MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Glaucoma – Ophthalmic Beta-Adrenergic Blockers** **Preferred Step Therapy Policy** • Betagan • Betimol • Betopic • Betopic S • Istalol • Timoptic • Timoptic in Ocudose • Timoptic XE	**Annual Review Date:** **05/22/2025** **Last Revised Date:** **05/22/2025**

OVERVIEW

Glaucoma is an ocular disorder that leads to an optic neuropathy characterized by changes in the optic nerve head (optic disk) that is associated with loss of visual sensitivity and field. The two major types of glaucoma are open-angle and closed-angle. Primary open-angle glaucoma (OAG) is the most common type of glaucoma, affecting up to 3 million individuals in the US. Reduction of intraocular pressure (IOP) is essential. An elevated IOP of > 22 mmHg (ocular hypertension, [OH]) may be treated even in the absence of nerve damage, especially in patients with other risk factors for glaucoma (e.g., severe myopia, Black race, family history of glaucoma). Reduction of IOP prevents progression or even onset of glaucoma. The beta-blocker ophthalmic solutions are indicated in the treatment of elevated IOP in patients with OH or open-angle glaucoma. The expected mechanism of action through which beta-adrenergic products reduce IOP is supposedly through reducing production of aqueous humor in the eye.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of one preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred product at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Preferred products:

- generic betaxolol 0.5% ophthalmic solution
- generic carteolol 1% ophthalmic solution
- generic levobunolol 0.5% ophthalmic solution
- generic timolol maleate 0.25% and 0.5% ophthalmic solution (generic to Timoptic)

Non-preferred products:

- Betagan
- Betimol (brand and generic)
- Betopic
- Betopic S
- Istalol (brand and generic)
- Timoptic
- Timoptic in Ocudose (brand and generic)
- Timoptic XE (brand and generic)

RECOMMENDED AUTHORIZATION CRITERIA

1. If the patient has tried one preferred product, authorization for a non-preferred product may be given.

2. If the patient has a known benzalkonium chloride or benzododecinium bromite sensitivity AND a known sensitivity to other ophthalmic preservatives AND cannot use timolol maleate 0.5% ophthalmic solution (generic to Timoptic in Ocudose), approve Timoptic in Ocudose 0.25%.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred products. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred products. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred products. If so, please list the contraindications to each preferred product [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred product after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred product for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred product for 90 days AND that the patient has been receiving the requested non-preferred product via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to

the requested non-preferred product) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other products, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Fiscella RG, Lesar TS, Edward D. Glaucoma. In: DiPiro JT, Talbert RL, Yee GC, et al., (Eds). *Pharmacotherapy - A Pathophysiologic Approach*. 7th ed. New York, NY: McGraw-Hill. 2008:1551-1564.
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- Betoptic S (betaxolol) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2021.