

QUANTITY LIMIT CRITERIA

DRUG CLASS COMBINATIONS LONG ACTING BETA2-ADRENERGIC AGONIST,
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)

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)

Beta Agonists-Long Acting Combination Oral Inhalation Limit Policy 34-H11-2017

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AIRDUO RESPICLICK
(fluticasone propionate/salmeterol)

BREO ELLIPTA
(fluticasone furoate/vilanterol)

DULERA
(mometasone/formoterol)

SYMBICORT
(budesonide/formoterol)

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

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 a long-term asthma control medication, such as an inhaled corticosteroid, in patients aged 4 years and older with reversible obstructive airway disease, including patients with symptoms of nocturnal asthma.

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 a long-term asthma control medication, such as an inhaled corticosteroid.

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 beta β -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 is a combination anticholinergic/long-acting beta β -adrenergic agonist (anticholinergic/LABA) 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.

Anoro Ellipta is NOT indicated for the treatment of asthma.

Bevespi Aerosphere

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

Bevespi Aerosphere is not indicated 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 airflow obstruction in 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 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 12 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:

Trelegy Ellipta

Trelegy Ellipta is a combination inhaled corticosteroid/anticholinergic/long-acting beta-adrenergic agonist indicated for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in

whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol. Trelegy Ellipta is NOT indicated for the treatment of asthma.

Important Limitations of Use

LABAs are NOT indicated for the relief of acute bronchospasm.

REFERENCES

1. Advair Diskus [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
2. Advair HFA [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
3. AirDuo Resplick [package insert]. Frazer, PA: Teva Respiratory, LLC; January 2018.
4. Anoro Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2017.
5. Arcapta Neohaler [package insert]. Marlborough MA: Sunovion Pharmaceuticals Inc.; March, 2017.
6. Bevespi Aerosphere [package insert]. Wilmington, DE: AstraZeneca; August 2017.
7. Breo Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
8. Brovana [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; February 2014.
9. Dulera [package insert]. Whitehouse Station, NJ: Schering Corp/MSD; December 2017.
10. Perforomist [package insert]. Napa, CA: Dey Pharmaceuticals; March 2013.
11. Serevent Diskus [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2016.
12. Stiolto Respimat [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016.
13. Striverdi Respimat [package insert.] Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals, Inc.: June 2016.
14. Symbicort [package insert]. Wilmington, DE: AstraZeneca. December 2017.
15. Trelegy Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2017.
16. Utibron Neohaler [package insert]. Marlborough MA: Sunovion Pharmaceuticals Inc.; November 2017.

LIMIT CRITERIA LONG-ACTING BETA2-ADRENERGIC AGONISTS:

Medication*	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit* 3 Months Limit*
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 60 vials (2mL each) per carton	2 packages (60 vials x 2mL) / 25 days 6 packages (180 vials x 2mL) / 75 days 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 60 vials (2mL each) per carton	2 package (60 vials x 2mL) / 25 days 6 packages (180 vials x 2mL) / 75 days 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 Respimat	2 inhalations once daily	2 inhalations	60 inhalations per 4gm cartridge	1 package (4gm) / 25 days 3 packages (4gm each) / 75 days

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

Medication*	Maintenance Dose	Maximum Daily Dose	Package Size	1 Month Limit* 3 Months Limit*
Anoro Ellipta	1 inhalation	1 inhalation	30 inhalations/60 blisters	1 package (60 blisters) / 25 days

	once daily		per inhaler	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
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 (180 capsules / 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 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*
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.*