Clinical Policy: Brinzolamide/Brimonidine (Simbrinza)
Reference Number: HIM.PA.15
Effective Date: 09.04.18
Last Review Date: 11.20
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 alpha2 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.

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

*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):
  o Hypersensitivity to any component of this product
  o Neonates and infants under the age of 2 years
- Boxed warning(s): none reported*
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open-angle glaucoma or ocular hypertension</td>
<td>Instill 1 drop in the affected eye(s) TID</td>
<td>3 drops/day per affected eye</td>
</tr>
</tbody>
</table>

VI. Product Availability

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

VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>09.04.18</td>
<td>11.18</td>
</tr>
<tr>
<td>4Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>08.19.19</td>
<td>11.19</td>
</tr>
<tr>
<td>4Q 2020 annual review: no significant changes; references reviewed and updated.</td>
<td>07.07.20</td>
<td>11.20</td>
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</tbody>
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
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.

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