Pharmacy Medical Necessity Guidelines: Fluticasone propionate HFA Step Therapy Program

Effective: October 1, 2026

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Fluticasone propionate HFA inhalation is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older.

According to the 2023 Global Initiative for Asthma Guidelines, the preferred delivery system of inhalations for children aged 5 years and younger is a pressurized metered-dose inhaler with a valved spacer (with or without a face mask, depending on the child's age). Children 6 years and older may also use other inhalation formulations, including the dry powder inhalations.

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Please refer to the table below for Fluticasone propionate HFA inhalation subject to this policy:

Drug	Coverage
Step-1	
Arnuity Ellipta	Covered
Qvar RediHaler	
Step-2	
Fluticasone propionate HFA inhalation	Covered for pediatrics up to 6 years of age Requires a trial with two (2) Step-1 medications for members 7 years and older

The following stepped approach applies to coverage of **Fluticasone propionate HFA inhalation** by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover Step-2 medications if the following criteria are met:

a) The patient has had a trial of two (2) Step-1 drugs within the previous 999 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

Step 2: The plan may cover **Fluticasone propionate HFA inhalation** on Step-2 if the following criteria are met:

1. The patient has had a trial of at least two (2) Step-1 medications as evidenced by physician's documented use, excluding the use of samples

OR

2. The patient has contraindication or intolerance to two (2) Step-1 medications (i.e., inability to use the preferred inhalation devices)

Limitations

1. Exception requests for approval of fluticasone propionate HFA inhalation will be limited to a period of 12 months.
2. Fluticasone propionate HFA inhalation is covered for members up through age 6. Once the member turns 7, step therapy will apply.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
4. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

References

1. Arnuity Ellipta (fluticasone furoate powder) [prescribing information]. Durham, NC: GlaxoSmithKline; October 2023.
2. Fluticasone propionate HFA [prescribing information]. Mason, OH: Prasco Laboratories, November 2021.
3. Global Initiative for Asthma. Global strategy for asthma management and prevention, updated July 2023. https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf
4. Pulmicort Flexhaler (budesonide aerosol, powder) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, October 2019.
5. QVAR REDIHALER (beclomethasone dipropionate HFA) [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC., September 2022.

Approval And Revision History

October 2023 P&T E-Vote: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 9, 2025: Effective 1/1/26, updated step therapy program to remove Pulmicort Flexhaler from step 1 drug.
- September 15, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.