

Pharmacy Medical Necessity Guidelines: Respiratory Inhalers

Effective: April 20, 2020

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: Commercial Products <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization Tufts Health Public Plans Products <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		Fax Numbers: RXUM: 617.673.0988	

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 12 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 12 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 18 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 tried and failed therapy with, 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) or Breo Ellipta (fluticasone furoate/salmeterol)

For the diagnosis of asthma,

1. The Member is diagnosed with asthma
- AND**
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with generic fluticasone/salmeterol (AirDuo, Advair Diskus) and either Dulera or budesonide/formoterol inhaler

For the diagnosis of COPD,

1. The Member is diagnosed with COPD
- AND**
2. The Member tried and failed therapy with budesonide/formoterol inhaler and generic fluticasone/salmeterol (Advair Diskus), 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 has tried and failed 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 has tried and failed or the provider indicates clinical inappropriateness of therapy with generic fluticasone/salmeterol (AirDuo, Advair Diskus)

Budesonide/formoterol fumarate (generic Symbicort)

For the diagnosis of asthma,

1. The member is diagnosed with asthma
- AND**
2. The Member tried and failed therapy with generic fluticasone/salmeterol (AirDuo, Advair Diskus)

For the diagnosis of COPD,

1. The member is diagnosed with COPD

AND

2. The Member has tried and failed therapy with 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]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair HFA® (fluticasone propionate/salmeterol) [prescribing information.] Research Triangle Park, NC: GlaxoSmithKline; February 2019.
3. Dulera (mometasone furoate/formoterol fumarate) [prescribing information]. Whitehouse Station, NJ: Merck and Co Inc; August 2019.
4. Symbicort (budesonide/formoterol fumarate) [prescribing information]. Wilmington, DE: AstraZeneca LP; July 2019.
5. Anoro Ellipta (umeclidinium/vilanterol) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline; July 2019.
6. Breo Ellipta (fluticasone/vilanterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
7. ProAir Digihaler (albuterol) [prescribing information]. Frazer, PA: Teva Pharmaceuticals LLC; December 2018.
8. ProAir RespiClick (albuterol) [prescribing information]. Horsham, PA; Teva Respiratory, LLC; April 2018.
9. AirDuo Respiclick (fluticasone/salmeterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals, LLC; February 2020.
10. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2020 report. Available at: https://goldcopd.org/wp-content/uploads/2019/12/GOLD-2020-FINAL-ver1.2-03Dec19_WMV.pdf. Accessed March 31, 2020.

APPROVAL HISTORY

January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 10, 2015: Added Anoro Ellipta and Breo Ellipta.
2. August 11, 2015: Modified to include ProAir RespiClick; approval duration modified to life of plan.
3. December 8, 2015: Modified to accommodate the diagnosis of asthma for Breo Ellipta.
4. January 1, 2016: Administrative change to rebranded template.
5. November 15, 2016: Reflected generic availability of levalbuterol inhaler. Added "requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria" to the limitations section.
6. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
7. October 18, 2017: Effective 1/1/2018, added approval criteria for Symbicort and Dulera. Updated criteria for Advair and Breo Ellipta. Added generic fluticasone/salmeterol as a preferred respiratory inhaler.
8. December 12, 2017: Effective 12/18/17, updated Advair and Breo Ellipta criteria to allow trial and failure with generic fluticasone/salmeterol for the treatment of COPD. Effective 4/1/18, updated Anoro Ellipta criteria to require a trial and failure with Spiriva Respimat or a long-acting beta-agonist (LABA).
9. May 8, 2018: May 8, 2018: Effective 5/30/18, Symbicort 80/4.5 will be available without restriction for members who are 6 through 11 years of age.
10. December 11, 2018: Effective 12/17/18, updated criteria for Anoro Ellipta to require trial and failure with either a long-acting anticholinergic or a long-acting beta-agonist. Administrative changes made to template.
11. August 13, 2019: Updated MNG to indicate that generic Advair Diskus is covered. Updated criteria for Advair HFA, Breo Ellipta, Dulera, and Symbicort to include generic Advair Diskus as an example

of a preferred generic fluticasone/salmeterol formulation. Updated the MNG to reflect that generic Ventolin HFA and generic Proair HFA are preferred.

12. October 15, 2019: Effective 1/1/2020, updated COPD criteria for Advair HFA to remove AirDuo as a trial option and require trial and failure with both Symbicort and generic fluticasone/salmeterol (Advair Diskus). Updated COPD criteria for Symbicort to require trial and failure with generic fluticasone/salmeterol (Advair Diskus). Specified that Proair criteria applies to Proair Respiclick.
13. November 12, 2019: Added criteria for Proair Digihaler to the MNG.
14. April 14, 2020: Effective 4/20/20, removed generic Proventil HFA and levalbuterol HFA from the MNG, as they are now covered. Updated the MNG to reflect that Symbicort is available generically.

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.

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