MEDICAL MUTUAL®

Drug Policy

Policy:	**Long-Acting Beta-Agonists (LABAs) for Chronic Obstructive Pulmonary Disease (COPD)**	**Annual Review Date: 10/17/2024**
Impacted Drugs:	• Generic formoterol fumarate	**Last Revised Date: 10/17/2024**

OVERVIEW

Inhaled long-acting beta$_2$-agonists (LABAs) are indicated for the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. They are not indicated to treat asthma or acute deteriorations of COPD. Both formoterol and arformoterol are administered by nebulization and are dosed every 12 hours.

POLICY STATEMENT

A step therapy program has been developed to encourage use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one preferred drug within the 130-day look-back period are excluded from step therapy.

Preferred Medications (Step 1)

- Generic arformoterol tartrate

Non-Preferred Medications (Step 2)

- Generic formoterol fumarate

PREFERRED STEP THERAPY CRITERIA

- Approve generic formoterol fumarate if the patient has tried generic arformoterol tartrate.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

Preferred Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics*; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent*; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following (1 or 2):
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

***Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as *. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Brovana® inhalation solution [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2019.
2. Gross NJ, Nelson HS, Lapidus RJ, et al. Efficacy and safety of formoterol fumarate delivered by nebulization to COPD patients. *Respir Med.* 2008;102:189-197.

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3. Hanrahan JP, Hanania NA, Calhoun WJ, et al. Effect of nebulized arformoterol on airway function in COPD: results from two randomized trials. *COPD.* 2008;5:25-34.
4. Baumgartner RA, Hanania NA, Calhoun WJ, Sahn SA, et al. Nebulized arformoterol in patients with COPD: A 12–week multicenter, randomized, double-blind, double-dummy, placebo- and active-controlled trial. *Clin Ther*. 2007;29(2):261-278.
5. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease © 2019 Global Initiative for Chronic Obstructive Lung Disease, Inc. Available at: http://www.goldcopd.org. Accessed on 8 October 2020.