



**Inhaled Respiratory Agents  
Effective 01/01/2022**

|                              |   |                     |  |
|------------------------------|---|---------------------|--|
| <b>Plan</b>                  | <input type="checkbox"/> MassHealth<br><input checked="" type="checkbox"/> MassHealth (PUF)<br><input type="checkbox"/> Commercial/Exchange | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization<br><input checked="" type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit (NLX)                                      |                     |  |
| <b>Specialty Limitations</b> | N/A   |                     |  |
| <b>Contact Information</b>   | <b>Specialty Medications</b>  |                     |  |
|                              | All Plans   | Phone: 866-814-5506 | Fax: 866-249-6155  |
|                              | <b>Non-Specialty Medications</b>  |                     |  |
|                              | MassHealth  | Phone: 877-433-7643 | Fax: 866-255-7569  |
|                              | Commercial  | Phone: 800-294-5979 | Fax: 888-836-0730  |
|                              | Exchange  | Phone: 855-582-2022 | Fax: 855-245-2134  |
|                              | <b>Medical Specialty Medications (NLX)</b>  |                     |  |
|                              | All Plans   | Phone: 844-345-2803 | Fax: 844-851-0882  |
| <b>Exceptions</b>            | N/A   |                     |  |

**Overview**

Inhaled respiratory agents are used for disease states such as chronic obstructive pulmonary disease and asthma. These categories of medications include anticholinergics, inhaled corticosteroids, short acting beta agonists, and combination inhaled corticosteroid with a long acting beta agonist.

| No PA   | PA Required   |
|---|---|
| <b>Anticholinergics</b>   |   |
| Atrovent HFA <sup>®</sup> (ipratropium inhalation aerosol)<br>Incruse <sup>®</sup> (umeclidinium)<br>ipratropium inhalation solution<br>Seebri <sup>®</sup> (glycopyrrolate inhalation powder)<br>Spiriva HandiHaler <sup>®</sup> (tiotropium inhalation powder)<br>Spiriva Respimat <sup>®</sup> (tiotropium inhalation solution)<br>Tudorza <sup>®</sup> (aclidinium) | Lonhala <sup>®</sup> (glycopyrrolate inhalation solution)<br>Yupelri <sup>®</sup> (revefenacin) |

| No PA  | PA Required  |
|--|--|
| <b>Inhaled Corticosteroids</b>   |  |
| Asmanex HFA <sup>®</sup> (mometasone inhalation aerosol)<br>Asmanex Twisthaler <sup>®</sup> (mometasone 110 mcg inhalation powder) <12 years of age<br>Asmanex Twisthaler <sup>®</sup> (mometasone 220 mcg inhalation powder) ≥12 years of age<br>Flovent <sup>®</sup> (fluticasone propionate inhalation aerosol, powder)<br>Pulmicort <sup>®</sup> # (budesonide inhalation powder) <13 years of age | Alvesco <sup>®</sup> (ciclesonide inhaler)<br>Armonair Digihaler <sup>®</sup> (fluticasone propionate inhalation powder)<br>Arnuity <sup>®</sup> (fluticasone furoate inhalation powder)<br>Asmanex Twisthaler <sup>®</sup> (mometasone 110 mcg inhalation powder) ≥12 years of age<br>Asmanex Twisthaler <sup>®</sup> (mometasone 220 mcg inhalation powder) <12 years of age<br>Pulmicort <sup>®</sup> (budesonide inhalation suspension) * ≥13 years of age<br>Qvar RediHaler <sup>®</sup> (beclomethasone inhaler) |
| <b>Short-Acting Beta Agonists</b>  |  |
| albuterol inhalation solution<br>ProAir HFA <sup>®</sup> (albuterol inhaler) §<br>ProAir RespiClick <sup>®</sup> (albuterol inhalation powder)<br>Xopenex HFA <sup>®</sup> (levalbuterol inhaler) ‡§   | Ventolin <sup>®</sup> (albuterol inhaler) †<br>ProAir <sup>®</sup> Digihaler (albuterol inhalation powder)<br>ProAir <sup>®</sup> Respiclick (albuterol inhalation powder)<br>Proventil <sup>®</sup> (albuterol inhaler) *<br>Xopenex <sup>®</sup> (levalbuterol inhalation solution)*   |
| <b>Combination Inhaled Corticosteroids/Long-Acting Beta Agonists</b>   |  |
| Advair <sup>®</sup> Diskus (fluticasone/salmeterol inhalation powder) #§<br>Advair <sup>®</sup> HFA (fluticasone/salmeterol inhalation aerosol)<br>Dulera <sup>®</sup> (mometasone/formoterol)<br>Symbicort <sup>®</sup> (budesonide/formoterol) ‡§  | Airduo RespiClick <sup>®</sup> (fluticasone/salmeterol inhalation powder) †<br>Breo <sup>®</sup> (fluticasone/vilanterol)<br>Airduo Digihaler <sup>®</sup> (fluticasone/salmeterol inhalation powder)  |

# This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

\* A-rated generic available, both brand and A-rated generic require PA.

† Authorized generic available, both brand and authorized generic require PA.

‡ Authorized generic available.

§ Brand Preferred over generic equivalents. A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

## Coverage Guidelines

Authorization requests will be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

**ProAir<sup>®</sup> Digihaler** (albuterol inhalation powder)

**ProAir<sup>®</sup> Respiclick** (albuterol inhalation powder)

**Proventil<sup>®</sup>** (albuterol inhaler) \*

**Ventolin<sup>®</sup>** (albuterol inhaler) †

Prescriber provides documentation of **ALL** of the following:



1. Member has a diagnosis of Asthma, chronic obstructive pulmonary disorder (COPD), or exercise-induced bronchospasm
2. Physician documentation of inadequate response, adverse reaction, or contraindication to albuterol inhaler (ProAir HFA<sup>®</sup>)
3. If the request is for BRAND NAME Proventil<sup>®</sup>, member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to the generic albuterol inhaler (Proventil<sup>®</sup>) (as per the Brand Name guideline)
4. If the request is for BRAND NAME Ventolin<sup>®</sup>, member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic

\*A-rated generic available, both brand and A-rated generic require PA

†Authorized generic available, both brand and authorized generic require PA

#### **Xopenex<sup>®</sup>** (levalbuterol inhalation solution)\*

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of asthma, COPD or EIB
2. **ONE** of the following:
  - a. Member is < 13 years of age
  - b. Clinical rationale for nebulized formulation (*See Appendix I: Medical Necessity for Nebulized Formulations*)
3. Physician documentation of inadequate response, adverse reaction, or contraindication to inhaled albuterol solution
4. If the request for BRAND NAME Xopenex<sup>®</sup> solution, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic levalbuterol solution (as per Generic over Brand criteria)

\*A-rated generic available, both brand and A-rated generic require PA

#### **Airduo Digihaler<sup>®</sup>** (fluticasone/salmeterol inhalation powder)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Physician documentation of inadequate response, adverse reaction, or contraindication to Advair<sup>®</sup> (fluticasone/salmeterol inhalation aerosol, powder)
3. Physician documentation of inadequate response, adverse reaction, or contraindication to Airduo<sup>®</sup> RespiClick (fluticasone/salmeterol inhalation powder)
4. Quantity limit of one inhaler per month

#### **Airduo RespiClick<sup>®</sup>** (fluticasone/salmeterol inhalation powder) †

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of asthma
2. Member meets **ONE** of the following:
  - a. Provider documented inadequate response or adverse reaction to Advair<sup>®</sup> (fluticasone/salmeterol inhalation aerosol, powder)
  - b. Clinical rationale for necessity of lower dose of fluticasone/salmeterol
  - c. Member is already receiving another RespiClick formulation
3. Quantity limit of one inhaler per month
4. If the request is for BRAND NAME AirDuo RespiClick<sup>®</sup>, member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic



**Breo<sup>®</sup>** (fluticasone/vilanterol) for COPD

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of chronic obstructive pulmonary disorder (COPD)
2. Member  $\geq 18$  years of age
3. Paid claims or prescriber documented inadequate response, adverse reaction, or contraindication to budesonide/formoterol
4. Quantity limit of one inhaler per month

**Breo<sup>®</sup>** (fluticasone/vilanterol) for Asthma

1. Member has a diagnosis of asthma
2. Member  $\geq 18$  years of age
3. Member meets **ONE** of the following:
  - a. Paid claims or prescriber attestation inadequate response, adverse reaction, or contraindication to Advair (fluticasone/salmeterol inhalation aerosol, powder) or budesonide/formoterol
  - b. Contraindication to both Advair<sup>®</sup> (fluticasone/salmeterol inhalation aerosol, powder) and budesonide/formoterol
4. Quantity limit of one inhaler per month

**Lonhala<sup>®</sup>** (glycopyrrolate inhalation solution) and **Yupelri<sup>®</sup>** (revefenacin inhalation solution)

Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of COPD
2. Member  $\geq 18$  years of age
3. Member meets **ONE** of the following:
  - a. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month
  - b. Clinical rationale for nebulized formulation (*See Appendix I: Medical Necessity for Nebulized Formulations*)
4. Physician documented inadequate response, adverse reaction or contraindication to ipratropium inhalation nebulizer solution
5. **ONE** of the following:
  - a. If request is for Lonhala Magnair<sup>®</sup> (glycopyrrolate) quantity limit of 60 mL per month
  - b. If request is for Yupelri<sup>®</sup> (revefenacin), quantity limit of 90 mL per month

**Alvesco<sup>®</sup>** (ciclesonide inhaler), **Arnuity<sup>®</sup>** (fluticasone furoate inhalation powder) and **Qvar RediHaler<sup>®</sup>** (beclomethasone inhaler)

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of asthma
2. The member meets **ONE** of the following:
  - a. Physician documentation of inadequate response or adverse reaction to ONE inhaled corticosteroid that does not require a prior authorization
  - b. Contraindication to ALL inhaled corticosteroids that do not require a prior authorization

Note: *Requests citing drug interactions with HIV antiretrovirals – See Appendix II*

**Armonair Digihaler<sup>®</sup>** (fluticasone inhalation powder)

Prescriber provides documentation of **ALL** of the following:



1. Member has a diagnosis of asthma
2. Physician documentation of inadequate response, adverse reaction, or contraindication to Flovent<sup>®</sup> (fluticasone inhalation aerosol, powder)
3. Inadequate response, adverse reaction, or contraindication to Arnuity<sup>®</sup> (fluticasone inhalation powder)

**Asmanex Twisthaler<sup>®</sup>** (mometasone inhalation powder) 110 µg members ≥12 years of age  
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of asthma
2. Clinical rationale for use of 110 µg strength in members ≥12 years of age

**Asmanex Twisthaler<sup>®</sup>** (mometasone inhalation powder) 220 µg members <12 years of age  
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of asthma
2. Clinical rationale for use of 220 µg strength in members <12 years of age

**Pulmicort<sup>®</sup>** (budesonide inhalation suspension) ≥ 13 years of age  
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of asthma
2. The member meets **ONE** of the following:
  - a. Member < 13 years of age
  - b. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month
  - c. Clinical rationale for nebulized formulation (*See Appendix I: Medical Necessity for Nebulized Formulations*)
3. If the request is for BRAND NAME Pulmicort<sup>®</sup> inhalation suspension, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic budesonide respules

### **Continuation criteria:**

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy. Claims history should demonstrate utilization of the medication.

### **Limitations**

1. Approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

|   |                       |
|---|-----------------------|
| Airduo RespiClick <sup>®</sup> (fluticasone/salmeterol inhalation powder) | 1 inhaler per 30 days |
| Breo <sup>®</sup> (fluticasone/vilanterol)                                | 1 inhaler per 30 days |
| Lonhala <sup>®</sup> (umeclidinium)                                       | 60mL per 30 days      |
| Yupelri <sup>®</sup> (revedfenacin)                                       | 90mL per 30 days      |

### **§Brand preferred over generic equivalent:**

A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

- albuterol inhaler (ProAir)
- levalbuterol inhaler
- budesonide/formoterol
- fluticasone/salmeterol powder and

- Wixela (fluticasone/salmeterol inhalation powder)

### **Appendix I: Medical Necessity for Nebulized Formulations**

- Manual dexterity issues preventing the use of an inhaler formulation.
- Member has tried inhaled formulations with an inadequate response that had resulted in the member being hospitalized.
- Difficulty manipulating inhaler in the setting of tracheostomy.
- Difficulty manipulating inhaler during severe, acute asthma attacks.

### **Appendix II: Drug Interactions with HIV Antiretrovirals**

Co-administration of several inhaled corticosteroids (e.g., budesonide, ciclesonide, fluticasone, and mometasone) with HIV protease inhibitors (e.g., atazanavir, darunavir) or elvitegravir/cobicistat can result in adrenal insufficiency and Cushing's syndrome from increased concentration of glucocorticoid. In contrast, co-administration of beclomethasone (e.g., Qvar<sup>®</sup>) is considered safe.

*Requests for Qvar<sup>®</sup> (beclomethasone) noting concomitant use of HIV protease inhibitors or elvitegravir/cobicistat can be approved without trials of less costly alternatives. Recertifications are contingent on members continuing on the interacting HIV antiretrovirals.*

### **Appendix III: Off-Label Indications for Pulmicort (budesonide) Respules\* ≥ 13 years of age**

#### Eosinophilic Esophagitis

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of eosinophilic esophagitis
2. Prescriber is a specialist (e.g., Allergy/Immunology, Otolaryngology, Rhinology, Pulmonology, ENT)
3. Paid claims or prescriber attestation of inadequate response, adverse reaction or contraindication to fluticasone inhalation aerosol, powder
4. If the request is for BRAND NAME Pulmicort<sup>®</sup>, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic budesonide respules (as per the Generic preferred over Brand)

#### Chronic sinusitis, Pansinusitis, Rhinitis, Nasal Polyposis

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of chronic sinusitis, pansinusitis, rhinitis, or nasal polyposis
2. Prescriber is a specialist (e.g., Allergy/Immunology, Otolaryngology, Rhinology, Pulmonology, ENT)
3. **ONE** of the following:
  - a. Paid claims or prescriber attestation of inadequate response, adverse reaction or contraindication to one commercially available intranasal steroid
  - b. Clinical rationale for budesonide irrigation/rinse with suspension formulation (*e.g. need for higher steroid concentration than commercially available products, need to reach the middle meatus, etc*)
4. If the request is for BRAND NAME Pulmicort<sup>®</sup>, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic budesonide respules (as per the Generic preferred over Brand)



## COPD

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of COPD
2. Prescriber is a specialist (e.g., Pulmonology)
3. **ONE** of the following:
  - a. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month
  - b. Clinical rationale for nebulized formulation (*See Appendix I: Medical Necessity for Nebulized Formulations*)
4. If the request is for BRAND NAME Pulmicort<sup>®</sup>, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic budesonide respules (as per the Generic preferred over Brand)

\*A-rated generic available, both brand and A-rated generic require PA

## **References**

N/A

## **Review History**

04/24/2017 – Reviewed

11/07/2020 – Retired ST for COPD; switched to PA for Inhaled Respiratory Agents; Effective 1/1/21  
Updated to be in compliance with the Masshealth partial unified formulary requirements; Added QL

03/17/2021 – Updated and reviewed; Updated to be in compliance with MassHealth Unified Pharmacy Product List (UPPL). Previously called MH Partial unified formulary (PUF). QL requirements removed for Incruse, Seebri, Spiriva and Tudorza, UM requirements removed for Advair, Dulara and Symbicort. Effective 05/01/21.

11/17/2021 – Reviewed and Updated for Nov P&T; matched MH UPPL; Guideline updated to add new agents to UPPL including: Armonair Digihaler<sup>®</sup> (fluticasone propionate inhalation powder), Xopenex<sup>®</sup> (levalbuterol inhalation solution), Proventil<sup>®</sup> (albuterol inhaler), and Airduo Digihaler<sup>®</sup> (fluticasone/salmeterol inhalation powder). to reflect prior authorization for ProAir Respiclick (previously did not require PA). Effective 01/01/2022

## **Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.