delaware first health

# Clinical Policy: Budesonide/Formoterol (Symbicort)

Reference Number: DE.PMN.228
Effective Date: 01.23
Last Review Date: 01.23
Line of Business: Medicaid

Revision Log

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

## Description

Budesonide/formoterol (Symbicort®) is a combination product containing a corticosteroid and a long acting beta-2 agonist.

## FDA Approved Indication(s)

Symbicort is indicated for the:

- Once-daily treatment of asthma in patients aged 18 years and older
- Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD)

Limitation(s) of use: Symbicort is not indicated for relief of acute bronchospasm.

## 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 Symbicort is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Asthma** (must meet all)**:**
1. Diagnosis of asthma;
2. Age ≥ 6 years;
3. Dose does not exceed (a or b):
   a. Age 6 to 11 years: 4 inhalations of 80 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 30 days);
   b. Age ≥ 12 years: 4 inhalations of 160 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 30 days).

**Approval duration: 12 months**

**B. Chronic Obstructive Pulmonary Disease** (must meet all)**:**
1. Diagnosis of COPD;
2. Age ≥ 18 years;
3. Dose does not exceed 4 inhalations of 160 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 30 days).

**Approval duration: 12 months**

**C. 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.PMN.53 for Medicaid.

## II. Continued Therapy
**A. All Indications in Section I** (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 (a or b):
   a. Asthma (i or ii):
      i. Age 6 to 11 years: 4 inhalations of 80 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 30 days);
      ii. Age ≥ 12 years: 4 inhalations of 160 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 30 days);
   b. COPD: 4 inhalations of 160 mcg budesonide/4.5 mcg formoterol per day (1 inhaler every 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.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.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information
*Appendix A: Abbreviation/Acronym Key*
COPD: chronic obstructive pulmonary disease
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 |
|---|---|---|
| fluticasone/ salmeterol | Asthma: 1 inhalation BID (starting dosage is based on asthma severity | Asthma: 500/50 mcg BID |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| (Advair Diskus) | COPD: 1 inhalation of 250/50 mcg BID | COPD: 250/50 mcg BID |

*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): primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures, hypersensitivity to any ingredient
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Asthma | Age 6 to 11 years: 2 inhalations of 80/4.5 mcg BID<br>Age ≥ 12 years: 2 inhalations of 80/4.5 or 160/4.5 mcg BID (starting dose is based on asthma severity) | 640/18 mcg/day |
| COPD | 2 inhalations of 80/4.5 or 160/4.5 mcg BID | 640/18 mcg/day |

## VI. Product Availability

Metered dose inhaler with inhalation aerosol containing budesonide/formoterol: 80/4.5 mcg, 160/4.5 mcg

## VII. References

1. Symbicort Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals; July 2019. Available at http://www.mysymbicort.com. Accessed December 10, 2019.
2. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report/. Accessed December 10, 2019.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2019 report). Available from: www.ginasthma.org. Accessed December 10, 2019.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published November 2019. Available at: http://www.goldcopd.org. Accessed December 10, 2019.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 01.23 | 01.23 |

**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.

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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.

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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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