BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 09/15/16**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE: 11/16/17
	ARCHIVE DATE:

AIRDUO™ RESPICLICK® (fluticasone-salmeterol) aerosol
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

AIRDUO™ RESPICLICK® (fluticasone-salmeterol) aerosol
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol (cont.)

Description:

Dulera (formoterol / mometasone) is indicated for the treatment of asthma in patients 12 years of age or older. Dulera is not indicated for the relief of acute bronchospasm.

Formoterol is a selective long-acting beta-2 adrenergic agonist that stimulates beta-2 receptors within the lung to cause bronchodilation. Beta-2 agonists stimulate intracellular adenyl cyclase to convert adenosine triphosphate to cyclic 3',5'-adenosine monophosphate (cyclic AMP). Elevated cyclic AMP causes relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from mast cells predominantly. Mometasone and budesonide are corticosteroids that have potent anti-inflammatory activity. While the precise mechanism of action of corticosteroids on COPS and asthma is not known, inflammation is an important component in the development of symptoms. Corticosteroids inhibit multiple cell types and inhibit mediators associated with inflammation and asthma and COPD.

The majority of inhaled medications for COPD and asthma are available as brand only products. There are a few generic nebulized options; all options that are administered via handheld device such as metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and inhaled mist delivery systems (such as Respimat) are brand only. There are many generic oral medications available for the treatment of COPD and asthma.

Definitions:

Classes of medications used in COPD and/or asthma (inhaled, non-nebulizer)

Bronchodilators	
Short-acting beta-agonists (SABA)†	albuterol (ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA) levalbuterol (Xopenex HFA)
Long-acting beta-agonists (LABA)†	formoterol (Foradil aerolizer) indacaterol (Arcapta Neohaler) olodaterol (Striverdi Respimat) salmeterol (Serevent Diskus)
Short-acting antimuscarinics (SAMA)†	ipratropium (Atrovent HFA)
Long-acting antimuscarinics (LAMA)†	aclidinium (Tudorza Pressair) glycopyrrolate (Seebri Neohaler) tiotropium (Spiriva, HandiHaler, Spiriva Respimat) umeclidinium (Incruse Ellipta)
Inhaled corticosteroids (ICS)†	beclomethasone (Qvar) budesonide (Pulmicort Flexhaler) ciclesonide (Alvesco) flunisolide (Aerospan) fluticasone (Arnuity Ellipta, Flovent Diskus, Flovent HFA) mometasone (Asmanex, Asmanex HFA)
Combination products	

Antimuscarinics/beta agonist†	ipratropium/albuterol (Combivent Respimat) glycopyrrolate/formoterol (Bevespi Aerosphere) glycopyrrolate/indacaterol (Utibron) tiotropium/olodaterol (Stiolto Respimat) umeclidinium/vilanterol (Anoro Ellipta)
ICS/LABA	budesonide/formoterol (Symbicort), fluticasone/salmeterol (Advair HFA, Advair Diskus) fluticasone/vilanterol (Breo Ellipta) mometasone/formoterol (Dulera)
† available as nebulized product: albuterol, levalbuterol, Brovana (arformoterol), Perforomist (formoterol), ipratropium, ipratropium/albuterol, Pulmicort Respules (budesonide)	

Dulera (mometasone furoate and formoterol fumarate dihydrate)

Medication class:
Beta2-Adrenergic Agonist and Oral Corticosteroid inhalant

FDA-approved indication(s):
- Treatment of asthma in patients 12 years and older.
- Not indicated for the relief of acute bronchospasm.

Recommended Dose:
- Starting dosage is based on prior asthma therapy and disease severity.
- Treatment of asthma in patients ≥12 years and older: 2 inhalations twice daily of DULERA 100 mcg/5 mcg or 200 mcg/5 mcg.

Maximum dosage
- Mometasone 200 mcg/formoterol 5 mcg (2 inhalations) twice daily

Available Dosage Forms:
- Inhalation aerosol containing a combination of mometasone furoate (100 or 200 mcg) and formoterol fumarate dihydrate (5mcg) per actuation.

Warnings and Precautions:
- Asthma-related death: Long-acting beta -adrenergic agonists increase the risk. Prescribe only for recommended patient populations.
- Deterioration of disease and acute episodes: Do not initiate in acutely deteriorating asthma or to treat acute symptoms.
- Use with additional long-acting beta -agonist: Do not use in combination because of risk of overdose.
- Localized infections: *Candida albicans* infection of the mouth and throat may occur. Monitor patients periodically for signs of adverse effects on the oral cavity. Advise patients to rinse the mouth following inhalation.
- Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal course of chickenpox or measles

can occur in susceptible patients. Use with caution in patients with these infections because of the potential for worsening of these infections.
- Transferring patients from systemic corticosteroids: Risk of impaired adrenal function when transferring from oral steroids. Taper patients slowly from systemic corticosteroids if transferring to Dulera.
- Hypercorticism and adrenal suppression: May occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Dulera slowly.
- Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir): Risk of increased systemic corticosteroid effects. Exercise caution when used with Dulera.
- Paradoxical bronchospasm: Discontinue Dulera and institute alternative therapy if paradoxical bronchospasm occurs.
- Patients with cardiovascular disorders: Use with caution because of beta-adrenergic stimulation.
- Decreases in bone mineral density: Monitor patients with major risk factors for decreased bone mineral content.
- Effects on growth: Monitor growth of pediatric patients.
- Glaucoma and cataracts: Monitor patients with change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts closely.
- Coexisting conditions: Use with caution in patients with aneurysm, pheochromocytoma, convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.
- Hypokalemia and hyperglycemia: Be alert to hypokalemia and hyperglycemia.

Airduo Respiclick (fluticasone-salmeterol)

Medication class:
Antiasthmatic and Bronchodilator Agents - Sympathomimetics, Adrenergic Combinations

FDA-approved indication(s):
- Treatment of asthma in patients 12 years and older.
- Not indicated for the relief of acute bronchospasm.

Recommended Dose:
- Starting dosage is based on prior asthma therapy and disease severity.
- Treatment of asthma in patients 12 years and older: 1 inhalation of Airduo Respiclick 55/14 mcg, 113/14 mcg, or 232/14 mcg twice daily.
- Do not use with a spacer or volume holding chamber

Available Dosage Forms:
- Inhalation Powder containing fluticasone propionate 55 mcg, 113 mcg, or 232 mcg and salmeterol (14 mcg) per actuation.

Warnings and Precautions:
- LABA increase the risk of asthma-related death and asthma-related hospitalizations. Prescribe only for recommended patient populations.
- Deterioration of asthma and acute episodes: Do not use for relief of acute symptoms. Patients require immediate reevaluation during rapidly deteriorating asthma.

AIRDUO™ RESPICLICK® (fluticasone-salmeterol) aerosol
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol (cont.)

- Do not use in combination with an additional medicine containing LABA because of risk of overdose.
- Localized infections: *Candida albicans* infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth with water without swallowing after inhalation to help reduce the risk.
- Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, parasitic infection, or ocular herpes simplex. Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Transferring patients from systemic corticosteroids: Risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to Airduo Respiclick.
- Hypercorticism and adrenal suppression: May occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Airduo Respiclick slowly.
- Paradoxical bronchospasm: Discontinue Airduo Respiclick and institute alternative therapy if paradoxical bronchospasm occurs.
- Use with caution in patients with cardiovascular or central nervous system disorders because of beta adrenergic stimulation.
- Decreases in bone mineral density: Monitor patients with major risk factors for decreased bone mineral content.
- Monitor growth of pediatric patients.
- Close monitoring for glaucoma and cataracts is warranted.
- Be alert to eosinophilic conditions, hypokalemia, and hyperglycemia.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.

Criteria:

- **Criteria for initial therapy: Dulera** (mometasone furoate and formoterol fumarate dihydrate) and **AirDuo Respiclick** (fluticasone-salmeterol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 12 years of age or older

  2. A confirmed diagnosis of asthma

  3. Individual is unable to use **at least two** of the following applicable agents by FDA approved indication due to not effective, experienced a significant adverse drug event, **OR** contraindication:
     - Advair Diskus or Advair HFA
     - Breo Ellipta
     - Symbicort
     - Fluticasone-Salmeterol (generic for Airduo Respiclick)

  Initial approval duration: 12 months

AIRDUO™ RESPICLICK® (fluticasone-salmeterol) aerosol
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol (cont.)

- **Criteria for continuation of coverage (renewal request): Dulera** (mometasone furoate and formoterol fumarate dihydrate) and **AirDuo Respiclick** (fluticasone-salmeterol) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual has been adherent with the medication
  2. The condition has not progressed or worsened while on therapy noted by in-frequent use of Albuterol or oral corticosteroids
  3. Individual has not developed any contraindications or other exclusions to its continued use

  Renewal duration: 12 months

Resources:

AirDuo Respiclick. Package Insert. Revised by manufacturer 2/2017. Accessed 10/12/17.

Dulera. Package Insert. Revised by manufacturer 6/201. Accessed 10/12/17.

Dulera. Package Insert. Revised by manufacturer 7/2016. Accessed 8/25/16.

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.