Inhaled Respiratory Agents
Effective January 1, 2021

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<td>☑ Pharmacy Benefit</td>
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<td>☑ MassHealth (PUF)</td>
<td>☑ Medical Benefit (NLX)</td>
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<td>☑ Commercial/Exchange</td>
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<tr>
<th>Specialty Limitations</th>
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<th>Non-Specialty Medications</th>
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<td></td>
<td>Phone: 866-814-5506</td>
<td>Phone: 877-433-7643</td>
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<td></td>
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<td>Fax: 866-249-6155</td>
<td>Fax: 866-255-7569</td>
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<td>Commercial</td>
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<td></td>
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<td>Phone: 800-294-5979</td>
<td>Phone: 855-582-2022</td>
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<td>Fax: 888-836-0730</td>
<td>Fax: 855-245-2134</td>
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<td>Phone: 855-582-2022</td>
<td>Phone: 844-345-2803</td>
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<td>Fax: 855-245-2134</td>
<td>Fax: 844-851-0882</td>
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| Exceptions | 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.

<table>
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<tr>
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<tbody>
<tr>
<td></td>
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<tr>
<td><strong>Anticholinergics</strong></td>
<td><strong>Incurs® (umeclidinium) &gt;1 inhaler/month</strong></td>
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<tr>
<td>Atrovent HFA® (ipratropium inhalation aerosol)</td>
<td>Incurs® (umeclidinium) &gt;1 inhaler/month</td>
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<td>≤1 inhaler/month</td>
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<td>Yupelri® (revefenacin)</td>
<td>Spiriva Respimat® (tiotropium inhalation solution) &gt;1 inhaler/month</td>
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**Coverage Guidelines**

Authorizations 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® Digihaler** (albuterol inhalation powder)
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. Member meets ONE of the following:
   a. Physician documented inadequate response or adverse reaction to TWO albuterol inhalers (one must be ProAir HFA® or ProAir RespiClick®)
b. Contraindication to **ALL** albuterol inhalers

**Ventolin**® (albuterol inhaler) † and **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 documented inadequate response, adverse reaction or contraindication to albuterol inhalers (ProAir HFA® ProAir RespiClick®, or Proventil®)
3. If the request is for BRAND NAME Ventolin®, 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

**Advair Diskus**® (fluticasone/salmeterol powder) §* and **Symbicort**® (budesonide/formoterol) †§
Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of Asthma OR chronic obstructive pulmonary disorder (COPD)
2. Quantity limit of one inhaler per month

§Brand preferred over generic (see criteria below)

**Advair HFA**® (fluticasone/salmeterol inhalation aerosol) and **Dulera**® (mometasone/formoterol)
Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of Asthma
2. Quantity limit of one inhaler per month

**Breo**® (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 ≥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**® (fluticasone/vilanterol) for Asthma
1. Member has a diagnosis of asthma
2. Member ≥18 years of age
3. Member meets **ONE** of the following:
   a. Paid claims or prescriber documented inadequate response, adverse reaction, or contraindication to budesonide/formoterol
   b. Contraindication to both Advair® (fluticasone/salmeterol inhalation aerosol, powder) and budesonide/formoterol
4. Quantity limit of one inhaler per month

**Airduo RespiClick**® (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® (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®, 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

Incruse® (umeclidinium) >1 inhaler/month
Seebri® (glycopyrrolate inhalation powder) >1 inhaler/month
Spiriva HandiHaler® (tiotropium inhalation powder) > 30 units/month
Tudorza® (aclidinium) >1 inhaler/month
Prescriber provides documentation of ALL of the following:
1. The member has a diagnosis of COPD
2. Physician documented inadequate response to the requested agent dosed at standard dosing
3. Physician documented inadequate response, adverse reaction or contraindication to a long-acting beta agonist
4. Physician documented inadequate response, adverse reaction or contraindication to an inhaled corticosteroid

Lonhala® (glycopyrrolate inhalation solution) and Yupelri® (revefenacin inhalation solution)
Prescriber provides documentation of ALL of the following:
1. The member has a diagnosis of COPD
2. Member ≥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® (glycopyrrolate), quantity limit of 60 mL per month
   b. If request is for Yupelri® (revefenacin), quantity limit of 90 mL per month

Spiriva Respimat® (tiotropium inhalation solution) >1 inhaler/month
Prescriber provides documentation of ALL of the following:
1. Member meets ONE of the following:
   a. The member has a diagnosis of COPD and request is for the 2.5 mcg/actuation formulation
   b. The member has a diagnosis of asthma and request is for the 1.25 mcg/actuation formulation
2. Physician documented inadequate response to the requested agent dosed at standard dosing
3. Physician documented inadequate response, adverse reaction or contraindication to a long-acting beta agonist
4. Physician documented inadequate response, adverse reaction or contraindication to an inhaled corticosteroid

Alvesco® (ciclesonide inhaler), Arnuity® (fluticasone furoate inhalation powder) and Qvar RediHaler® (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. 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
3. ONE of the following:
   a. If request is for Alvesco® or Qvar RediHaler®, quantity limit of two inhalers per month
   b. If request is for Arnuity®, quantity limit of one inhaler per month

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

Asmanex Twikhaler® (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 (see Appendix IV)

Asmanex Twikhaler® (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 (see Appendix IV)

Pulmicort® (budesonide inhalation suspension)
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. Quantity limit of 120 mL/month
4. If the request is for BRAND NAME Pulmicort® 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

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<thead>
<tr>
<th>FIRST-LINE</th>
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<tr>
<td>Spiriva Respimat</td>
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<td>Incruse Ellipta</td>
<td>Tudorza Pressair</td>
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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:
   - Advair HFA® (fluticasone/salmeterol inhalation aerosol) 1 inhaler per 30 days
   - Advair Diskus® (fluticasone/salmeterol inhalation powder) 1 inhaler per 30 days
### Airduo RespiClick® (fluticasone/salmeterol inhalation powder)
- 1 inhaler per 30 days

### Alvesco® (ciclesonide inhaler)
- 2 inhalers per 30 days

### Arnunity® (fluticasone furoate inhalation powder)
- 1 inhaler per 30 days

### Breo® (fluticasone/vilanterol)
- 1 inhaler per 30 days

### Dulera® (mometasone/formoterol)
- 1 inhaler per 30 days

### Incruse® (umeclidinium)
- 1 inhaler per 30 days

### ipratropium inhalation solution
- 1 inhaler per 30 days

### Lonhala® (glycopyrrolate inhalation solution)
- 60mL per 30 days

### ProAir HFA® (albuterol inhaler)
- 2 inhalers per 30 days

### Qvar RediHaler® (beclomethasone inhaler)
- 2 inhalers per 30 days

### Seebrí® (glycopyrrolate inhalation powder)
- 1 inhaler per 30 days

### Spiriva HandiHaler® (tiotropium inhalation powder)
- 30 units per 30 days

### Spiriva Respimat® (tiotropium inhalation solution)
- 1 inhaler per 30 days

### Symbicort® (budesonide/formoterol)
- 1 inhaler per 30 days

### Tudorza® (aclidinium)
- 1 inhaler per 30 days

### Xopenex HFA® (levalbuterol inhaler)
- 2 inhalers per 30 days

### Yupelri® (revefenacin)
- 90mL per 30 days

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### §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

### 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®) is considered safe.

*Requests for Qvar® (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.*

### References

N/A

### Review History
04/24/2017 – Reviewed
07/07/2020 – 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.

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