**Description:**

Dulera (formoterol / mometasone) is indicated for the treatment of asthma in patients 12 years of age or older. Symbicort (formoterol / budesonide) is indicated for the treatment of asthma in patients 6 years of age or older and is indicated for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) and emphysema. Neither is 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
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol
SYMBICORT® (budesonide and formoterol fumarate dehydrate) aerosol (cont.)

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)

<table>
<thead>
<tr>
<th>Bronchodilators</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-acting beta-agonists (SABA)†</td>
<td>albuterol (ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA), levalbuterol (Xopenex HFA)</td>
</tr>
<tr>
<td>Long-acting beta-agonists (LABA)†</td>
<td>formoterol (Foradil aerolizer), indacaterol (Arcapta Neohaler), olodaterol (Striverdi Respimat), salmeterol (Serevent Diskus)</td>
</tr>
<tr>
<td>Short-acting antimuscarinics (SAMA)†</td>
<td>ipratropium (Atrovent HFA)</td>
</tr>
<tr>
<td>Long-acting antimuscarinics (LAMA)†</td>
<td>aclidinium (Tudorza Pressair), glycopyrrolate (Seebri Neohaler), tiotropium (Spiriva, Handihaler, Spiriva Respimat), umeclidinium (Incruse Ellipta)</td>
</tr>
</tbody>
</table>

**Inhaled corticosteroids (ICS)†**  
beclomethasone (Qvar)  
budesonide (Pulmicort Flexhaler)  
ciclesonide (Alvesco)  
flunisolide (Aerospan)  
fluticasone (Aruinity 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 (Stioltio 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, levvalbuterol, Brovana (arformoterol), Perforomist (formoterol), ipratropium, ipratropium/albuterol, Pulmicort Respules (budesonide)
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol
SYMBICORT® (budesonide and formoterol fumarate dehydrate) aerosol (cont.)

Drug related events:

Ineffective / failure
Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened

A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

Adverse Drug Event: Allergic reaction / Hypersensitivity / Intolerance
Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual’s outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals’ body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Allergic reaction / hypersensitivity – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline

Intolerance – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record

Contraindication
Use of a drug that is not recommended by the manufacturer or FDA labelling

Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental

Non-adherence
Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record
**DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol**

**SYMBICORT® (budesonide and formoterol fumarate dehydrate) aerosol**

( ctr.)

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**Precertification:**

Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.

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](http://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.

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**Criteria:**

See “Resources” section for FDA-approved dosage.

- Precertification for Dulera (mometasone furoate and formoterol fumarate dihydrate) and Symbicort (budesonide and formoterol fumarate dehydrate) requires completion of the specific request form in its entirety. 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 will be returned.

- Initial therapy: FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Dulera (mometasone furoate and formoterol fumarate dihydrate) is considered medically necessary when ALL of the following criteria are met:

  1. Individual is 12 years of age or older
  2. Medical record documentation of a confirmed diagnosis of asthma
  3. Medical record documentation that individual is unable to use ALL 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
  4. Absence of ALL of the following contraindications:
     - Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures
     - Hypersensitivity to any of the ingredients of Dulera
DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol  
SYMBICORT® (budesonide and formoterol fumarate dehydrate) aerosol (cont.)

5. Absence of ALL of the following exclusions:
   - Simultaneous use with another long-acting beta-2 adrenergic agonist
   - Use in acute episodes of bronchospasm or acutely deteriorating asthma

➤ **Continuation of coverage (renewal request):** Dulera is considered *medically necessary* with documentation of ALL of the following:

1. The individual has benefited from therapy but remains at high risk
2. The condition has not progressed or worsened while on therapy
3. Individual has not developed any contraindications or other exclusions to its continued use

➤ Dulera (mometasone furoate and formoterol fumarate dihydrate) for all other indications not previously listed is considered *experimental or investigational* based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

➤ **Initial therapy:** FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Symbicort (budesonide and formoterol fumarate dehydrate) is considered *medically necessary* when ALL of the following criteria are met:

1. Individual is 6 years of age or older
2. Medical record documentation of a confirmed diagnosis of ONE of the following:
   - Asthma
   - Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema
3. Medical record documentation that individual is unable to use ALL 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
4. Absence of ALL of the following contraindications:
   - Primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures
   - Hypersensitivity to any of the ingredients of Symbicort
5. Absence of ALL of the following exclusions:
   - Simultaneous use with another long-acting beta-2 adrenergic agonist
   - Use in acute episodes of bronchospasm or acutely deteriorating asthma

   ➢ **Continuation of coverage (renewal request):** Symbicort is considered *medically necessary* with documentation of ALL of the following:

   1. The individual has benefited from therapy but remains at high risk
   2. The condition has not progressed or worsened while on therapy
   3. Individual has not developed any contraindications or other exclusions to its continued use

   ➢ Symbicort (budesonide and formoterol fumarate dehydrate) for all other indications not previously listed is considered *experimental or investigational* based upon:

   1. Lack of final approval from the Food and Drug Administration, and
   2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
   3. Insufficient evidence to support improvement of the net health outcome, and
   4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
   5. Insufficient evidence to support improvement outside the investigational setting.

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**Resources:**


FDA-approved indication and dosage:
## DULERA® (mometasone furoate and formoterol fumarate dihydrate) aerosol
### SYMBCORT® (budesonide and formoterol fumarate dehydrate) aerosol (cont.)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
</table>
| Dulera is a combination product containing a corticosteroid and a long-acting beta-adrernergic agonist indicated for:  
  - Treatment of asthma in patients 12 years of age and older.  
  Important limitations:  
  - Not indicated for the relief of acute bronchospasm. | For oral inhalation only.  
  Treatment of asthma in patients ≥12 years: 2 inhalations twice daily of DULERA 100 mcg/5 mcg or 200 mcg/5 mcg. Starting dosage is based on prior asthma therapy. |
| Symbicort is a combination product containing a corticosteroid and a long-acting beta-adrernergic agonist indicated for:  
  - Treatment of asthma in patients 6 years of age and older.  
  - Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.  
  Important limitations:  
  - Not indicated for the relief of acute bronchospasm. | For oral inhalation only.  
  Treatment of asthma in patients >12 years: 2 inhalations twice daily of SYMBCORT 80/4.5 or 160/4.5. Starting dosage is based on asthma severity.  
  Treatment of asthma in patients aged 6 to less than 12 years: 2 inhalations of SYMBCORT 80/4.5 twice daily.  
  Maintenance treatment of airflow obstruction in COPD: 2 inhalations of SYMBCORT 160/4.5 twice daily |