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

Reference Number: IL.ERX.PMN.254
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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 Envolve Pharmacy Solutions 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., budesonide/formoterol [generic Symbicort®]);
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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
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 2020 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:
  - 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 August 14, 2020.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published December 2019. Available at: http://www.goldcopd.org/. Accessed August 14, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.