Pharmacy Medical Necessity Guidelines: Respiratory Inhalers

Effective: December 9, 2025

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

- **ProAir Digihaler (albuterol)** is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease. It is also approved for the prevention of exercise-induced bronchospasm in patients 4 years of age and older. ProAir Digihaler contains a built-in electronic module that detects, records, and stores data on inhaler events for transmission to the mobile application. Use of the mobile application is not required for administration of medication to the patient.
- **ProAir RespiClick (albuterol)** is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.
- **Advair HFA (fluticasone propionate/salmeterol)** is indicated for treatment of asthma in patients aged 12 years and older.
- **Anoro Ellipta (umeclidinium/vilanterol)** is indicated for the maintenance treatment of airflow obstruction in patients with COPD, including bronchitis and emphysema.
- **Breo Ellipta (fluticasone furoate/vilanterol)** is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD. It is also indicated for once-daily treatment of asthma in patients aged 5 years and older.
- **Dulera (mometasone furoate/formoterol fumarate)** is indicated for the treatment of asthma in patients 5 years and older.
- **Symbicort (budesonide/formoterol)** is indicated for the treatment of asthma in patients 6 years and older. Symbicort (budesonide 160 mcg/formoterol 4.5 mcg) is also indicated for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including bronchitis and emphysema.

Generic Ventolin HFA, generic Proventil HFA, generic Proair HFA, and levalbuterol HFA are our preferred short-acting beta-agonist inhalers. Generic fluticasone propionate/salmeterol (generic AirDuo, generic Advair Diskus) is our preferred long-acting beta-agonist/inhaled corticosteroid combination inhaler and is available without prior authorization.

- Fluticasone propionate/salmeterol (generic AirDuo) is indicated for the treatment asthma in patients 12 years of age and older.
- Fluticasone propionate/salmeterol (generic Advair Diskus) is indicated for the treatment of asthma in patients 4 years of age and older, as well as for maintenance of treatment in patients with COPD.
- Albuterol HFA is indicated for the treatment and prevention of bronchospasm in patients 4 year and older with reversible obstructive airway disease; and for the prevention of exercise-induced bronchospasm.

Incruse Ellipta and Spiriva Respimat 1.25 mcg are our preferred long-acting muscarinic antagonist inhalers.

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred respiratory inhaler for Members when the following criteria for a particular regimen are met and limitations do not apply:

ProAir Respiclick, ProAir Digihaler

1. The Member had an inadequate response or adverse reaction to, or the provider indicates clinical inappropriateness of therapy with, generic albuterol HFA inhaler

AND

2. **For ProAir Digihaler only:** the provider submits a clinical rationale why the member requires digital monitoring of short-acting beta-agonist use as well as a treatment plan indicating how the data from ProAir DigiHaler will be used to improve patient care

Advair HFA (fluticasone propionate/salmeterol)

Asthma:

1. The Member is diagnosed with asthma

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, or the provider indicates clinical inappropriateness of therapy with generic fluticasone/salmeterol (AirDuo, Advair Diskus) and either Dulera or budesonide/formoterol inhaler

COPD:

1. The Member is diagnosed with COPD

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, budesonide/formoterol inhaler and generic fluticasone/salmeterol (Advair Diskus)

Breo Ellipta (fluticasone furoate/vilanterol)

Asthma:

1. The Member is diagnosed with asthma

AND

2. The Member meets ONE of the following:
    a. The Member is less than 6 years of age AND had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, generic fluticasone/salmeterol (AirDuo, Advair Diskus) and Dulera

    OR

    b. The Member is 6 years of age or older AND had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, generic fluticasone/salmeterol (AirDuo, Advair Diskus) and either Dulera or budesonide/formoterol inhaler

COPD:

1. The Member is diagnosed with COPD

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, budesonide/formoterol inhaler and generic fluticasone/salmeterol (Advair Diskus)

Anoro Ellipta (umeclidinium/vilanterol)

1. The Member is diagnosed with COPD

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, either a long-acting anticholinergic (for example, Incruse Ellipta) or a long-acting beta-agonist (for example, Striverdi Respimat)

Dulera (mometasone/formoterol furoate)

1. The Member is diagnosed with asthma

AND

2. The Member meets ONE of the following:
    a. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, generic fluticasone/salmeterol (AirDuo, Advair Diskus)

    OR

    b. The Member is using Dulera as needed for asthma exacerbations **AND** the Member had an inadequate response, adverse reaction or contraindication to generic budesonide/formoterol or the provider indicates clinical inappropriateness of therapy with budesonide/formoterol

Budesonide/formoterol fumarate (generic Symbicort)

Asthma:

1. The member is diagnosed with asthma

AND

2. The Member meets ONE of the following:
   a. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of treatment of therapy with, generic fluticasone/salmeterol (AirDuo, Advair Diskus)

OR

   b. The Member is using budesonide/formoterol as needed for asthma exacerbations

COPD:

1. The member is diagnosed with COPD

AND

2. The Member had an inadequate response, adverse reaction, or contraindication to, or the provider indicates clinical inappropriateness of therapy with, generic fluticasone/salmeterol (Advair Diskus)

LIMITATIONS

1. Budesonide/formoterol 80/4.5 is available without restriction for Members with asthma are ages 6 through 11 years.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria

CODES

None

REFERENCES

1. Advair Diskus (fluticasone propionate/salmeterol) [prescribing information]. Durham, NC: GlaxoSmithKline; June 2023.
2. Advair HFA (fluticasone propionate/salmeterol) [prescribing information]. Durham, NC: GlaxoSmithKline; July 2023.
3. AirDuo Respiclick (fluticasone/salmeterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals, LLC; September 2022.
4. Anoro Ellipta (umeclidinium/vilanterol) [prescribing information]. Durham; GlaxoSmithKline; June 2023.
5. Breo Ellipta (fluticasone/vilanterol) [prescribing information]. Durham, NC: GlaxoSmithKline; May 2023.
6. Dulera (mometasone furoate/formoterol fumarate) [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.
7. Global Initiative for Asthma. Global strategy for asthma management and prevention, updated 2020. https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf. Accessed 23 October 2023.
8. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2022 report. Available at: https://goldcopd.org/2023-gold-report-2/. Accessed 23 October 2023.
9. ProAir Digihaler (albuterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals LLC; September 2020.
10. ProAir RespiClick (albuterol) [prescribing information]. Parsippany, PA; Teva Respiratory, LLC; September 2020.
11. Symbicort (budesonide/formoterol fumarate) [prescribing information]. Wilmington, DE: AstraZeneca LP; July 2019.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Effective February 1, 2024, updated previous trial language throughout MNG. Updated asthma criteria for Breo Ellipta to require trial and failure with generic Advair Diskus and Dulera for members less than 6 years of age to account for Breo Ellipta's updated age indication. Updated Pharmacy UM fax number.
2. November 12, 2024: No changes
3. December 9, 2025: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.