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Coverage Policy Number ..... IP0022

# Corticosteroid / Long-Acting Beta<sub>2</sub>-Agonist Combination Inhalers

## Table of Contents

Overview ..... 1  
Medical Necessity Criteria ..... 2  
Reauthorization Criteria ..... 9  
Authorization Duration ..... 9  
Background ..... 9  
References ..... 10

## Related Coverage Resources

### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

## Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered corticosteroid/long-acting beta<sub>2</sub>-agonist combination inhaler products:

- **Advair Diskus<sup>®</sup>** (fluticasone/salmeterol inhalation powder)
- **Advair HFA<sup>®</sup>** (fluticasone/salmeterol inhalation aerosol)
- **AirDuo<sup>™</sup> RespiClick<sup>®</sup>** (fluticasone/ salmeterol inhalation powder)
- **Breo Ellipta<sup>®</sup>** (fluticasone/vilanterol inhalation powder)
- **fluticasone-salmeterol HFA** oral inhalation
- **fluticasone/salmeterol multidose** dry powder inhaler (generic for AirDuo Respiclick)
- **fluticasone/vilanterol** inhalation powder
- **Symbicort<sup>®</sup>** (budesonide/ formoterol inhalation aerosol)

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Non-Covered Product	Criteria
<p><b>Advair Diskus</b> (fluticasone/salmeterol inhalation powder)</p>	<p><b>Standard/Performance Drug List Plans:</b> Advair Diskus is considered medically necessary when there is documentation of <b>BOTH</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Trial of <b>fluticasone/salmeterol inhalation powder or Wixela™ Inhub™</b> (bioequivalent generic products) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</li> <li>2. <b>ONE</b> the following (by diagnosis, age and/or ability to use device type):             <ol style="list-style-type: none"> <li>A. <b>Asthma and age 18 years or older.</b> Failure, contraindication, or intolerance to <b>THREE</b> of the following:                 <ol style="list-style-type: none"> <li>i. Advair HFA (fluticasone/ salmeterol)</li> <li>ii. Breo Ellipta (fluticasone/ vilanterol)</li> <li>iii. budesonide/ formoterol (generic for Symbicort)</li> <li>iv. Dulera (mometasone/ formoterol)</li> </ol> </li> <li>B. <b>Asthma, age 18 years or older, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to Breo Ellipta (fluticasone/vilanterol)</li> <li>C. <b>Asthma and age 12 to less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>TWO</b> of the following:                 <ol style="list-style-type: none"> <li>i. Advair HFA (fluticasone/ salmeterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> <li>iii. Dulera (mometasone/ formoterol)</li> </ol> </li> <li>D. <b>Asthma, age 12 to less than 18 years of age, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b></li> <li>E. <b>Asthma and age 6 to 11 years.</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following:                 <ol style="list-style-type: none"> <li>i. Dulera (mometasone/ formoterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> </ol> </li> <li>F. <b>Asthma and 5 years of age to less than 6 years of age.</b> Failure, contraindication, or intolerance to Dulera (mometasone/ formoterol)</li> <li>G. <b>Asthma and less than 5 years of age</b></li> <li>H. <b>Asthma, age is less than 12 years of age, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)</b></li> <li>I. <b>COPD.</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following:                 <ol style="list-style-type: none"> <li>i. Breo Ellipta (fluticasone/ vilanterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> </ol> </li> <li>J. <b>COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to Breo Ellipta (fluticasone/ vilanterol)</li> </ol> </li> </ol> <p><b>Value/Advantage/Cigna Total Savings Drug List Plans:</b></p>

Non-Covered Product	Criteria
	<p>Advair Diskus is considered medically necessary when there is documentation of <b>BOTH</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Trial of <b>fluticasone/salmeterol inhalation powder or Wixela™ Inhub™</b> (bioequivalent generic products) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</li> <li>2. <b>ONE</b> the following (by diagnosis, age and/or ability to use device type): <ol style="list-style-type: none"> <li>A. <b>Asthma and age 18 years or older.</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ol style="list-style-type: none"> <li>i. Dulera (mometasone/ formoterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> </ol> </li> <li>B. <b>Asthma, age 18 years or older, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b></li> <li>C. <b>Asthma and age 12 to less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ol style="list-style-type: none"> <li>i. Dulera (mometasone/ formoterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> </ol> </li> <li>D. <b>Asthma, age 12 to less than 18 years of age, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b></li> <li>E. <b>Asthma and age 6 to 11 years.</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ol style="list-style-type: none"> <li>i. Dulera (mometasone/ formoterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> </ol> </li> <li>F. <b>Asthma and 5 years of age to less than 6 years of age.</b> Failure, contraindication, or intolerance to Dulera (mometasone/ formoterol)</li> <li>G. <b>Asthma and less than 5 years of age</b></li> <li>H. <b>Asthma, age is less than 12 years of age, and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)</b></li> <li>I. <b>COPD.</b> Failure, contraindication, or intolerance to budesonide/ formoterol (generic for Symbicort)</li> <li>J. <b>COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI)</b></li> </ol> </li> </ol>
<p><b>Advair HFA</b> (fluticasone/salmeterol inhalation aerosol)</p>	<p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b> Advair HFA is considered medically necessary when there is documentation of <b>ONE</b> of the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. <b>Age 18 years or older.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>2. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> </ol>

Non-Covered Product	Criteria
	<p>3. <b>Low inspiratory flow rate and unable to use a dry powder inhaler (DPI).</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following:</p> <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> </ul>
<p><b>AirDuo RespiClick</b> (fluticasone/ salmeterol inhalation powder)</p>	<p><b><u>Standard/Performance Drug List Plans:</u></b> AirDuo RespiClick is considered medically necessary when there is documentation of <b>ONE</b> the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. <b>Age 18 years or older.</b> Failure, contraindication, or intolerance to <b>FOUR</b> of the following: <ul style="list-style-type: none"> <li>A. Advair HFA (fluticasone/ salmeterol)</li> <li>B. Breo Ellipta (fluticasone/ vilanterol)</li> <li>C. budesonide/ formoterol (generic for Symbicort)</li> <li>D. Dulera (mometasone/ formoterol)</li> <li>E. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>2. <b>Age 18 years or older and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ul style="list-style-type: none"> <li>A. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> <li>B. Breo Ellipta (fluticasone/vilanterol)</li> </ul> </li> <li>3. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>THREE</b> of the following: <ul style="list-style-type: none"> <li>A. Advair HFA (fluticasone/ salmeterol)</li> <li>B. Breo Ellipta (fluticasone/ vilanterol)</li> <li>C. budesonide/ formoterol (generic for Symbicort)</li> <li>D. Dulera (mometasone/ formoterol)</li> <li>E. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>4. <b>Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ul style="list-style-type: none"> <li>A. Breo Ellipta (fluticasone/ vilanterol)</li> <li>B. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> </ol> <p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b> AirDuo RespiClick is considered medically necessary when there is documentation of <b>ONE</b> the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. <b>Age 18 years or older.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/ formoterol)</li> <li>C. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>2. <b>Age 18 years or older and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> <li>3. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/ formoterol)</li> </ul> </li> </ol>

Non-Covered Product	Criteria
	<p>C. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</p> <p>4. <b>Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</p>
<p><b>Breo Ellipta</b> (fluticasone/vilanterol inhalation powder)</p>	<p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b> Breo Ellipta is considered medically necessary when there is documentation of <b>ONE</b> of the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>2. <b>Less than 12 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>3. <b>Less than 5 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ol style="list-style-type: none"> <li>A. Dulera (mometasone/formoterol)</li> <li>B. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>4. <b>Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> <li>5. <b>COPD.</b> Failure, contraindication, or is intolerance to <b>BOTH</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. luticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ol> </li> <li>6. <b>COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or is intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ol>
<p><b>fluticasone-salmeterol HFA</b> oral inhalation</p>	<p><b><u>Standard/Performance/Legacy Drug List Plans:</u></b> Fluticasone-salmeterol HFA is considered medically necessary when there is documentation of <b>BOTH</b> of the following:</p> <ol style="list-style-type: none"> <li>1. Trial of Advair HFA (the brand product)</li> <li>2. <b>ONE</b> the following (by diagnosis, age and/or ability to use device type): <ol style="list-style-type: none"> <li>A. <b>Age 18 years or older.</b> Failure, contraindication, or intolerance to <b>THREE</b> of the following: <ol style="list-style-type: none"> <li>i. Breo Ellipta (fluticasone/ vilanterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> <li>iii. Dulera (mometasone/formoterol)</li> <li>iv. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>B. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>TWO</b> of the following:</li> </ol> </li> </ol>

Non-Covered Product	Criteria
	<ul style="list-style-type: none"> <li>i. Breo Ellipta (fluticasone/ vilanterol)</li> <li>ii. budesonide/ formoterol (generic for Symbicort)</li> <li>iii. Dulera (mometasone/formoterol)</li> <li>iv. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> <p><b>C. Low inspiratory flow rate and unable to use a dry powder inhaler (DPI):</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following:</p> <ul style="list-style-type: none"> <li>i. budesonide/ formoterol (generic for Symbicort)</li> <li>ii. Dulera (mometasone/formoterol)</li> </ul> <p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b>  Fluticasone-salmeterol HFA is considered medically necessary when there is documentation of <b>ONE</b> of the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. <b>Age 18 years or older.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>2. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>3. <b>Low inspiratory flow rate and unable to use a dry powder inhaler (DPI).</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> </ul> </li> </ol>
<b>fluticasone/salmeterol multidose</b> dry powder inhaler (generic for AirDuo Respiclick)	<p><b><u>Standard/Performance/Legacy Drug List Plans:</u></b>  Fluticasone/salmeterol multidose dry powder inhaler is considered medically necessary when there is documentation of <b>ONE</b> the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. Failure, contraindication, or intolerance to <b>FOUR</b> of the following: <ul style="list-style-type: none"> <li>A. Advair HFA (fluticasone/ salmeterol)</li> <li>B. Breo Ellipta (fluticasone/ vilanterol)</li> <li>C. budesonide/ formoterol (generic for Symbicort)</li> <li>D. Dulera (mometasone/ formoterol)</li> <li>E. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>2. <b>Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ul style="list-style-type: none"> <li>A. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> <li>B. Breo Ellipta (fluticasone/vilanterol)</li> </ul> </li> <li>3. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>THREE</b> of the following: <ul style="list-style-type: none"> <li>A. Advair HFA (fluticasone/ salmeterol)</li> <li>B. Breo Ellipta (fluticasone/ vilanterol)</li> </ul> </li> </ol>

Non-Covered Product	Criteria
	<p>C. budesonide/ formoterol (generic for Symbicort)  D. Dulera (mometasone/ formoterol)  E. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</p> <p>4. <b>Less than 18 years of age and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following:  A. Breo Ellipta (fluticasone/ vilanterol)  B. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</p> <p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b>  Fluticasone/salmeterol multidose dry powder inhaler is considered medically necessary when there is documentation of <b>ONE</b> the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/ formoterol)</li> <li>C. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>2. <b>Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> <li>3. <b>Less than 18 years of age.</b> Failure, contraindication, or intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/ formoterol)</li> <li>C. fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>4. <b>Less than 18 years of age AND unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or intolerance to fluticasone/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol>
<p><b>fluticasone/ vilanterol</b> inhalation powder</p>	<p><b><u>Standard/Performance/Legacy Drug List Plans:</u></b>  Fluticasone / vilanterol inhalation powder is considered medically necessary when there is documentation of <b>BOTH</b> of the following:</p> <ol style="list-style-type: none"> <li>1. There is a documented inability to obtain Breo Ellipta inhaler (the brand name product)</li> <li>2. <b>ONE</b> the following (by diagnosis, age and/or ability to use device type): <ol style="list-style-type: none"> <li>A. Failure, contraindication, or is intolerance to <b>ALL</b> of the following: <ol style="list-style-type: none"> <li>i. budesonide/ formoterol (generic for Symbicort)</li> <li>ii. Dulera (mometasone/formoterol)</li> <li>iii. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ol> </li> <li>B. <b>Less than 12 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ol style="list-style-type: none"> <li>i. budesonide/ formoterol (generic for Symbicort)</li> <li>ii. Dulera (mometasone/formoterol)</li> <li>iii. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ol> </li> <li>C. <b>Less than 5 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following:</li> </ol> </li> </ol>

Non-Covered Product	Criteria
	<ul style="list-style-type: none"> <li>i. Dulera (mometasone/formoterol)</li> <li>ii. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> <p><b>D. Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or is intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</p> <p><b>E. COPD.</b> Failure, contraindication, or is intolerance to <b>BOTH</b> of the following:</p> <ul style="list-style-type: none"> <li>i. budesonide/ formoterol (generic for Symbicort)</li> <li>ii. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ul> <p><b>F. COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or is intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</p> <p><b><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></b>  Fluticasone / vilanterol inhalation powder is considered medically necessary when there is documentation of <b>ONE</b> of the following (by diagnosis, age and/or ability to use device type):</p> <ol style="list-style-type: none"> <li>1. Failure, contraindication, or is intolerance to <b>ALL</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ul> </li> <li>2. <b>Less than 12 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. Dulera (mometasone/formoterol)</li> <li>C. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>3. <b>Less than 5 years of age.</b> Failure, contraindication, or intolerance to <b>ONE</b> of the following: <ul style="list-style-type: none"> <li>A. Dulera (mometasone/formoterol)</li> <li>B. fluticasone propionate/salmeterol inhalation powder OR Wixela™ Inhub™ (fluticasone/salmeterol)</li> </ul> </li> <li>4. <b>Unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or is intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> <li>5. <b>COPD.</b> Failure, contraindication, or is intolerance to <b>BOTH</b> of the following: <ul style="list-style-type: none"> <li>A. budesonide/ formoterol (generic for Symbicort)</li> <li>B. fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ul> </li> <li>6. <b>COPD and unable to coordinate breath and actuation with a metered-dose inhaler (MDI).</b> Failure, contraindication, or is intolerance to fluticasone propionate/salmeterol inhalation powder OR Wixela Inhub (fluticasone/salmeterol)</li> </ol>
<b>Symbicort</b> (budesonide/ formoterol inhalation aerosol)	Documented trial of <b><u>budesonide/ formoterol inhalation aerosol</u></b> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction



Non-Covered Product	Criteria

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Continuation of corticosteroid/long-acting beta<sub>2</sub>-agonist combination inhaler products is considered medically necessary for continued use when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration is up to 12 months.  
 Reauthorization approval duration is up to 12 months.

## Background

### OVERVIEW

The inhaled corticosteroid (ICS)/long-acting beta<sub>2</sub>-agonist (LABA) combination inhalers are indicated for the treatment of asthma.<sup>1-6</sup> Age indications vary by agent. Fluticasone propionate and salmeterol inhalation powder (Advair Diskus, generics [including Wixela Inhub]), Breo Ellipta, and Symbicort (and authorized generic) are also indicated for the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive lung disease (COPD), including chronic bronchitis and/or emphysema.<sup>1,3,5</sup> Advair HFA (and authorized generic) and Dulera are not FDA-approved for the treatment of COPD; however, both products have been studied for this use.<sup>2,4,7-9</sup> AirDuo Digihaler and AirDuo RespiClick (and authorized generic) also have not specifically been studied in patients with COPD. However, these agents were filed as a New Drug Application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.<sup>6</sup> This approval pathway relies in part upon evidence not developed by the applicant. In the case of these agents, the literature and safety and effectiveness evidence supporting the approval and use of Advair Diskus (indicated in patients with COPD) are considered part of the evidence supporting the approval and use of the AirDuo products. Of note, another ICS/LABA inhaler, Symbicort Aerosphere<sup>®</sup> (budesonide/formoterol fumarate inhalation aerosol), was approved in 2023 for the maintenance treatment of patients with COPD. However, the manufacturer currently has no plans to launch this product in the US and this product is not targeted in this policy.

### Guidelines

The 2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for the diagnosis, management, and prevention of COPD support the use of combination ICS/LABA therapy in select highly symptomatic patients who are at high risk for COPD exacerbations.<sup>10</sup> The ICS/LABAs are also featured prominently in the 2023 Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention. They are recommended as part of the step-wise treatment algorithm for patients ≥ 6 years of age.<sup>29</sup> European Respiratory Society (ERS) guidelines on the diagnosis and treatment of chronic cough in adults and children (2020) recommend a short-term trial (2 to 4 weeks) of ICS and long-acting bronchodilator (e.g. a LABA) combination in adults with chronic cough and fixed airflow obstruction.<sup>30</sup>

### Other Uses with Supportive Evidence

There are also data to support the use of ICS/LABA inhalers in patients with postinfectious cough. Subacute postinfectious cough may have multiple possible underlying etiologies, including asthma.<sup>11,12</sup> The underlying cause of the cough must be determined before making therapeutic decisions. In this situation, ICS/LABA combination therapy may be used as diagnostic empiric therapy in determining the cause of cough (i.e., rule out asthma). When a patient with subacute cough presents with wheezes, rhonchi, or crackles with a normal chest

radiograph, it may be a reasonable option to consider therapy with an inhaled bronchodilator and ICS. If cough following an upper respiratory tract infection persists for > 8 weeks, diagnoses other than postinfectious cough should be considered.

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