BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Respiratory Agents – Unified Formulary

Policy Number: 9.141
Version Number: 2.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Anticholinergics	
Lonhala® (glycopyrrolate inhalation solution)	Incruse® (umeclidinium) Spiriva HandiHaler® (tiotropium inhalation powder) Spiriva Respimat® (tiotropium inhalation solution) Tudorza® (aclidinium)
Inhaled Corticosteroids	

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Drugs that require PA	No PA
Alvesco® (ciclesonide inhaler) Armonair Digihaler® (fluticasone proprionate inhalation poder) 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)	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) Pulmicort® # (budesonide inhalation suspension) <13 years of age
Short-Acting Beta Agonists	
ProAir® Digihaler (albuterol inhalation powder) ProAir RespiClick® (albuterol inhalation powder) Proventil® (albuterol inhaler)* Xopenex® (levalbuterol inhalation solution)* Ventolin® (albuterol inhaler) †	albuterol inhalation solution ProAir HFA® (albuterol inhaler)§ Xopenex HFA® (levalbuterol inhaler) ‡§
Combination Inhaled Corticosteroids/Long-Acting Beta Agonists	
Airduo Digihaler® (fluticasone/salmeterol inhalation powder) Airduo RespiClick® (fluticasone/salmeterol inhalation powder) † Breo® (fluticasone/vilanterol)	Advair® (fluticasone/salmeterol inhalation powder) # § Advair® (fluticasone/salmeterol inhalation aerosol) Dulera® (mometasone/formoterol) Symbicort® (budesonide/formoterol) †§ Wixela® (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. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Approval Criteria:

Short-Acting Beta Agonists	
ProAir® Digihaler (albuterol inhalation powder) **ProAir® Respiclick** (albuterol inhalation powder)	1. Diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or exercise-induced bronchoconstriction (EIB); **AND** 2. Documented inadequate response, adverse reaction or contraindication ProAir HFA® *(Claims are NOT sufficient)*; **AND** 3. **If the request is for BRAND NAME Proventil®:** Medical records documenting an inadequate response or adverse reaction to the generic albuterol inhaler (Proventil®); **OR**

Proventil® (albuterol inhaler) * **Ventolin®** (albuterol inhaler) †	4. **If the request is for BRAND NAME Ventolin®:** Medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic
Xopenex® (levalbuterol inhalation solution)*	1. Diagnosis of asthma, chronic obstructive pulmonary disease (COPD), or exercise-induced bronchoconstriction (EIB); **AND** 2. **ONE** of the following: a. Member is less than 13 years of age; **OR** b. Clinical rationale for nebulized formulation **AND** 3. Documented inadequate response, adverse reaction, or contraindication to inhaled albuterol solution *(Claims are NOT sufficient);* **AND** 4. **If the request for BRAND NAME Xopenex® solution**: Medical records documenting an inadequate response or adverse reaction to the generic levalbuterol solution
Combination Long-Acting Beta Agonists and Inhaled Corticosteroids	
Airduo Digihaler® (fluticasone/salmeterol inhalation powder)	1. Diagnosis of asthma; **AND** 2. Documented inadequate response, adverse reaction, or contraindication to Advair® (fluticasone/salmeterol inhalation aerosol, powder) *(Claims are NOT sufficient);* **AND** 3. Documented inadequate response, adverse reaction, or contraindication to Airduo® RespiClick (fluticasone/salmeterol inhalation powder) *(Claims are NOT sufficient)*
Airduo RespiClick® (fluticasone/salmeterol inhalation powder) †	1. Diagnosis of asthma; **AND** 2. **ONE** of the following: a. Inadequate response or adverse reaction to Advair® (fluticasone/salmeterol inhalation aerosol, powder) *(Claims are NOT sufficient);* **OR** b. Clinical rationale for necessity of lower dose of fluticasone/salmeterol ; **OR** c. Member is already receiving another RespiClick formulation **AND** 3. **If the request is for BRAND NAME AirDuo RespiClick®**: Medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic

Breo® (fluticasone/vilanterol)	1. Diagnosis of chronic obstructive pulmonary disease (COPD); **AND** a. Member 18 years of age or older; **AND** b. Documented inadequate response, adverse reaction, or contraindication to budesonide/formoterol *(Claims history is sufficient);* 2. Diagnosis of asthma a. Member 18 years of age or older; **AND** b. **ONE** of the following: i. Inadequate response or adverse reaction to Advair® (fluticasone/salmeterol inhalation aerosol, powder) or budesonide/formoterol (*Claims are sufficient)* ii. Contraindication to both Advair® (fluticasone/salmeterol inhalation aerosol, powder) and budesonide/formoterol
Long-Acting Anticholinergics	
Lonhala® (glycopyrrolate inhalation solution)	1. Diagnosis of chronic obstructive pulmonary disease (COPD); **AND** 2. Member 18 years of age or older; **AND** 3. **ONE** of the following: a. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month; **OR** b. Clinical rationale for nebulized formulation **AND** 4. Documented inadequate response, adverse reaction or contraindication to ipratropium inhalation nebulizer solution *(Claims are NOT sufficient)*
Inhaled Corticosteroids	
Alvesco® (ciclesonide inhaler) **Arnuity®** (fluticasone furoate inhalation powder) **Qvar RediHaler®** (beclomethasone inhaler)	1. Diagnosis of asthma 2. **ONE** of the following: a. Documented inadequate response or adverse reaction to ONE inhaled corticosteroid that does not require a prior authorization *(Claims are NOT sufficient)* b. Documented contraindication to ALL inhaled corticosteroids that do not require a prior authorization
Armonair Digihaler® (fluticasone inhalation powder)	1. Diagnosis of asthma; **AND** 2. Documented inadequate response, adverse reaction, or contraindication to Flovent® (fluticasone inhalation aerosol, powder) *(Claims history is NOT sufficient);* **AND**

	3. Documented inadequate response, adverse reaction, or contraindication to Arnuity® (fluticasone inhalation powder) *(Claims history is NOT sufficient)*
Asmanex Twisthaler® (mometasone inhalation powder) 110 µg members ≥12 years of age	1. Diagnosis of asthma; **AND** 2. Clinical rationale for use of 110 µg strength in members 12 years of age or older
Asmanex Twisthaler® (mometasone inhalation powder) 220 µg members <12 years of age	1. Diagnosis of asthma 2. Clinical rationale for use of 220 µg strength in members less than 12 years of age
Pulmicort® (budesonide inhalation suspension)* ≥ 13 years of age	1. Diagnosis of asthma; **AND** a. **ONE** of the following: i. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month; **OR** ii. Clinical rationale for nebulized formulation b. **If the request is for BRAND NAME Pulmicort® inhalation suspension**: Medical records documenting an inadequate response or adverse reaction to the generic budesonide Respules **OR** 2. Diagnosis of eosinophilic esophagitis; **AND** a. Prescriber is a specialist (e.g., Allergy/Immunology, Otolaryngology, Rhinology, Pulmonology, ENT); **AND** b. Inadequate response, adverse reaction or contraindication to fluticasone inhalation aerosol, powder *(Claims history is sufficient);* **AND** c. **If the request is for BRAND NAME Pulmicort® inhalation suspension: M**edical records documenting an inadequate response or adverse reaction to the generic budesonide Respules **OR** 3. Diagnosis of chronic sinusitis, pansinusitis, rhinitis, or nasal polyposis; **AND** a. Prescriber is a specialist (e.g., Allergy/Immunology, Otolaryngology, Rhinology, Pulmonology, ENT); **AND** b. **ONE** of the following: i. Inadequate response, adverse reaction or contraindication to one commercially available

	intranasal steroid *(Claims history is sufficient);* **OR** 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)* **AND** c. **If the request is for BRAND NAME Pulmicort® :** Medical records documenting an inadequate response or adverse reaction to the generic budesonide respules **OR** 4. Diagnosis of chronic obstructive pulmonary disease (COPD); **AND** a. Prescriber is a specialist (e.g., Pulmonology); **AND** b. **ONE** of the following: i. Member has a claim for a nebulized respiratory product and no claims for inhalers within the last month **OR**; ii. Clinical rationale for nebulized formulation c. **If the request is for BRAND NAME Pulmicort® :** Medical records documenting an inadequate response or adverse reaction to the generic budesonide respules
Duration/Quantity of Authorization:	Prior authorization may be issued for **1 year.**
Recertification Criteria:	Prescriber must document positive response to therapy. Claims history should demonstrate utilization of the medication. Recertifications may be issued **for up to 1 year.**

Appendix:

Appendix I: Medical Necessity for Nebulized Formulations

Medical necessity for nebulized formulations should be evaluated on a case by case basis. Generally, members should be trained to use an inhaler where appropriate. However, in some cases there may be barriers to using an inhaler appropriately or previous attempts to treat asthma/COPD with inhaled formulations may have resulted in negative patient outcomes. Commonly approvable reasons include the following:

- 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.

References

1. Advair Diskus® (fluticasone propionate/salmeterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2020.
2. Advair HFA® (fluticasone propionate/salmeterol) [prescribing information.] Research Triangle Park, NC: GlaxoSmithKline; August 2021.
3. AirDuo Digihaler (fluticasone propionate/salmeterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals LLC; July 2021.
4. AirDuo RespiClick (fluticasone/salmeterol) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals, LLC; July 2021.
5. Alvesco (ciclesonide) [prescribing information]. Zug, Switzerland: Covis Pharma; October 2020
6. Armonair Digihaler (fluticasone propionate) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals, LLC; February 2020.
7. Arnuity Ellipta (fluticasone furoate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2021.
8. Asmanex HFA (mometasone furoate) [prescribing information]. Jersey City, NJ: Organon and Co; June 2021.
9. Asmanex Twisthaler (mometasone furoate) [prescribing information]. Jersey City, NJ: Organon and Co; June 2021.
10. Breo Ellipta (fluticasone/vilanterol) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2021.
11. Dulera (mometasone furoate/formoterol fumarate) [prescribing information]. Jersey City, NJ:: Organon and Co; June 2021. 2375123 7 Pharmacy Medical Necessity Guidelines: Respiratory Inhalers
12. Flovent Diskus (fluticasone propionate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2020.
13. Flovent HFA (fluticasone propionate) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
14. ProAir DigiHaler (albuterol) [prescribing information]. Parsippany, NJ: Teva Respiratory LLC; September 2020.
15. Pulmicort Flexhaler (budesonide) [prescribing information]. Wilmington, DE: AzstraZeneca LP; October 2019.

16. Pulmicort Respules (budesonide) [prescribing information]. Wilmington, DE: AzstraZeneca LP; October 2019.
17. Qvar Redihaler (beclomethasone) [prescribing information]. Parsippany, NJ: Teva Respiratory; January 2021.
18. Spiriva HandiHaler (tiotropium bromide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; February 2018.
19. Spiriva Respimat (tiotropium bromide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; August 2020.
20. Symbicort (budesonide/formoterol fumarate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2019.
21. Tudorza Pressair (aclidinium bromide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2019.
22. Xopenex HFA (levalbuterol tartrate) inhalation aerosol [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; December 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.141 MH PDL Respiratory Agents Inhaled Policy created for partial unified formulary.	1/1/2021	P&T Committee
2/8/2021	Updated policy to reflect 1/22/21 state changes: removal of QL restrictions on ICS agents (Alvesco, Arnuity, Qvar Redihaler, budesonide inhalation suspension) and ICS-formoterol inhalers (Dulera and Symbicort), PA restriction on Dulera and Symbicort removed, PA restriction on Pulmicort Respules for individuals <13 years of age removed, PA and QL removed for	2/8/2021	P&T Committee

Policy Revisions History			
	both Advair formulations, Incruse, Seebri, Spiriva and Tudorza.		
2/26/2021	Updated policy to reflect 2/12/21 FAQ changes	2/26/2021	P&T Committee
4/22/2021	Updated policy to reflect 4/15/22 changes from MH. Guideline updated to provide clarification to stability section	4/22/2021	P&T Committee
7/23/2021	Updated policy to reflect 6/21/21 changes from MH: Atrovent HFA® (ipratropium inhalation aerosol), ipratropium inhalation solution, and Seebri® (glycopyrrolate inhalation powder) were removed from the reference table. Yupelri® (revefenacin) was removed from UPPL.	9/1/2021	P&T Committee
8/12/2021	Annual Review: no changes	12/1/2021	P&T Committee
11/1/2021	MH UPPL Update: 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). Guideline updated to reflect prior authorization for ProAir Respiclick (previously did not require PA) due to higher net cost than brand ProAir HFA. Additionally, the PA criteria for ProAir Digihaler, ProAir Respiclick, Proventil, Ventolin are now in the same box looking for trial with brand ProAir HFA.	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.