STEP THERAPY POLICY

POLICY: Ophthalmic – Glaucoma – Beta-Adrenergic Blockers Step Therapy Policy

- Betaxolol 0.5% ophthalmic solution (generic only)
- Betimol® (timolol 0.25% and 0.5% ophthalmic solution [generic for 0.5% strength] – Akorn)
- Carteolol 1% ophthalmic solution (generic only)
- Istalol® (timolol maleate 0.5% ophthalmic solution – Bausch + Lomb, generic)
- Levobunolol 0.5% ophthalmic solution (generic only)
- Timoptic® (timolol maleate 0.25% and 0.5% ophthalmic solution – Bausch + Lomb, generic)
- Timoptic® in Ocudose® (timolol maleate 0.25% and 0.5% ophthalmic solution – Bausch + Lomb, generic)
- Timoptic XE® (timolol maleate 0.25% and 0.5% ophthalmic gel forming solution – Bausch + Lomb, generic)

REVIEW DATE: 10/23/2024; selected revision 01/15/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The beta-adrenergic blocker ophthalmic products are indicated for the treatment of **elevated intraocular pressure (IOP)** in patients with ocular hypertension or open-angle glaucoma.[1-7]

Ophthalmic beta-adrenergic blockers have demonstrated good efficacy and tolerability and are commonly prescribed to treat glaucoma. In general, ophthalmic beta-adrenergic blockers lower IOP by 20% to 25%.[8]

Timoptic in Ocudose is a preservative-free product.[6] All of the other listed ophthalmic beta-blockers are preserved with benzalkonium chloride (BAK), except timolol gel forming solution, which is preserved with benzododecinium bromide.[1-5,7]

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic betaxolol 0.5% ophthalmic solution, generic carteolol 1% ophthalmic solution, generic levobunolol 0.5% ophthalmic solution, generic timolol maleate 0.25% ophthalmic solution (generic to Timoptic), generic timolol maleate 0.5% ophthalmic solution (generic to Timoptic)

Step 2: Betimol, Istalol (brand and generic), Timoptic, Timoptic in Ocudose (brand and generic), Timoptic XE (brand and generic), generic timolol 0.5% ophthalmic solution (generic to Betimol)

Ophthalmic – Glaucoma – Beta-Adrenergic Blockers Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient has a known benzalkonium chloride (BAK) sensitivity, approve Timoptic in Ocudose (brand and generic) or Timoptic XE (brand and generic).

REFERENCES

1. Istalol® ophthalmic solution [prescribing information]. Tampa, FL: Bausch + Lomb; March 2022.
2. Timoptic® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; April 2022.
3. Timoptic XE® ophthalmic gel forming solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; March 2022.
4. Betaxolol 0.5% ophthalmic solution [prescribing information]. Lake Forest, IL: Akorn; June 2016.
5. Carteolol 1% ophthalmic solution [prescribing information]. Fort Worth, TX: Alcon; August 2021.
6. Timoptic® in Ocudose® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; April 2022.
7. Betimol® ophthalmic solution [prescribing information]. Waltham, MA: Thea; May 2023.

8. Prum BE, Rosenberg LF, Gedde SJ, et al. The American Academy of Ophthalmology. Primary Open-Angle Glaucoma Preferred Practice Pattern®. 2021. Available at: https://www.aaojournal.org/article/S0161-6420(20)31024-1/fulltext. Accessed on October 17, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Generic levobunolol 0.25% ophthalmic solution:** This product was removed from Step 1; obsolete product.	10/11/2023
Annual Revision	**Betagan:** This product was removed from Step 2; obsolete product. **Generic metipranolol 0.3% ophthalmic solution:** This product was removed from Step 1; obsolete product. **Generic timolol maleate 0.25% ophthalmic solution (generic to Timoptic in Ocudose):** This product was added to Step 1. **Exception criteria:** The criterion allowing approval of Timoptic Ocudose 0.25% in patients with 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) was removed because the generic product (timolol maleate 0.25% ophthalmic solution) was added to Step 1.	10/23/2024
Selected Revision	**Generic timolol maleate 0.5% ophthalmic solution (generic to Istalol), generic timolol maleate 0.25% ophthalmic gel forming solution (generic to Timoptic XE), generic timolol maleate 0.5% ophthalmic gel forming solution (generic to Timoptic XE), generic timolol maleate 0.25% ophthalmic solution (generic to Timoptic in Ocudose), generic timolol maleate 0.5% ophthalmic solution (generic to Timoptic in Ocudose):** These products were removed from Step 1 and added to Step 2. **Generic timolol maleate ophthalmic solution (generic to Timoptic):** These products remain in Step 1; and are noted as "generic timolol maleate 0.25% ophthalmic solution (generic to Timoptic), generic timolol maleate 0.5% ophthalmic solution (generic to Timoptic)". **Generic timolol maleate 0.5% ophthalmic solution (generic to Betimol):** This agent was added to Step 2. **Exception criterion:** Added exception criterion for Timoptic in Ocudose (brand and generic) and Timoptic XE (brand and generic) for patients with "known benzalkonium chloride (BAK) sensitivity".	01/15/2025