cyclosporine ophthalmic

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cequa (cyclosporine ophthalmic solution) 0.09%	May be subject to quantity limit
Restasis (cyclosporine ophthalmic emulsion) 0.05%	
cyclosporine ophthalmic emulsion 0.05% (generic Restasis)	
Vevye (cyclosporine ophthalmic solution) 0.1%	

APPROVAL CRITERIA

Requests for Cequa (cyclosporine ophthalmic solution), Restasis (cyclosporine ophthalmic emulsion), cyclosporine ophthalmic emulsion 0.05% (generic Restasis) or Vevye (cyclosporine ophthalmic solution) may be approved if the following criteria are met:

I. Individual is 16 years of age or older for Restasis (cyclosporine ophthalmic emulsion) or cyclosporine ophthalmic emulsion 0.05% (generic Restasis) (multi-dose bottle or single-dose vial) requests;
OR
II. Individual is 18 years of age or older for Cequa (cyclosporine ophthalmic solution) or or Vevye (cyclosporine ophthalmic solution) requests;

AND
III. Individual is using to treat moderate to severe dry eye disease (AAO 2023); **AND**
IV. Individual has had an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO 2018):
   A. Tear break-up time (less than 10 seconds); **OR**
   B. Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes; **OR**
   C. Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes); **OR**
   D. Fluorescein clearance test/tear function index; **OR**
   E. Tear osmolarity (indicating tear film instability); **OR**
   F. Tear lactoferrin concentrations in the lacrimal gland (decreased); **OR**
   G. Matrix metalloproteinase-9 (MMP-9) test;

AND

V. For Cequa (cyclosporine ophthalmic solution), Restasis (cyclosporine ophthalmic emulsion) or Vevye requests, documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two preferred agents [cyclosporine ophthalmic emulsion 0.05% (generic Restasis single-dose vial), Xiidra (lifitegrast ophthalmic solution)];

OR

VI. Individual has a known hypersensitivity to any ingredient in cyclosporine ophthalmic emulsion 0.05% (generic Restasis single-dose vial) or Xiidra which is not also present in the requested non-preferred agent (Cequa, Restasis or Vevye).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. Akpek EK, Wirta DL, Downing JE, et al. Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease: The ESSENCE-2 Randomized Clinical Trial. JAMA Ophthalmol. 2023 May 1;141(5):459-466. doi: 10.1001/jamaophthalmol.2023.0709. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10080403/
5. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2023. Available at: https://www.aao.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2023.
6. Sheppard JD, Kurata F, Epitropoulos AT, Krösser S, Vittitow JL; MOJAVE Study Group. NOV03 for Signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction: The Randomized Phase 3 MOJAVE Study. *Am J Ophthalmol*. 2023;252:265-274. doi:10.1016/j.ajo.2023.03.008
7. Sheppard JD, Wirta DL, McLaurin E, et al. A Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase 2B/3 ESSENCE Study. *Cornea*. 2021;40(10):1290-1297. doi:10.1097/ICO.0000000000002633.
8. Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for Dry Eye Disease Associated with Meibomian Gland Dysfunction: Results of the Randomized Phase 3 GOBI Study. Ophthalmology. 2023 May;130(5):516-524. doi: 10.1016/j.ophtha.2022.12.021.