Inhaled Respiratory Agents
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth UPPL ☐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	
Incruse® (umeclidinium) Spiriva HandiHaler® (tiotropium inhalation powder) § Spiriva Respimat® (tiotropium inhalation solution) Tudorza® (aclidinium)	Lonhala® (glycopyrrolate inhalation solution) 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 Diskus® (fluticasone propionate inhalation powder) Flovent HFA® (fluticasone propionate inhalation aerosol) § Pulmicort® (budesonide inhalation powder) Pulmicort® # (budesonide inhalation suspension) <13 years of age	Alvesco® (ciclesonide inhaler) Armonair Digihaler® (fluticasone propionate inhalation powder) 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) * ≥13 years of age Qvar RediHaler® (beclomethasone inhaler)
Short-Acting Beta Agonists	
albuterol inhalation solution ProAir HFA® (albuterol inhaler) ± Proventil® (albuterol inhaler) ± Ventolin® (albuterol inhaler) ± Xopenex HFA® (levalbuterol inhaler) ‡	albuterol inhaler± ProAir® Digihaler (albuterol inhalation powder) ProAir® Respiclick (albuterol inhalation powder) Xopenex® (levalbuterol inhalation solution)*
Combination Inhaled Corticosteroids/Long-Acting Beta Agonists	
Advair® (fluticasone/salmeterol inhalation powder) #§ Advair® (fluticasone/salmeterol inhalation aerosol) Dulera® (mometasone/formoterol) § Symbicort® (budesonide/formoterol) ‡§ Wixela® (fluticasone/salmeterol inhalation) ||	Airduo Digihaler® (fluticasone/salmeterol inhalation powder) Airduo RespiClick® (fluticasone/salmeterol inhalation powder) † Breo® (fluticasone/vilanterol) †§
Combination Inhaled Corticosteroid/Long-Acting Anticholinergic/Long-Acting Beta Agonist	
	Breztri® (budesonide/glycopyrrolate/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.
|| For Wixela® (fluticasone/salmeterol inhalation powder), requires a trial of the brand name Advair prior to approval
±Brand and A-rated generic available for Proventil®. Brand and authorized generic available for Ventolin®. Brand Proair HFA® is discontinued as of 10/1/22 and A-rated generic is available. Generic products will reject PA required. Brand name products will pay at the pharmacy without PA.

Coverage Guidelines

Authorizations requests will be reviewed on a case by case basis for members new to the plan 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:

albuterol inhaler
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of asthma, COPD or EIB
2. Medical records documenting an inadequate response or adverse reaction to an albuterol product available without PA

ProAir® Digihaler (albuterol inhalation powder)
ProAir® Respiclick (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 (EIB)
2. Physician documentation of inadequate response, adverse reaction, or contraindication to albuterol inhaler (ProAir HFA®, Proventil®, or Ventolin®)

Xopenex® (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® 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 Brand Name guideline)

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

Airduo Digihaler® (fluticasone/salmeterol 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 Advair® (fluticasone/salmeterol inhalation aerosol, powder)
3. Physician documentation of inadequate response, adverse reaction, or contraindication to Airduo® RespiClick (fluticasone/salmeterol inhalation powder)
4. Requested quantity is ≤1 inhaler/30 days

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. Requested quantity is ≤1 inhaler/30 days
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

Breo® (fluticasone/vilanterol)
Prescriber provides documentation of **ONE** of the following:

1. Member has a diagnosis of **chronic obstructive pulmonary disorder (COPD)** and ALL of the following:
    a. Member ≥18 years of age
    b. Paid claims or prescriber documented inadequate response, adverse reaction, or contraindication to budesonide/formoterol
    c. Requested quantity is ≤1 inhaler/30 days
2. Member has a diagnosis of **asthma** and ALL of the following:
    a. Member ≥18 years of age
    b. Member meets **ONE** of the following:
        i. Paid claims or prescriber attestation inadequate response, adverse reaction, or contraindication to Advair (fluticasone/salmeterol inhalation aerosol, powder) or budesonide/formoterol
        ii. Contraindication to both Advair® (fluticasone/salmeterol inhalation aerosol, powder) and budesonide/formoterol
    c. Requested quantity is ≤1 inhaler/30 days

Lonhala® (glycopyrrolate inhalation solution) and **Yupelri®** (revefenacin inhalation solution)
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of COPD
2. Member ≥18 years of age
3. Member meets **ONE** of the following:
    a. Member has a recent pharmacy claim for a nebulized respiratory product and no pharmacy recent claims for inhalers within the last 30 days or ≥15 days of therapy within the last 30 days
    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) requested quantity is ≤ 60 mL/30 days
    b. If request is for Yupelri® (revefenacin), quantity limit of 90 mL per month

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. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** inhaled corticosteroids available without prior authorization

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

Armonair Digihaler® (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® (fluticasone inhalation aerosol, powder)
3. Physician documentation of inadequate response, adverse reaction, or contraindication to Arnuity® (fluticasone inhalation powder)

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

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

Pulmicort® (budesonide inhalation suspension) ≥ 13 years of age
Prescriber provides documentation of **ONE** of the following:

1. Member has a diagnosis of **asthma** and ALL of the following:
    a. The member meets **ONE** of the following:
        i. Member has a recent claim for a nebulized respiratory product and no recent claims for inhalers within the last 30 days or ≥15 days of therapy within the last 30 days
        ii. Clinical rationale for nebulized formulation *(See Appendix I: Medical Necessity for Nebulized Formulations)*
    b. 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 (as per the Brand Name guideline)
2. Member has a diagnosis of **eosinophilic esophagitis** and ALL of the following:
    a. Prescriber is a specialist (e.g., Allergy/Immunology, Gastroenterology, Otolaryngology, Rhinology, Pulmonology, ENT)
    b. Paid claims or physician documentation of inadequate response, adverse reaction or contraindication to fluticasone inhalation aerosol, powder
    c. For BRAND NAME Pulmicort®, 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 Brand Name and Non-Preferred Generic Drugs guideline)
3. Member has a diagnosis of **chronic sinusitis, pansinusitis, rhinitis, or nasal polyposis** and ALL of the following:
    a. Prescriber is a specialist (e.g., Allergy/Immunology, Otolaryngology, Rhinology, Pulmonology, ENT)
    b. **ONE** of the following:

i. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to one commercially available intranasal steroid
ii. 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)*

c. For BRAND NAME Pulmicort®, 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 Brand Name and Non-Preferred Generic Drugs guideline)

4. Member has a diagnosis of **COPD** and ALL of the following:
   a. Prescriber is a specialist (e.g., Pulmonology)
   b. **ONE** of the following:
      i. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last 30 days
      ii. Medical necessity for nebulized formulation *(See Appendix I: Medical Necessity for Nebulized Formulations)*
   c. For BRAND NAME Pulmicort®, 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 Brand Name and Non-Preferred Generic Drugs guideline)

Breztri® (budesonide/glycopyrrolate/formoterol)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of COPD
2. Member is ≥18 years of age
3. **ONE** of the following:
   a. Physician documentation of inadequate response to ≥ 3 months of the following combination of the separate agents: Bevespi® (glycopyrrolate/formoterol) and Pulmicort® (budesonide inhalation powder) twice daily
   b. Adverse reaction to the following combination of the separate agents: Bevespi® (glycopyrrolate/formoterol) and Pulmicort® (budesonide inhalation powder)
   c. Clinical rationale why member cannot utilize the following combination of the separate agents: Bevespi® (glycopyrrolate/formoterol) and Pulmicort® (budesonide inhalation powder) twice daily
4. Quantity limit of one inhaler per month

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® (fluticasone/salmeterol inhalation powder)	1 inhaler per 30 days
Breo® (fluticasone/vilanterol)	1 inhaler per 30 days
Breztri® (budesonide/glycopyrrolate/formoterol)	1 inhaler per 30 days
Lonhala® (umeclidinium)	60mL 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 HFA
- budesonide/formoterol
- fluticasone propionate inhalation aerosol
- fluticasone/vilanterol
- mometasone/formoterol
- tiotropium inhalation powder
- Wixela (fluticasone/salmeterol inhalation powder)

Appendix I: Medical Necessity for Nebulized Formulations

Documentation of **ONE** of the following is sufficient 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
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® (fluticasone propionate inhalation powder), Xopenex® (levalbuterol inhalation solution), Proventil® (albuterol inhaler), and Airduo Digihaler® (fluticasone/salmeterol inhalation powder). to reflect prior authorization for ProAir Respiclick (previously did not require PA). Effective 01/01/2022
03/16/2022 – Reviewed and Updated for March P&T; Guideline updated to reflect Spiriva HandiHaler® (tiotropium inhalation powder) is now brand preferred.

05/18/2022 – Reviewed and Updated for May P&T; Matched MH UPPL. Guideline updated to remove Xopenex HFA from the brand preferred over generic list. Effective 07/01/22.
07/20/2022 – Reviewed and Updated for July P&T; Matched MH UPPL. Guideline updated to reflect that Breo will be brand preferred pending generic availability. Effective 9/01/22.
11/16/2022 – Reviewed and Updated for Nov P&T; Matched MH UPPL. Effective 12/1/22. Guideline update: Brand Proventil and Ventolin will be brand preferred without PA and all other generic albuterol inhalers will require a PA. Effective 2/1/23. Guideline updated to add footnote for "Wixela® (fluticasone/salmeterol inhalation powder), requires a trial of the brand name Advair prior to approval". Added new drug Breztri® (budesonide/glycopyrrolate/formoterol).
01/11/2023 - Reviewed and updated for Jan P&T. Added gastroenterologist as a potential specialist for off-label utilization of budesonide nebs for eosinophilic esophagitis. QL formatting changed from "per month" to "per 30 days". Criteria for off-label indications for Pulmicort suspension ≥ 13 years of age was moved from appendix to coverage guidelines. Updated formatting for Breo for COPD and Asthma. Effective 3/1/23.

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