

CLINICAL POLICY

Budesonide/Glycopyrrolate/Formoterol Fumarate

Clinical Policy: Budesonide/Glycopyrrolate/Formoterol Fumarate (Breztri Aerosphere)

Reference Number: CP.PMN.254

Effective Date: 12.01.20

Last Review Date: 8.16.22

[Revision Log](#)

Line of Business: Commercial, Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Budesonide/glycopyrrolate/formoterol fumarate (Breztri Aerosphere™) is a combination of an inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA), and long-acting beta₂-adrenergic agonist (LABA).

FDA Approved Indication(s)

Breztri Aerosphere is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Limitation(s) of use: Not indicated for relief of acute bronchospasm or for the treatment of asthma.

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 Breztri Aerosphere is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Obstructive Pulmonary Disease (must meet all):

1. Diagnosis of COPD;
2. Age ≥ 18 years;
3. Failure of one of the following (a or b) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:
 - a. One LABA (e.g., Serevent®) in combination with one LAMA (e.g., Spiriva)
 - b. One ICS in combination with a LABA (e.g., Symbicort, Wixela);
4. Dose does not exceed 4 inhalations per day (one canister per 30 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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (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 4 inhalations per day (one canister per 30 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 12 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): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid, or evidence of coverage documents;
- B. Asthma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

GOLD: Global Initiative for Chronic Obstructive Lung Disease

ICS: inhaled corticosteroid

LABA: long-acting beta₂ adrenergic agonist

LAMA: long-acting anticholinergic

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
Serevent [®] (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Stiverdi [®] Respimat [®] (olodaterol)	2 inhalations (total 5 mcg) QD	5 mcg/day
Tudorza [®] Pressair [®] (aclidinium)	1 inhalation (400 mcg) BID	800 mcg/day
budesonide/formoterol (Symbicort [®])	2 inhalations of 80/4.5 mcg BID	2 inhalations of 80/4.5 mcg BID

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluticasone/salmeterol (Advair® Diskus®)	1 inhalation (250/50 mcg) BID	500/100 mcg/day

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 budesonide, glycopyrrolate, formoterol fumarate, or to any of the excipients.
- Boxed warning(s): none reported.

Appendix D: General Information

- Per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD guidelines, combination therapy (LAMA + LABA, ICS + LABA, or ICS + LAMA + LABA) is recommended for Group D patients (i.e., those who are very symptomatic and are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
 - o For those with more severe symptoms, LAMA + LABA may be used.
- For those with a history of asthma or blood eosinophil counts at least 300 cells/uL, LABA + ICS may be used.

For those who are inadequately controlled by dual therapy, triple therapy with ICS + LAMA + LABA may be used.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	2 inhalations by mouth BID	4 inhalations/day

VI. Product Availability

Inhalation aerosol: Pressurized metered dose inhaler containing a combination of budesonide (160 mcg), glycopyrrolate (9 mcg), and formoterol fumarate (4.8 mcg) per inhalation

VII. References

1. Breztri Aerosphere Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2020. Available at: www.breztri.com. Accessed September 21, 2021.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2021 report). Available at: <http://www.goldcopd.org>. Accessed September 21, 2021. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2021 report). Available from: www.ginasthma.org. Accessed September 21, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PMN.254 Budesonide/Glycopyrrolate/Formoterol Fumarate (Breztri Aerosphere) for HFS PDL.	10.1.20	10.13.20
3Q 2022 Annual Review: updated logo, added Wixela and removed Advair section 1A, reviewed and updated references	8.17.22	

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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.

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.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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