New Drug Overview

Byqlovi (clobetasol propionate)
PDL Category: Ophthalmic Anti-Inflammatory

Introduction

Disease Background:

- A cataract is described as an opacity of the eye lens that may result in blurred or altered vision, problems with glare, or in very progressed cases, blindness (*Jacobs 2026*).
  - A substantial reason for blindness globally is due to cataracts (*Jacobs 2026*). Furthermore, progressive and irreversible loss of vision may occur if cataracts are not treated surgically (*Trubnik et al 2026*).
  - In the United States, the prevalence of cataract in older adults aged 65 years or older has increased from approximately 15.7 million cases in 2014 to 19.6 million cases in 2021 (*Jacobs 2026*). In addition, the cataract prevalence is predicted to double from 24.4 million to about 50 million by 2050 (*Trubnik et al 2026*).
    - Furthermore, it is estimated that approximately 95 million people globally have cataract-related visual impairment (*Trubnik et al 2026*).
- While cataracts can be a part of the aging process and happen frequently with increasing age, poor nutrition, metabolic insults, extreme exposure to the sun or other sources of radiation, trauma, and some medications can intensify the development (*Jacobs 2026*).
- The main clinical features include difficulty in seeing, which generally deteriorates over time (*Trubnik et al 2026*) and typically appears as bilateral symptoms (*Jacobs 2026*).
- If symptoms interfere with one's ability to achieve the needs of daily living, then cataract surgery is indicated (*Jacobs 2026*).
  - Corticosteroid or nonsteroidal anti-inflammatory (NSAID) drops are frequently prescribed for after surgery to help reduce postoperative pain, inflammation, and the potential for macular edema (an inflammatory complication that may restrict recovery of vision).
- Byqlovi was FDA approved in 2024.

Pharmacology/Usage

- Byqlovi (clobetasol propionate) is a synthetic corticosteroid that has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.
  - Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is not clear.
  - However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Indications

Table 1. Food and Drug Administration Approved Indications

Indication	Byqlovi (clobetasol propionate)
• For the treatment of post-operative inflammation and pain following ocular surgery.	✔

(Prescribing information: Byqlovi 2025)

- Information on indications, mechanism of action, pharmacokinetics, dosing, safety, and clinical efficacy summary has been obtained from the prescribing information for the individual products, except where noted otherwise.

Dosing and administration

Table 2. Dosing and Administration

Drug	Available Formulations	Route	Usual Recommended Frequency	Comments
Byqlovi (clobetasol)	Ophthalmic Suspension 0.05%: 0.5mg/ml.	OP	Instill 1 drop into affected eye BID beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.	• Wash hands well before each use. • If using other eye drops in addition to Byqlovi, wait at least 5 minutes between instillation of Byqlovi and other eye drops.

See the current prescribing information for full details.

Clinical Efficacy Summary

- The efficacy was assessed in 2 multicenter, randomized, double-masked, vehicle-controlled trials (Study 1 and Study 2) that included adults who had ≥10 cells in the anterior chamber after cataract surgery.
  - Patients were assigned to Byqlovi 0.05% (N=366) or vehicle (N=382). One drop was self-administered BID for 14 days, beginning on the day after surgery.
  - Complete resolution of inflammation (an anterior chamber cell count of 0 maintained through day 15 without rescue medication) and complete resolution of pain (a patient-reported pain grade of 0 maintained through day 15 without rescue medication) were assessed at post-operative day (POD) 4, 8, and 15.
  - The co-primary efficacy endpoints were the proportion of subjects with Anterior Chamber Cell (ACC) count=0 (ACC grade=0) at POD8 maintained through POD15, and the proportion of subjects with Ocular Pain Grade=0 at POD4 maintained through POD15.
    - In the intent-to-treat analysis, both co-primary efficacy endpoints were statistically significantly better in the Byqlovi-treated patients compared to vehicle-treated patients ($p<0.01$).
    - Results are presented below, which was obtained from the prescribing information.
      - The percent of patients with anterior chamber cell count = 0 at POD8 includes 32.6% with Byqlovi vs 10.7% with vehicle in Study 1 and 29.7% with Byqlovi vs 13% vehicle in study 2.
      - The percent of patients with anterior chamber cell count = 0 at POD15 includes 58.6% with Byqlovi vs 15.7% with vehicle in Study 1 and 57.8% with Byqlovi vs 18.9% with vehicle in Study 2.
      - The percent of patients with complete resolution of pain at POD4 was 77.3% with Byqlovi vs 43.7% with vehicle in Study 1 and 85.4% with Byqlovi vs 52.4% with vehicle in Study 2.
      - The percent of patients with complete resolution of pain at POD8 was 82.3% with Byqlovi vs 42.8% with vehicle in Study 1 and 87% with Byqlovi vs 45.5% with vehicle in Study 2.
      - The percent of patients with complete resolution of pain at POD15 was 90.6% with Byqlovi vs 42.1% with vehicle in Study 1 and 86.5% with Byqlovi vs 48.7% with vehicle in Study 2.

Clinical guidelines

- There are currently no published guidelines found addressing the use of Byqlovi.
- **American Academy of Ophthalmology (AAO): Cataract in the Adult eye, Preferred Practice Pattern** (Miller et al 2022)**.**

- Postoperative treatment regimens may be different among practitioners:
  - Topical corticosteroids and NSAIDs may be used for prophylaxis of chronic macular edema (CME) and to control postoperative inflammation.
    - One treatment was not listed as being more effective than another.

Safety summary

- **Contraindications:**
  - In most active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

- **Box Warning:** None.

- **Warnings and precautions:**
  - Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity, and fields of vision.
    - Steroids should be used with caution in the presence of glaucoma. If Byqlovi is used for 10 days or longer, intraocular pressure (IOP) should be monitored.
  - Prolonged use of corticosteroids may result in posterior subcapsular cataract formation.
  - The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.
  - In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining.
  - Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection.
    - If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
  - Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
  - Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion must be considered in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal culture should be taken when appropriate.
  - Do not allow the dropper tip to touch any surface, as this may contaminate the ophthalmic suspension.
  - Byqlovi should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of Byqlovi. The preservative in Byqlovi may be absorbed by soft contact lenses. Lenses may be reinserted after 15 minutes following administration of Byqlovi.

- **Common adverse drug reactions**:
  - Listed % incidence for adverse drug reactions= reported % incidence for drug (Byqlovi). Please note that there was no placebo data in the prescribing information to compare with.
    - The most frequently reported ocular adverse events that occurred in ≥1% of subjects in clinical studies included eye inflammation (2%), corneal edema (2%), anterior chamber inflammation (2%), cystoid macular edema (2%), intraocular pressure elevation (1%), photophobia (1%), and vitreous detachment (1%). Many of these reactions may have been the consequence of the surgical procedure.

- **Drug interactions:** None.

- **Special populations:**
  - There is no pregnancy category for this medication; however, the risk summary indicates that there are no adequate and well-controlled studies of use in pregnant women to inform drug-associated risks. Plasma concentrations of clobetasol propionate were minimal following topical ophthalmic administration of Byqlovi. Byqlovi should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
  - The safety and efficacy of use in the pediatric population have not been established.

Conclusion

- A cataract is described as an opacity of eye lens that may result in blurred or altered vision, problems with glare, or in very progressed cases, blindness (*Jacobs 2026*).
  - If symptoms interfere with one's ability to achieve the needs of daily living, then cataract surgery is indicated.
  - Corticosteroid or nonsteroidal anti-inflammatory drops are frequently prescribed for after surgery to help reduce postoperative pain, inflammation, and the potential for macular edema (an inflammatory complication that may restrict recovery of vision).
- Byqlovi is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.
- Its efficacy was assessed in 2 randomized, double-masked, vehicle-controlled studies that included patients who had ≥10 cells in the anterior chamber after cataract surgery.
  - The co-primary endpoints were the proportion of subjects with ACC count = 0 at POD8 maintained through POD15, and the proportion of subjects with Ocular Pain Grade = 0 at POD4 maintained through POD15.
    - In the intent-to-treat analysis, both co-primary efficacy endpoints were statistically significantly better in the Byqlovi-treated patients compared to vehicle-treated patients ($p<0.01$).
- Guidelines do not currently include Byqlovi but do include discussion on use of topical corticosteroids or NSAIDs for postoperative inflammation after cataract surgery.

- There is no evidence to suggest that Byqlovi is safer or more effective than other currently preferred, more cost-effective medications. It is therefore recommended that Byqlovi remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

- **PDL Placement:**
  - ☐ Preferred
  - ☒ Non-Preferred

References

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- Jacobs DS. Cataract in adults. UpToDate website. Updated January 30, 2026. Accessed June 15, 2026. www.uptodate.com.
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- Trubnik V, Rae-Grant A, Fedorowicz Z. Cataracts in adults. Dynamed website. Last updated May 5, 2026. Accessed June 15, 2026. www.dynamed.com.

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