Oscar Clinical Guideline: brimonidine/timolol (Combigan) (PG103, Ver. 6)

# brimonidine/timolol (Combigan)

## 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

Glaucoma is a chronic condition characterized by the damage to the optic nerve, which if left untreated, can lead to vision loss and ultimately, blindness. Often, but not always, this damage is associated with elevated intraocular pressure (IOP). There are several types of glaucoma, the most common being primary open-angle glaucoma. Angle-closure glaucoma and congenital glaucoma are typically managed by surgical intervention, while primary open-angle glaucoma is primarily managed pharmacologically. Ocular hypertension is diagnosed when one has elevated ocular pressure, without visual field loss or damage to the optic nerve. The overarching goal of treatment is to reduce IOP, which is currently the only modifiable risk factor for glaucoma. IOP reduction can be achieved by decreasing the production of aqueous humor or by increasing the outflow of this fluid from the anterior chamber of the eye. Therapeutic approaches include prostaglandins (e.g., latanoprost [Xalatan, Iyuzeh], bimatoprost [Durysta, Lumigan], travoprost [iDose TR, Travatan Z]), beta-blockers (e.g., timolol [Betimol], betaxolol [Betoptic-S]), alpha-adrenergic agonists (e.g., brimonidine [Alphagan P]), or laser therapy.

The American Academy of Ophthalmology recommends considering medication efficacy, side effects, and dosing frequency when selecting a pharmacological treatment, as these factors can significantly influence adherence to, and subsequent effectiveness of, therapy.

Brimonidine and timolol, which are combined in an ophthalmic solution (Combigan), can reduce IOP in those with open-angle glaucoma or ocular hypertension. This medication may be indicated when an individual requires adjunctive or replacement therapy due to inadequate IOP control. Brimonidine is a selective alpha-agonist and timolol is a beta-blocker, with the hypotensive effect of brimonidine being additive to timolol. The brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5% (Combigan) is FDA-approved for the treatment of glaucoma or ocular hypertension for topical ophthalmic use.

## Definitions

"Ocular hypertension" refers to a condition where the pressure inside the eye, known as intraocular pressure (IOP), is consistently higher than normal ranges. It's important to note that ocular hypertension does not necessarily imply damage to the optic nerve, but it is a risk factor for developing glaucoma.

"Open-angle glaucoma" is a form of glaucoma characterized by an anatomically normal angle between the iris and cornea, but a dysfunction in the eye's natural drainage system. This dysfunction leads to the build-up of fluid, increased IOP, and over time, can cause progressive damage to the optic nerve. This condition, also known as primary or chronic glaucoma, typically develops slowly and painlessly and can lead to a gradual loss of vision if not effectively managed.

## Medical Necessity Criteria for Initial Authorization

The Plan considers brimonidine/timolol (Combigan) medically necessary when ALL of the following criteria are met:

1. The member is 2 years of age or older*; AND*
2. The member has a documented diagnosis of open-angle glaucoma or ocular hypertension*; AND*
3. The member is unable to use, or has tried and failed the individual components (brimonidine and timolol) as separate products taken concomitantly*; AND*
4. The member has tried and failed TWO (2) of the following drugs, each from a different class:
    a. Prostaglandins; *and/or*
        i. Bimatoprost; *or*
        ii. Latanaprost; *or*
        iii. Tafluprost; *or*
        iv. Travoprost; *or*
    b. Beta-blockers; *and/or*
        i. Betaxolol Hcl*; or*
        ii. Carteolol Hcl*; or*
        iii. Levobunolol Hcl*; or*
    c. Carbonic anhydrase inhibitors; *and/or*
        i. Brinzolamide*; or*
        ii. Dorzolamide Hcl*; or*
    d. Alpha agonists; *and/or*

i. Apraclonidine Hcl (Iopidine)*; or*

e. Combination therapy; *and/or*

*i.* Brinzolamide/Brimonidine (Simbrinza)*; or*

ii. Dorzolamide Hcl/Timolol maleate (Cosopt)*; AND*

5. Chart documentation is provided for review to validate the above-listed requirements.

If the above prior authorization criteria are met, brimonidine/timolol (Combigan) will be approved for up to 12 months.

## Medical Necessity Criteria for Reauthorization

Reauthorization for up to 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 12 months) shows the member has experienced a therapeutic response to the requested medication as evidenced by ONE (1) of the following:
    a. clinical improvement in symptoms since starting the requested medication; *or*
    b. disease stability since starting the requested medication*; AND*
3. The member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

## Experimental or Investigational / Not Medically Necessary

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

## References


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## Clinical Guideline Revision / History Information

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