

difluprednate ophthalmic drops (Durezol)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Durezol (difluprednate) is an ophthalmic steroid eye drop used to treat endogenous anterior uveitis or for inflammation and pain associated with eye surgery. Uveitis is inflammation inside the eye and can be treated with topical steroids. Surgery on the eye can cause pain and inflammation, which can be treated with steroid or non-steroidal anti-inflammatory drug (NSAID) eye drops.

Definitions

"Endogenous anterior uveitis" is inflammation of the middle of the eye not associated with an infection or other external factor. If left untreated, other eye disorders such as glaucoma, cataract or retinal swelling can develop and possibly cause loss of vision.

"Non-steroidal anti-inflammatory drug (NSAID)" is a type of medication that is prescribed to reduce pain and inflammation.

“Steroid” is a class of medications used to reduce inflammation in various conditions, such as uveitis.

Medical Necessity Criteria for Initial Authorization

The Plan considers **difluprednate ophthalmic drops (Durezol)** medically necessary when the following criteria are met:

1. Is being used for the treatment of **ONE** (1) of the following indications:
 - a. endogenous anterior uveitis; **or**
 - b. inflammation and pain following ocular surgery; **AND**
2. The member is unable to use or has tried and failed **ONE** (1) of the following alternatives:
 - a. Dexamethasone Sodium Phosphate 0.1% Ophthalmic Solution; **or**
 - b. FML Forte Liquifilm 0.25% Ophthalmic Suspension; **or**
 - c. Prednisolone Acetate 1% Ophthalmic Suspension.

If the above prior authorization criteria is met, Durezol (difluprednate) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **ALL** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. recent chart documentation (within the last 6 months) shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** of the following:
 - a. clinical improvement (e.g., reduction of ocular inflammation (anterior chamber cell clearing)) in symptoms since starting the requested medication; **or**
 - b. disease stability (e.g., absence of ocular pain) since starting the requested medication
3. The member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

Experimental or Investigational / Not Medically Necessary

Durezol (difluprednate) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Birnbaum AD, Jiang Y, Tessler HH, Goldstein DA. Elevation of intraocular pressure in patients with uveitis treated with topical difluprednate. *Arch Ophthalmol*. 2011;129(5):667-668.
2. Durezol (difluprednate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020.
3. Kessel L, Tendal B, Jørgensen KJ, et al. Post-cataract prevention of inflammation and macular edema by steroid and nonsteroidal anti-inflammatory eye drops: a systematic review. *Ophthalmology*. 2014;121(10):1915.
4. Korenfeld MS, Silverstein SM, Cooke DL, et al, "Difluprednate Ophthalmic Emulsion 0.05% for Postoperative Inflammation and Pain," *J Cataract Refract Surg*, 2009, 35(1):26-34.
5. Rosenbaum JT. Uveitis Treatment. UpToDate.com. Available at: https://www.uptodate.com/contents/uveitis-treatment?search=uveitis&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2. Updated November 27, 2019. Accessed September 15, 2020.
6. Shahab MA, Mir TA, Zafar S. Optimizing drug therapy for non-infectious uveitis. *Int Ophthalmol*. 2018 Jun 30.
7. Sheppard JD, Toyos MM, Kempen JH, Kaur P, Foster CS. Difluprednate 0.05% versus prednisolone acetate 1% for endogenous anterior uveitis: a phase III, multicenter, randomized study. *Invest Ophthalmol Vis Sci*. 2014;55(5):2993-3002.
8. Wilson ME, O'Halloran H, VanderVeen D, et al. Difluprednate versus prednisolone acetate for inflammation following cataract surgery in pediatric patients: a randomized safety and efficacy study. *Eye (Lond)*. 2016;30(9):1187-1194.

Clinical Guideline Revision / History Information

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