED (WHEN REQUIRED BY THE PLAN) AND YOUR PATIENT'S INFORMATION IS CORRECT AND COMPLETE BEFORE SUBMITTING THE PA REQUEST

*Not all of these requirements may apply, and there may be other requirements not included in this list.
[†]Some plans may deny coverage for Xiidra if it is prescribed to manage dry eyes during the perioperative period of elective eye surgery (eg, LASIK). Check with your patient's insurance for specific information.

Please Note: Novartis is unable to complete a PA form or coverage determination form, guide you about what to write on these forms, provide PA criteria if it is not publicly available, or talk to you about a patient's personal health information. The information included in this document may be necessary to obtain a PA decision for a medication. It is important to review the insurer's guidelines for obtaining a PA, as these can differ depending on the insurer, the medication being prescribed, and other factors. Guidance included in this document is not inclusive and does not guarantee patient coverage for a product.

Please see Indication and Important Safety Information on reverse side. Please see accompanying Full Prescribing Information.

These diagnosis code examples are provided for general informational purposes only and are not intended to be directive, a guarantee of coverage, or a substitute for an independent clinical decision.

EXAMPLE ICD-10 CODES FOR DRY EYE DIAGNOSIS²

DESCRIPTION	RIGHT	LEFT	BILATERAL	UNSPECIFIED
Dry eye syndrome: tear film insufficiency, NOS (lacrimal gland)	H04.121	H04.122	H04.123	H04.129
Keratoconjunctivitis sicca, not specified as Sjögren's syndrome	H16.221	H16.222	H16.223	H16.229
Punctate keratitis	H16.141	H16.142	H16.143	H16.149
Unspecified keratoconjunctivitis	H16.201	H16.202	H16.203	H16.209
Exposure keratoconjunctivitis	H16.211	H16.212	H16.213	H16.219
Unspecified superficial keratitis	H16.101	H16.102	H16.103	H16.109
Sicca syndrome (Sjögren) with keratoconjunctivitis—M35.01				
Sicca syndrome (Sjögren), unspecified—M35.00				

EXAMPLE ICD-10 CODES FOR DRY EYE SYMPTOMS²

DESCRIPTION	RIGHT	LEFT	BILATERAL	UNSPECIFIED
Visual discomfort	H53.141	H53.142	H53.143	H53.149
Ocular pain	H57.11	H57.12	H57.13	H57.10
Unspecified epiphora	H04.201	H04.202	H04.203	H04.209
Other visual disturbances—H53.8				

INDICATION

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

IMPORTANT SAFETY INFORMATION

Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Please see accompanying Full Prescribing Information.

NOS, not otherwise specified.

Reference: 1. American Academy of Ophthalmology. Dry eye syndrome preferred practice pattern. <https://www.aao.org/Assets/8bb0fe82-84c8-4020-89e6-e123667fb654/636777165099570000/dry-eye-syndrome-preferred-practice-pattern-2018-pdf>. Published September 22, 2018. Accessed April 8, 2020. **2.** Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2020/icd10cm_tabular_2020.pdf. Published 2020. Accessed March 5, 2020.