Inhaled Respiratory Agents
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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.

No PA	PA Required
Anticholinergics	
Atrovent HFA® (ipratropium inhalation aerosol) Incruse® (umeclidinium) ≤1 inhaler/month ipratropium inhalation solution Seebri® (glycopyrrolate inhalation powder) ≤1 inhaler/month Spiriva HandiHaler® (tiotropium inhalation powder) ≤30 units/month Spiriva Respimat® (tiotropium inhalation solution) ≤1 inhaler/month Tudorza® (aclidinium) ≤1 inhaler/month	Incruse® (umeclidinium) >1 inhaler/month Lonhala® (glycopyrrolate inhalation solution) Seebri® (glycopyrrolate inhalation powder) >1 inhaler/month Spiriva HandiHaler® (tiotropium inhalation powder) >30 units/month Spiriva Respimat® (tiotropium inhalation solution) >1 inhaler/month Tudorza® (aclidinium) >1 inhaler/month Yupelri® (revefenacin)

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

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

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 Twisthaler® (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 years of age *(see Appendix IV)*

Asmanex Twisthaler® (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

FIRST-LINE	SECOND-LINE
Spiriva Respimat Incruse Ellipta	Spiriva Handihaler Tudorza Pressair

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
Arnuity® (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
Seebri® (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

§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
0/07/2020 – 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

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.