

# QUANTITY LIMIT CRITERIA

**DRUG CLASS** LONG ACTING BETA2-ADRENERGIC AGONIST, COMBINATIONS  
ORAL INHALATION

**BRAND NAME**  
(generic)

**LONG-ACTING BETA2-ADRENERGIC AGONIST:**

**BROVANA**  
(arformoterol tartrate)

**PERFOROMIST**  
(formoterol)

**SEREVENT DISKUS**  
(salmeterol)

**STRIVERDI RESPIMAT**  
(olodaterol)

**LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC:**

**ANORO ELLIPTA**  
(umeclidinium/vilanterol)

**BEVESPI AEROSPHERE**  
(glycopyrrolate/formoterol)

**DUAKLIR PRESSAIR**  
(aclidinium/formoterol)

**STIOLTO RESPIMAT**  
(tiotropium bromide/olodaterol)

**LONG-ACTING BETA2-ADRENERGIC AGONIST / CORTICOSTEROID:**

**ADVAIR DISKUS**  
(fluticasone propionate/salmeterol)

**ADVAIR HFA**  
(fluticasone propionate/salmeterol)

**AIRDUO DIGIHALER**  
(fluticasone propionate/salmeterol)

**AIRDUO RESPICLICK**  
(fluticasone propionate/salmeterol)

**BREO ELLIPTA**  
(fluticasone furoate/vilanterol)

**DULERA**  
(mometasone/formoterol)

**SYMBICORT**  
(budesonide/formoterol)

**SYMBICORT AEROSPHERE**  
(budesonide/formoterol)

**LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC / CORTICOSTEROID:**  
**BREZTRI AEROSPHERE**  
(budesonide/glycopyrrolate/formoterol fumarate)

**TRELEGY ELLIPTA**  
(fluticasone furoate/umeclidinium/vilanterol)

**Status: CVS Caremark® Criteria**  
**Type: Quantity Limit**

## **POLICY**

### **FDA-APPROVED INDICATIONS**

#### **Long-Acting Beta2-Adrenergic Agonist:**

##### **Brovana**

Brovana (arformoterol tartrate) Inhalation Solution is indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Brovana Inhalation Solution is for use by nebulization only.

##### ***Important Limitations of Use***

Brovana Inhalation solution is not indicated to treat acute deteriorations of chronic obstructive pulmonary disease. Brovana Inhalation Solution is not indicated to treat asthma. The safety and effectiveness of Brovana Inhalation Solution in asthma have not been established.

##### **Perforomist**

Perforomist (formoterol fumarate) Inhalation Solution is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

##### ***Important Limitations of Use***

Perforomist Inhalation Solution is not indicated to treat acute deteriorations of chronic obstructive pulmonary disease. Perforomist Inhalation Solution is not indicated to treat asthma. The safety and effectiveness of Perforomist Inhalation Solution in asthma have not been established.

##### **Serevent Diskus**

#### **Treatment of Asthma**

Serevent Diskus is indicated for the treatment of asthma and in the prevention of bronchospasm only as concomitant therapy with an ICS in patients aged 4 years and older with reversible obstructive airway disease, including patients with symptoms of nocturnal asthma. LABA, such as salmeterol, the active ingredient in Serevent Diskus, as monotherapy

(without ICS) increase the risk of asthma-related death. Use of Serevent Diskus for the treatment of asthma without concomitant use of an ICS is contraindicated. Use Serevent Diskus only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on an ICS. Do not use Serevent Diskus for patients whose asthma is adequately controlled on low- or medium-dose ICS.

#### ***Pediatric and Adolescent Patients***

Available data from controlled clinical trials suggest that LABA as monotherapy increase the risk of asthma-related hospitalization in pediatric and adolescent patients. For pediatric and adolescent patients with asthma who require addition of a LABA to an ICS, a fixed-dose combination product containing both an ICS and a LABA should ordinarily be used to ensure adherence with both drugs. In cases where use of a separate ICS and a LABA is clinically indicated, appropriate steps must be taken to ensure adherence with both treatment components. If adherence cannot be assured, a fixed-dose combination product containing both an ICS and a LABA is recommended.

#### ***Important Limitation of Use***

Serevent Diskus is NOT indicated for the relief of acute bronchospasm.

#### **Prevention of Exercise-Induced Bronchospasm**

Serevent Diskus is also indicated for prevention of exercise-induced bronchospasm (EIB) in patients aged 4 years and older. Use of Serevent Diskus as a single agent for the prevention of EIB may be clinically indicated in patients who do not have persistent asthma. In patients with persistent asthma, use of Serevent Diskus for the prevention of EIB may be clinically indicated, but the treatment of asthma should include an ICS.

#### **Maintenance Treatment of Chronic Obstructive Pulmonary Disease**

Serevent Diskus is indicated for the long-term twice-daily administration in the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) (including emphysema and chronic bronchitis).

#### ***Important Limitation of Use***

Serevent Diskus is NOT indicated for the relief of acute bronchospasm.

#### **Striverdi Respimat**

Striverdi Respimat is a long-acting beta<sub>2</sub>-agonist indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

#### ***Important Limitations of Use***

Striverdi Respimat is not indicated to treat acute deteriorations of COPD.

Striverdi Respimat is not indicated to treat asthma. The safety and effectiveness of Striverdi Respimat in asthma have not been established.

#### **Long-Acting Beta2-Adrenergic Agonist / Anticholinergic:**

##### **Anoro Ellipta**

Anoro Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### ***Limitations of Use***

Anoro Ellipta is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma. The safety and efficacy of Anoro Ellipta in asthma have not been established.

##### **Bevespi Aerosphere**

Bevespi Aerosphere is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### ***Limitations of Use:***

Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

##### **Duaklir Pressair**

Duaklir Pressair is a combination of acclidinium bromide (an anticholinergic) and formoterol fumarate (a LABA) indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### ***Limitations of Use***

Duaklir Pressair is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

##### **Stiolto Respimat**

Stiolto Respimat is a combination of tiotropium and olodaterol indicated for long-term, once-daily maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

##### ***Important Limitations of Use***

Stiolto Respimat is not indicated to treat acute deteriorations of COPD.

Stiolto Respimat is not indicated to treat asthma. The safety and effectiveness of Stiolto Respimat in asthma have not been established.

### **Long-Acting Beta2-Adrenergic Agonist / Corticosteroid:**

#### Advair Diskus

##### **Treatment of Asthma**

Advair Diskus is indicated for the twice-daily treatment of asthma in patients aged 4 years and older. Advair Diskus should be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta<sub>2</sub>-adrenergic agonist (LABA).

##### **Maintenance Treatment of Chronic Obstructive Pulmonary Disease**

Advair Diskus 250/50 is indicated for the twice-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Advair Diskus 250/50 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. Advair Diskus 250/50 twice daily is the only approved dosage for the treatment of COPD because an efficacy advantage of the higher strength Advair Diskus 500/50 over Advair Diskus 250/50 has not been demonstrated.

##### *Important Limitation of Use*

Advair Diskus is NOT indicated for the relief of acute bronchospasm.

#### Advair HFA

Advair HFA is indicated for treatment of asthma in adult and adolescent patients aged 12 years and older. Advair HFA should be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta<sub>2</sub>-adrenergic agonist (LABA).

##### *Limitations of Use*

Advair HFA is not indicated for the relief of acute bronchospasm.

#### AirDuo Digihaler

AirDuo Digihaler is indicated for the treatment of asthma in adult and pediatric patients aged 12 years and older. AirDuo Digihaler should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta<sub>2</sub>-adrenergic agonist (LABA).

##### *Limitations of Use:*

AirDuo Digihaler is not indicated for the relief of acute bronchospasm.

#### AirDuo Respiclick

AirDuo Respiclick is indicated for the treatment of asthma in adult and pediatric patients aged 12 years and older. AirDuo Respiclick should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta<sub>2</sub>-adrenergic agonist (LABA).

##### *Limitations of Use:*

AirDuo Respiclick is not indicated for the relief of acute bronchospasm.

#### Breo Ellipta

##### **Maintenance Treatment of Chronic Obstructive Pulmonary Disease**

Breo Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### **Maintenance Treatment of Asthma**

Breo Ellipta is indicated for the maintenance treatment of asthma in patients aged 5 years and older.

##### *Limitations of Use*

Breo Ellipta is NOT indicated for the relief of acute bronchospasm.

#### Dulera

Dulera is indicated for the twice-daily treatment of asthma in patients 5 years of age and older. Dulera should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta<sub>2</sub>-adrenergic agonist (LABA).

##### *Important Limitations of Use:*

Beta Agonists-Long Acting, Combinations Oral Inhalation Limit Policy 34-H 10-2023.docx

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Dulera is NOT indicated for the relief of acute bronchospasm.

#### Symbicort

##### **Treatment of Asthma**

Symbicort is indicated for the treatment of asthma in patients 6 years of age and older. Symbicort should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long-acting beta2-adrenergic agonist (LABA).

##### **Maintenance Treatment of Chronic Obstructive Pulmonary Disease (COPD)**

Symbicort 160/4.5 is indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema. Symbicort 160/4.5 is also indicated to reduce exacerbations of COPD. Symbicort 160/4.5 is the only strength indicated for the treatment of COPD.

##### **Important Limitations of Use:**

Symbicort is NOT indicated for the relief of acute bronchospasm.

#### Symbicort Aerosphere

Symbicort Aerosphere is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### **Limitations of Use:**

Symbicort Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

##### **Long-Acting Beta2-Adrenergic Agonist / Anticholinergic / Corticosteroid:**

#### Breztri Aerosphere

Breztri Aerosphere is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### **Limitations of Use:**

Breztri Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

#### Trelegy Ellipta

##### **Maintenance Treatment of Chronic Obstructive Pulmonary Disease**

Trelegy Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

##### **Maintenance Treatment of Asthma**

Trelegy Ellipta is indicated for the maintenance treatment of asthma in patients aged 18 years and older.

##### **Limitations of Use**

Trelegy Ellipta is NOT indicated for the relief of acute bronchospasm.

#### **Compendial Uses**

Symbicort, Dulera: maintenance and reliever therapy<sup>20-23</sup>

<b>INITIAL LIMIT QUANTITY LONG-ACTING BETA2-ADRENERGIC AGONIST:</b>				
<b>Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength</b>				
<b>PLEASE NOTE:</b> Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.				
<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Month Limit*</b>
Brovana (arformoterol tartrate)	nebulization of 1 vial (2 mL) twice daily	2 vials (2 mL each)	30 vials (2 mL each) per carton	2 packages (60 vials x 2 mL) / 25 days 6 packages (180 vials x 2 mL) / 75 days
			60 vials (2 mL each) per carton	1 package (60 vials x 2 mL) / 25 days 3 packages (180 vials x 2 mL) / 75 days
Perforomist (formoterol)	nebulization of 1 vial (2 mL)	2 vials (2 mL each)	30 vials (2 mL each) per carton	2 packages (60 vials x 2 mL) / 25 days 6 packages (180 vials x 2 mL) / 75 days

	twice daily		60 vials (2 mL each) per carton	1 package (60 vials x 2 mL) / 25 days 3 packages (180 vials x 2 mL) / 75 days
Serevent Diskus (salmeterol)	1 inhalation twice daily	2 inhalations	60 blisters per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days
Striverdi Respimat (olodaterol)	2 inhalations once daily	2 inhalations	60 inhalations per 4 gm cartridge	1 package (4 gm) / 25 days 3 packages (4 gm each) / 75 days

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

#### **INITIAL LIMIT QUANTITY LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC:**

**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Month Limit*</b>
Anoro Ellipta (umeclidinium/ vilanterol)	1 inhalation once daily	1 inhalation	30 inhalations (60 blisters) per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days
Bevespi Aerosphere (glycopyrrolate/ formoterol)	2 inhalations twice daily	4 inhalations	120 inhalations per 10.7 gm canister	1 package (10.7 gm) / 25 days 3 packages (10.7 gm each) / 75 days
Duaklir Pressair (aclidinium/ formoterol)	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Stiolto Respimat (tiotropium bromide/ olodaterol)	2 inhalations once daily	2 inhalations	60 inhalations per 4 gm cartridge	1 package (4 gm) / 25 days 3 packages (4 gm each) / 75 days

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

#### **INITIAL LIMIT QUANTITY LONG-ACTING BETA2-ADRENERGIC AGONIST / CORTICOSTEROID:**

**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Month Limit*</b>
Advair Diskus (fluticasone propionate/ salmeterol)	1 inhalation twice daily	2 inhalations	60 blisters per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days
Advair HFA (fluticasone propionate/ salmeterol)	2 inhalations twice daily	4 inhalations	120 inhalations per 12 gm canister	1 package (12 gm) / 25 days 3 packages (12 gm each) / 75 days
AirDuo Digihaler (fluticasone propionate/ salmeterol)	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
AirDuo Respiclick (fluticasone propionate/ salmeterol)	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Breo Ellipta (fluticasone furoate/ vilanterol)	1 inhalation once daily	1 inhalation	30 inhalations (60 blisters) per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days

Dulera (mometasone/ formoterol)	2 inhalations twice daily	4 - 10 inhalations	120 inhalations per 13 gm canister	3 packages (13 gm each) / 25 days 9 packages (13 gm each) / 75 days
Symbicort (budesonide/ formoterol)	2 inhalations twice daily	4 - 12 inhalations	120 inhalations per 10.2 gm or 10.3 gm canister (depending on product)	3 packages (10.3 gm each) / 25 days 9 packages (10.3 gm each) / 75 days
Symbicort Aerosphere (budesonide/ formoterol)	2 inhalations twice daily	4 inhalations	120 inhalations per 10.7 gm canister	1 package (10.7 gm) / 25 days 3 packages (10.7 gm each) / 75 days
<i>*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.</i>				

#### **INITIAL LIMIT QUANTITY LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC / CORTICOSTEROID:**

**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

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<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Month Limit*</b>
Breztri Aerosphere (budesonide/ glycopyrrolate/ formoterol fumarate)	2 inhalations twice daily	4 inhalations	120 inhalations per 10.7 gm canister	1 package (10.7 gm) / 25 days 3 packages (10.7 gm each) / 75 days
Trelegy Ellipta (fluticasone furoate/ umeclidinium/ vilanterol)	1 inhalation once daily	1 inhalation	30 inhalations (60 blisters) per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days
<i>*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.</i>				

#### **REFERENCES**

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