BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

AIRSUPRA™ (albuterol & budesonide) inhalation Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Airsupra (albuterol & budesonide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist, Allergist, or Immunologist
2. Individual is 18 years of age or older
3. Individual has a confirmed diagnosis of asthma
4. Requested agent to be used as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations

5. Individual has a history of at least 1 severe asthma exacerbation in the previous year

6. Individual is receiving **ONE** of the following scheduled asthma maintenance therapies for 3 months:
    a. Medium-to-high-dose inhaled corticosteroid (ICS)
    b. Medium-to-high-dose ICS and **ONE** additional maintenance therapy from the following: leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), or theophylline
    c. Low-to-high-dose ICS in combination with long-acting beta-agonist (LABA) with or without **ONE** additional maintenance therapy from the following: LTRA, LAMA, or theophylline

7. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. Prebronchodilator forced expiratory volume in 1 second (FEV1) of $\geq$ 40 to < 90% predicted normal value
    b. Confirmed reversibility defined as increase in FEV1 $\geq$ 12% and $\geq$ 200 mL relative to baseline after albuterol

8. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

9. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **Symbicort or generic** used as needed for asthma exacerbations

10. The individual does **NOT** have FDA-label contraindication of hypersensitivity to albuterol or budesonide

11. Individual does not have chronic obstructive pulmonary disease or other significant lung disease (e.g., chronic bronchitis, emphysema, bronchiectasis with the need of treatment, cystic fibrosis, or bronchopulmonary dysplasia)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Airsupra (albuterol & budesonide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist, Allergist, or Immunologist

2. Requested agent to be used as-needed treatment or prevention of bronchoconstriction

3. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
    a. Asthma symptoms are controlled
    b. Infrequent use of rescue medications or need for oral corticosteroids
    c. Reduced emergency room or urgent care visits for acute asthma
    d. Reduced hospitalizations for asthma

4. Individual has been adherent with the medication

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
    a. Deterioration/destabilization of asthma or continues to experience symptoms of asthma after using or requires more doses than usual of Airsupra
    b. Paradoxical bronchospasms that occurs following dosing of Airsupra
    c. Clinically significant cardiovascular effect such as increase in pulse rate, blood pressure, other symptoms
    d. Electrocardiogram (ECG) changes, such as flattening of the T wave, prolongation of the QTc interval, and ST-segment depression
    e. Hypersensitivity reaction

7. Individual does not have chronic obstructive pulmonary disease or other significant lung disease (e.g., chronic bronchitis, emphysema, bronchiectasis with the need of treatment, cystic fibrosis, or bronchopulmonary dysplasia)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Airsupra (albuterol & budesonide) is a combination of albuterol, a beta2-adrenergic agonist and budesonide, a corticosteroid, indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Adults and adolescents (12 years and older)

Daily dosage (mcg)			
DRUG	**LOW**	**MEDIUM**	**HIGH**

Beclomethasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclomethasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide (DPI)	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	NA	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

Bronchodilators	
Short-acting antimuscarinics (SAMA)	ipratropium (Atrovent HFA)
Short-acting beta-agonists (SABA)	albuterol (ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA) levalbuterol (Xopenex HFA)
Long-acting antimuscarinics (LAMA)	aclidinium (Tudorza Pressair) glycopyrrolate (Seebri Neohaler) tiotropium (Spiriva, HandiHaler, Spiriva Respimat) umeclidinium (Incruse Ellipta)
Long-acting beta-agonists (LABA)	arformoterol (Brovana) – nebulized solution formoterol (Foradil aerolizer) formoterol (perforomist) – nebulized solution indacaterol (Arcapta Neohaler) olodaterol (Striverdi Respimat) salmeterol (Serevent Diskus)
Bronchodilator combination products	
SAMA / SABA	ipratropium / albuterol (Combivent Respimat)
LAMA / LABA	glycopyrrolate / formoterol (Bevespi Aerosphere) glycopyrrolate / indacaterol (Utibron) tiotropium / olodaterol (Stiolto Respimat) umeclidinium / vilanterol (Anoro Ellipta)
Corticosteroids	

Inhaled corticosteroids (ICS)	beclomethasone (Qvar) budesonide (Pulmicort Flexhaler) ciclesonide (Alvesco) flunisolide (Aerospan) fluticasone (Arnuity Ellipta, Flovent Diskus, Flovent HFA) mometasone (Asmanex, Asmanex HFA)
Corticosteroid-bronchodilator combination products	
ICS / LABA	budesonide / formoterol (Symbicort) fluticasone / salmeterol (Advair HFA, Advair Diskus) fluticasone / vilanterol (Breo Ellipta) mometasone / formoterol (Dulera)
ICS / SABA	budesonide / albuterol (Airsupra)

Resources:

Airsupra (albuterol & budesonide) product information, revised by AstraZeneca Pharmaceuticals LP. 03-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 23, 2024.

Hartert T, Bacharier LB. An overview of asthma management in children and adults. In: UpToDate, Wood RA, Bochner BS, Dieffenbach P, TePas E. (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2024. Topic last updated June 14, 2024. Accessed September 30, 2024.

Papi A, Chipps BE, Beasley R, et al.: Albuterol–Budesonide Fixed-Dose Combination Rescue Inhaler for Asthma. NEJM 2022 June 02; 386 (22): 2071-2083. DOI: 10.1056/NEJMoa2203163. Accessed November 13, 2023. Re-evaluated September 30, 2024.

Chipps BE, Israel E, Beasley R, et al.: Chest 2023 Sept;164(3):585-595. Accessed October 18, 2024.

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org. Accessed September 30, 2024.