Clinical Policy: Brinzolamide/Brimonidine (Simbrinza)

Reference Number: HIM.PA.15
Effective Date: 09.04.18
Last Review Date: 11.20 Revision Log
Line of Business: HIM

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Brinzolamide/brimonidine tartrate ophthalmic suspension 1%/0.2% (Simbrinza®) is a fixed combination of a carbonic anhydrase inhibitor and an alpha$_2$ adrenergic receptor agonist.

FDA Approved Indication(s)

Simbrinza is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Simbrinza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ocular Hypertension or Open-Angle Glaucoma (must meet all)**:**

1. Diagnosis of open-angle glaucoma or ocular hypertension;
2. Failure of a prostaglandin analog (e.g., latanoprost, travoprost, bimatoprost, tafluprost) in combination with a beta blocker (e.g., timolol), unless contraindicated or clinically significant adverse effects are experienced;
3. Age ≥ 2 years;
4. Dose does not exceed 1 bottle per 25 days.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Ocular Hypertension or Open-Angle Glaucoma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 bottle per 25 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
prostaglandin analogs (e.g., latanoprost, travoprost, bimatoprost, tafluprost)	Refer to prescribing information	Refer to prescribing information
timolol 0.25% or 0.5%	Instill 1 drop in the affected eye(s) BID	2 drops/day/eye

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Hypersensitivity to any component of this product
  - Neonates and infants under the age of 2 years
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Open-angle glaucoma or ocular hypertension	Instill 1 drop in the affected eye(s) TID	3 drops/day per affected eye

VI. Product Availability

Ophthalmic drops (8 mL bottle): 1% (10 mg/mL) brinzolamide with 0.2% (2 mg/mL) brimonidine tartrate

VII. References

1. Simbrinza Prescribing Information. Fort Worth, TX: Alcon Laboratories, Inc.; November 2015. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/simbrinza.pdf. Accessed July 7, 2020.
2. National Health Service. Glaucoma and ocular hypertension treatment guidelines (topical products) version 2.0. Oxford University Hospitals 2018. Available at: http://www.oxfordshireccg.nhs.uk/professional-resources/documents/clinical-guidelines/ophthalmology/Glaucoma-and-Ocular-Hypertension-Treatment-Guidelines.pdf. Accessed August 19, 2019.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Primary Open-Angle Glaucoma. San Francisco, CA: American Academy of Ophthalmology; 2015. Available at: www.aao.org/ppp. Accessed August 19, 2019.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 19, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.04.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.19.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.07.20	11.20

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.