

# QUANTITY LIMIT CRITERIA

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

**BRAND NAME**  
(generic)

**LONG-ACTING BETA2-ADRENERGIC AGONISTS:**

**ARCAPTA NEOHALER**  
(indacaterol)

**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)

**UTIBRON NEOHALER**  
(glycopyrrolate/indacaterol)

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

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

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

**AIRDUO**  
(fluticasone propionate/salmeterol)

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

**DULERA**  
(mometasone/formoterol)

**SYMBICORT**  
(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 Agonists:**

##### Arcapta Neohaler

Arcapta Neohaler is a long-acting beta -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.

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

##### 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.

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.

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 inhaled corticosteroid (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.

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.

#### *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).

#### Striverdi Respimat

Striverdi Respimat is a long-acting beta2-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.

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 indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Anoro Ellipta is NOT indicated for the treatment of asthma. The safety and efficacy of Anoro Ellipta in asthma have not been established.

#### Bevespi Aerosphere

Bevespi Aerosphere is a combination of glycopyrrolate and formoterol fumarate indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Bevespi Aerosphere is not indicated for the treatment of asthma.

#### Duaklir Pressair

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

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.

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

#### Utibron Neohaler

Utibron Neohaler is a combination of indacaterol and glycopyrrolate indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Utibron Neohaler is NOT indicated for the treatment of asthma.

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

#### 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-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.

#### Advair HFA

Advair HFA is indicated for the twice-daily treatment of asthma in 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 -adrenergic agonist (LABA).

#### AirDuo Digihaler

AirDuo Digihaler is indicated for the treatment of asthma in 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 beta2 adrenergic agonist (LABA).

#### AirDuo Respiclick

AirDuo Respiclick is indicated for the treatment of asthma in 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 adrenergic agonist (LABA).

#### Breo Ellipta

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

Breo Ellipta 100/25 is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo Ellipta 100/25 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. Breo Ellipta 100/25 once daily is the only strength indicated for the treatment of COPD.

##### *Treatment of Asthma*

Breo Ellipta is indicated for the once-daily treatment of asthma in patients aged 18 years and older. Breo Ellipta 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 -adrenergic agonist (LABA).

#### 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 beta2-adrenergic agonist (LABA).

#### 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 beta -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.

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

#### Breztri Aerosphere

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

#### Trelegy Ellipta

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

Trelegy Ellipta 100/62.5/25 mcg 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.

### **Important Limitations of Use**

LABAs are NOT indicated for the relief of acute bronchospasm.

LABAs are NOT indicated to treat acute deteriorations of chronic obstructive pulmonary disease.

## REFERENCES

1. Advair Diskus [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair HFA [package insert]. Research Triangle Park, NC: GlaxoSmithKline; February 2019.
3. AirDuo Digihaler [package insert]. Frazer, PA: Teva Respiratory, LLC; July 2019.
4. AirDuo Respiclick [package insert]. Frazer, PA: Teva Respiratory, LLC; November 2018.
5. Anoro Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2019.
6. Arcapta Neohaler [package insert]. Marlborough MA: Sunovion Pharmaceuticals Inc.; May, 2019.
7. Bevespi Aerosphere [package insert]. Wilmington, DE: AstraZeneca; May 2019.
8. Breo Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
9. Breztri Aerosphere [package insert]. Wilmington, DE: AstraZeneca; July 2020.
10. Brovana [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; May 2019.
11. Duaklir Pressair [package insert]. Morrisville, NC: Circassia Pharmaceuticals Inc.; March 2019.
12. Dulera [package insert]. Whitehouse Station, NJ: Schering Corp/MSD; August 2019.
13. Perforomist [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2019.
14. Serevent Diskus [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2019.
15. Stiolto Resimat [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2019.
16. Striverdi Resimat [package insert.] Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals, Inc.: May 2019.
17. Symbicort [package insert]. Wilmington, DE: AstraZeneca. July 2019.
18. Trelegy Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
19. Utibron Neohaler [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.

<b>LIMIT CRITERIA LONG-ACTING BETA2-ADRENERGIC AGONISTS:</b>				
<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Months Limit*</b>
Arcapta Neohaler	inhalation of the powder contents of 1 capsule once daily	1 capsule	30 capsules per box	1 package (30 capsules) / 25 days 3 packages (30 capsules each) / 75 days
Brovana	nebulization of 1 vial (2mL) twice daily	2 vials (2mL each)	30 vials (2mL each) per carton	2 packages (60 vials x 2mL) / 25 days 6 packages (180 vials x 2mL) / 75 days
			60 vials (2mL each) per carton	1 package (60 vials x 2mL) / 25 days 3 packages (180 vials x 2mL) / 75 days
Perforomist	nebulization of 1 vial (2 mL) twice daily	2 vials (2mL each)	30 vials (2mL each) per carton	2 packages (60 vials x 2mL) / 25 days 6 packages (180 vials x 2mL) / 75 days
			60 vials (2mL each) per carton	1 package (60 vials x 2mL) / 25 days 3 packages (180 vials x 2mL) / 75 days
Serevent Diskus	1 inhalation twice daily	2 inhalations	60 blisters per inhaler	1 package (60 blisters) / 25 days 3 packages (60 blisters each) / 75 days
Striverdi Resimat	2 inhalations once daily	2 inhalations	60 inhalations per 4gm cartridge	1 package (4gm) / 25 days 3 packages (4gm each) / 75 days

<b>LIMIT CRITERIA LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC:</b>				
<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit* 3 Months Limit*</b>
Anoro Ellipta	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	2 inhalations twice daily	4 inhalations	120 inhalations per 10.7gm canister	1 package (10.7gm) / 25 days 3 packages (10.7gm each) / 75 days
Duaklir Pressair	1 inhalation twice daily	2 inhalations	30 inhalations per inhaler	2 packages (30 inh each) / 25 days 6 packages (30 inh each) / 75 days
			60 inhalations per inhaler	1 package (60 inh) / 25 days 3 packages (60 inh each) / 75 days

Stiolto Respimat	2 inhalations once daily	2 inhalations	60 inhalations per 4gm cartridge	1 package (4gm) / 25 days 3 packages(4gm each) / 75 days
Utibron Neohaler	1 inhalation twice daily	2 inhalations	60 capsules per box	1 package (60 capsules) / 25 days 3 packages (60 capsules each) / 75 days

**LIMIT CRITERIA LONG-ACTING BETA2-ADRENERGIC AGONIST / CORTICOSTEROIDS:**

Medication*	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit* 3 Months Limit*
Advair Diskus	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	2 inhalations twice daily	4 inhalations	120 inhalations per 12gm canister	1 package (12gm) / 25 days 3 packages (12gm each) / 75 days
AirDuo Digihaler	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
AirDuo Respiclick	1 inhalation twice daily	2 inhalations	60 inhalations per inhaler	1 package / 25 days 3 packages / 75 days
Breo Ellipta	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	2 inhalations twice daily	4 inhalations	120 inhalations per 13gm canister	1 package (13gm) / 25 days 3 packages (13gm each) / 75 days
Symbicort	2 inhalations twice daily	4 inhalations	120 inhalations per 10.2gm canister	1 package (10.2gm) / 25 days 3 packages (10.2gm each) / 75 days

**LIMIT CRITERIA LONG-ACTING BETA2-ADRENERGIC AGONIST / ANTICHOLINERGIC / CORTICOSTEROIDS:**

Medication*	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit* 3 Months Limit*
Breztri Aerosphere	2 inhalations twice daily	4 inhalations	120 inhalations per 10.7gm canister	1 package (10.7gm) / 25 days 3 packages (10.7gm each) / 75 days
Trelegly Ellipta	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

\*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.

\*The limit criteria apply to both brand and generic, if available.