MEDICAL MUTUAL®

Drug Policy

Policy:	**Inhaled Corticosteroid (ICS)/Long-Acting Beta2 Agonist (LABA) Combination Preferred Step Therapy Policy**	**Annual Review Date:** **11/21/2024** **Last Revised Date:** **11/21/2024**
Impacted Drugs:	**Advair Diskus** **AirDuo Digihaler** **Symbicort**	

OVERVIEW

The corticosteroid/long-acting beta$_2$-agonist (LABA) combination inhalers are indicated for the treatment of asthma. Age indications vary by agent. Fluticasone propionate and salmeterol inhalation powder (Advair Diskus, generics [including Wixela Inhub]), Breo Ellipta, and Symbicort, generics [including Breyna] are also indicated for the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive lung disease (COPD), including chronic bronchitis and/or emphysema.[1,3,5] Advair HFA and Dulera are not FDA-approved for the treatment of COPD; however, both products have been studied for this use.[2,4,7-9] The AirDuo products also have not specifically been studied in patients with COPD. However, these agents were filed as a New Drug Application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.[6] This approval pathway relies in part upon evidence not developed by the applicant. In the case of these agents, the literature and safety and effectiveness evidence supporting the approval and use of Advair Diskus (indicated in patients with COPD) are considered part of the evidence supporting the approval and use of the AirDuo products.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the 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: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: fluticasone/salmeterol inhalation powder (generic to Advair Diskus [including Wixela Inhub®]), Advair HFA, Breo Ellipta, Dulera, budesonide/formoterol inhalation aerosol (generic to Symbicort [including Breyna™])

Step 2: Advair Diskus**,** AirDuo Digihaler, Symbicort

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 2 years

Step Therapy Exception Criteria
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 diagnosis and/or patient characteristics* ; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the 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. 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. Advair Diskus® inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair® HFA inhalation aerosol [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
3. Symbicort® inhalation aerosol [prescribing information]. Wilmington, DE: AstraZeneca; December 2017.
4. Dulera® inhalation aerosol [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
5. Breo® Ellipta® inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
6. AirDuo® RespiClick®/AirDuo® Digihaler™ inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; July 2021.
7. Tashkin DP, Doherty DE, Kerwin E, et al. Efficacy and safety characteristics of mometasone furoate/formoterol fumarate fixed-dose combination in subjects with moderate to very severe COPD: findings from pooled analysis of two randomized, 52-week placebo-controlled trials. *Int J Chron Obstruct Pulmon Dis.* 2012;7:73-86.
8. Koser A, Westerman J, Sharma S, et al. Safety and efficacy of fluticasone propionate/salmeterol hydrofluoroalkane 134a metered-dose-inhaler compared with fluticasone propionate/salmeterol diskus in patients with chronic obstructive pulmonary disease. *Open Respir Med J.* 2010;4:86-91.
9. Doherty DE, Tashkin DP, Kerwin E, et al. Effects of mometasone furoate/formoterol fumarate fixed-dose combination formulation on chronic obstructive pulmonary disease (COPD): results from a 52-week Phase III trial in subjects with moderate-to-very severe COPD. *Int J Chron Obstruct Pulmon Dis.* 2012;7:57-71.