

## Clinical Policy: Inhaled Long-acting Beta<sub>2</sub> Agonists and Combination Products

Reference Number: HIM.PA.74

Effective Date: 12/14

Last Review Date: 08/17

[Revision Log](#)

Line of Business: Health Insurance Marketplace

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

### Description

The following are long-acting beta<sub>2</sub> agonists (LABAs) and combination products requiring prior authorization: arformoterol (Brovana<sup>®</sup>), indacaterol (Arcapta<sup>™</sup> Neohaler<sup>™</sup>), olodaterol (Striverdi<sup>®</sup> Respimat<sup>®</sup>), and umeclidinium/vilanterol (Anoro<sup>®</sup> Ellipta<sup>®</sup>).

### FDA approved indication

The above LABAs and combination products are indicated for the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Limitation of use: The above LABAs and combination products are not indicated to treat asthma or acute deteriorations (e.g., acute bronchospasms) of COPD.

### Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

## I. Initial Approval Criteria

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

1. Diagnosis of chronic obstructive pulmonary disease;
2. Failure of a formulary short-acting bronchodilator (i.e., short-acting anticholinergic: ipratropium, Atrovent; short-acting beta<sub>2</sub> agonist: albuterol, ProAir HFA, Proventil HFA, Ventolin) at up to maximally indicated doses, unless all options are contraindicated or clinically significant adverse effects are experienced;
3. If Brovana is requested, member is unable to use Arcapta Neohaler, Anoro Ellipta, and Striverdi Respimat due to documented mental or physical disability;
4. Request does not exceed:
  - a. Anoro Ellipta: umeclidinium 62.5 mcg/vilanterol 25 mcg/day (1 inhaler/30 days);
  - b. Arcapta Neohaler: 75 mcg/day (1 inhaler/30 days);
  - c. Brovana: 30 mcg/day;
  - d. Striverdi Respimat: 5 mcg/day (1 inhaler/30 days).

**Approval duration: 12 months**

### B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed:
  - a. Anoro Ellipta: umeclidinium 62.5 mcg/vilanterol 25 mcg/day (1 inhaler/30 days);
  - b. Arcapta Neohaler: 75 mcg/day (1 inhaler/30 days);
  - c. Brovana: 30 mcg/day;
  - d. Striverdi Respimat: 5 mcg/day (1 inhaler/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 HIM.PHAR.21 if requested indication is NOT 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 - HIM.PHAR.21 or evidence of coverage documents

**IV. Appendices/General Information**

*Appendix A: Abbreviation Key*

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

LABA: long-acting beta<sub>2</sub> adrenergic agonist

**V. References**

1. Anoro Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2016. Available at: [www.anoro.com](http://www.anoro.com). Accessed December 8, 2016.
2. Arcapta Neohaler Prescribing Information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; March 2017. Available at <https://www.arcapta.com/>. Accessed February 26, 2018.
3. Brovana Prescribing Information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; February 2014. Available at <http://www.brovana.com>. Accessed December 9, 2016.
4. Striverdi Respimat Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016. Available at: [www.striverdi.com](http://www.striverdi.com). Accessed December 9, 2016.
5. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of COPD, 2017 report. Available from: [www.goldcopd.org](http://www.goldcopd.org). Accessed April 12, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
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### Inhaled Long-acting Beta<sub>2</sub> Agonists and Combination Products

Reviews, Revisions, and Approvals	Date	Approval Date
Reformatted guideline to new format. Added Workflow reference document.	12/15	12/15
Removed Foradil from policy as it has been discontinued by the manufacturer and is no longer available on market. Removed criteria for exercise-induced bronchospasm as Foradil was the only drug covered by this policy indicated for that use. Updated references. Removed workflow document. Removed sections: <b>A.</b> Serevent will be used together with and inhaled corticosteroid <b>OR</b> <b>B.</b> Advair will be used alone	09/16	11/16
Removed Advair Diskus, Advair HFA, and Symbicort from policy as they no longer require PA, and deleted asthma criteria set as none of the agents covered by this policy are indicated for asthma. Added Anoro Ellipta and Striverdi Respimat to policy as they require PA. Updated references.  Clinical changes made to criteria: - Added trial duration of 4 weeks per GOLD guidelines. - Added maximum dose (and quantity limit when applicable) for all agents. - Added requirement for positive response to therapy on re-auth.	12/16	02/17
Removed trial duration per GOLD guideline 2017 update which recommends follow-up within 1-4 weeks (vs 4-6 weeks in the 2016 guidelines)	04/17	08/17

#### **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,

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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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