



## 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 – Akorn)
  - Carteolol 1% ophthalmic solution (generic only)
  - Istalol® (timolol maleate 0.5% ophthalmic solution – Bausch + Lomb, generic)
  - Levobunolol 0.5% ophthalmic solution (generic only)
  - Metipranolol 0.3% 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 [0.5% strength is available generically])
  - Timoptic XE® (timolol maleate 0.25% and 0.5% ophthalmic gel forming solution – Bausch + Lomb, generic)

**REVIEW DATE:** 10/11/2023

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### **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. 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.<sup>1-9</sup>

Beta-adrenergic blockers generally lower IOP by 20% to 30%.<sup>10</sup> The beta-adrenergic blockers reduce IOP to a similar degree, although betaxolol lowers IOP to a lesser

extent than the nonselective agents (e.g., timolol maleate, levobunolol, carteolol, metipranolol ophthalmic solutions).

Timoptic in Ocudose is a preservative-free product. 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.<sup>1-9</sup>

## **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.

**Ophthalmic – Glaucoma – Beta-Adrenergic Blockers 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.**

**Step 1:** generic betaxolol 0.5% ophthalmic solution, generic carteolol 1% ophthalmic solution, generic levobunolol 0.5% ophthalmic solution, generic metipranolol 0.3% ophthalmic solution, generic timolol maleate 0.25% ophthalmic gel forming solution, generic timolol maleate 0.5% ophthalmic gel forming solution, generic timolol maleate 0.25% ophthalmic solution, generic timolol maleate 0.5% ophthalmic solution, generic timolol maleate 0.5% ophthalmic solution (generic to Timoptic in Ocudose)

**Step 2:** Betagan, Betimol, Istalol, Timoptic, Timoptic in Ocudose, Timoptic XE

## **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 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%.

## **REFERENCES**

1. Istalol® ophthalmic solution [prescribing information]. Tampa, FL: Bausch + Lomb; March 2022.
2. Betagan® ophthalmic solution [prescribing information]. Madison, NJ: Allergan; September 2021.
3. Timoptic® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; April 2022.
4. Timoptic XE® ophthalmic gel forming solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; March 2022.
5. Betaxolol 0.5% ophthalmic solution [prescribing information]. Lake Forest, IL: Akorn; June 2016.
6. Carteolol 1% ophthalmic solution [prescribing information]. Fort Worth, TX: Alcon; August 2021.
7. Metipranolol ophthalmic solution [prescribing information]. Fort Worth, TX: Falcon; August 2011.

8. Timoptic® in Ocudose® ophthalmic solution [prescribing information]. Bridgewater, NJ: Bausch + Lomb; April 2022.
9. Betimol® ophthalmic solution [prescribing information]. Lake Forest IL: Akorn; July 2018.
10. 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.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/28/2022
Annual Revision	<b>Generic levobunolol 0.25% ophthalmic solution:</b> Removed from Step 1 – obsolete product.	10/11/2023

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