

DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Pulmonary – Corticosteroid/Long-Acting Beta₂-Agonist Combination Inhalers Drug Quantity Management Policy – Per Rx
- Advair Diskus[®] (fluticasone propionate/salmeterol inhalation powder – GlaxoSmithKline, generic [including Wixela Inhub[®]])
 - Advair[®] HFA (fluticasone propionate/salmeterol inhalation aerosol – GlaxoSmithKline)
 - AirDuo[®] Digihaler[™] (fluticasone propionate/salmeterol inhalation powder – Teva)
 - AirDuo[®] RespiClick[®] (fluticasone propionate/salmeterol inhalation powder – Teva, generic)
 - Breo[®] Ellipta[®] (fluticasone furoate/vilanterol inhalation powder – GlaxoSmithKline; generic)
 - Dulera[®] (mometasone furoate/formoterol fumarate inhalation aerosol – Merck)
 - Symbicort[®] (budesonide/formoterol fumarate inhalation aerosol – AstraZeneca, generic)

REVIEW DATE: 01/11/2023

OVERVIEW

All of the inhaled corticosteroid (ICS) and long-acting beta₂-agonist (LABA) combination inhalers are indicated for the **treatment of asthma**.¹⁻⁷ Breo Ellipta is indicated in patients ≥ 18 years of age; Advair HFA, AirDuo RespiClick, and AirDuo Digihaler are indicated in patients ≥ 12 years of age. Symbicort, Dulera, and Advair Diskus are indicated in patients ≥ 6 years of age, ≥ 5 years of age, and ≥ 4 years of age, respectively.

- Advair Diskus, Symbicort, and Breo Ellipta are also approved for the **maintenance treatment of chronic obstructive pulmonary disease (COPD) and to reduce COPD exacerbations**.

Dosing/Availability

Dosing and Availability of the ICS/LABA combination inhalers is in Table 1.

Table 1. Dosing and Availability of the ICS/LABA Combination Products.¹⁻⁷

Brand (generic)	Dosage Form	Available Strength(s)	Doses per Package	Asthma Dosing	COPD Dosing
Advair Diskus [®] (fluticasone propionate/salmeterol inhalation powder, generic [including Wixela Inhub])	DPI	100/50 mcg	14 blisters/inhaler* 60 blisters/inhaler	≥ 12 years of age: one inhalation BID (initial dose based on asthma severity and previous therapy). • Max dose: one inhalation of 500/50 mcg BID. 4 to 11 years of age: One inhalation of 100/50 mcg BID.	One inhalation of 250/50 mcg BID.
		250/50 mcg	14 blisters/inhaler* 60 blisters/inhaler		
		500/50 mcg	14 blisters/inhaler* 60 blisters/inhaler		
Advair [®] HFA (fluticasone propionate/salmeterol inhalation aerosol)	pMDI	45/21 mcg	60 inhalations/canister* 120 inhalations/canister	≥ 12 years of age: Two inhalations BID (initial dose based on asthma severity and previous therapy) • Max dose: two inhalations of 230/21 mcg BID.	NA
		115/21 mcg	60 inhalations/canister* 120 inhalations/canister		
		230/21 mcg	60 inhalations/canister* 120 inhalations/canister		

Table 1 (continued). Dosing and Availability of the ICS/LABA Combination Products.¹⁻⁷

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Brand (generic)	Dosage Form	Available Strength(s)	Doses per Package	Asthma Dosing	COPD Dosing
AirDuo [®] Digihaler™ (fluticasone propionate/ salmeterol inhalation powder)	DPI w/ a built in electronic module	55/14 mcg	60 actuations/canister	≥ 12 years of age: One inhalation BID (initial dose based on asthma severity and previous therapy) • Max dose: One inhalation of 232/14 mcg BID.	NA
		113/14 mcg	60 actuations/canister		
		232/14 mcg	60 actuations/canister		
AirDuo RespiClick [®] (fluticasone propionate/ salmeterol inhalation powder, authorized generic)	DPI	55/14 mcg	60 actuations/canister	≥ 12 years of age: One inhalation BID (initial dose based on asthma severity and previous therapy). • Max dose: One inhalation of 232/14 mcg BID.	NA
		113/14 mcg	60 actuations/canister		
		232/14 mcg	60 actuations/canister		
Breo [®] Ellipta [®] (fluticasone furoate/ vilanterol inhalation powder, authorized generic)	DPI	100/25 mcg	14 inhalations (28 blisters)/canister* 30 inhalations (60 blisters)/canister	≥ 18 years of age: One inhalation QD (initial dose based on asthma severity and previous therapy). • Max dose: One inhalation of 200/25 mcg QD	One inhalation of 100/25 mcg QD
		200/25 mcg	14 inhalations (28 blisters)/canister* 30 inhalations (60 blisters)/canister		
Dulera [®] (mometasone furoate/ formoterol fumarate inhalation aerosol)	pMDI	50/5 mcg	120 inhalations/canister	≥ 12 years of age: Two inhalations BID (initial dose based on asthma severity and previous therapy). • Max dose: Two inhalations of 200/5 mcg BID. 5 to < 12 years of age: Two inhalations BID of 50/5mcg.	NA
		100/5 mcg	60 inhalations/canister* 120 inhalations/canister		
		200/5 mcg	60 inhalations/canister* 120 inhalations/canister		
Symbicort [®] (budesonide/ formoterol fumarate inhalation aerosol, authorized generic)	pMDI	80/4.5 mcg	60 inhalations/canister* 120 inhalations/canister	≥ 12 years of age: Two inhalations BID (initial dose based on asthma severity and previous therapy). • Max dose: Two inhalations of 160/4.5 mcg BID. ≥ 6 years of age: Two inhalations of 80/4.5 mcg BID.	Two inhalations of 160/4.5 mcg BID
		160/4.5 mcg	60 inhalations/canister* 120 inhalations/canister		

ICS – Inhaled corticosteroid; LABA – Long-acting beta₂-agonist; COPD – Chronic obstructive pulmonary disease; DPI – Dry-powder inhaler; * Institutional pack; BID – Twice daily; pMDI – Pressurized metered-dose inhaler; NA – Not applicable; QD – Once daily.

Guidelines

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention (2022) recommends low-dose ICS/formoterol as the preferred initial asthma reliever therapy for the majority of symptomatic patients ≥ 12 years of age.⁸ In patients with more severe symptoms, a medium-dose ICS/formoterol is recommended to be used as both reliever and maintenance therapy. Of note, the two ICS/LABA combination inhalers containing and ICS with formoterol that are available in the US are Symbicort and Dulera, neither of which is FDA-approved to be dosed “as needed”. However, the vast majority of the data to support this dosing is with Symbicort’s active ingredients, budesonide and formoterol. Therefore, an exception is provided below for Symbicort for patients who are using it according to these guideline recommendations.

POLICY STATEMENT

01/11/2023

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This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of the corticosteroid/long-acting beta₂-agonist combination inhalers. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Brand (generic)	Strength	Package Size(s)	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Advair (fluticasone propionate/salmeterol powder, [including Inhub])	100/50 mcg	14 blisters/inhaler*	1 inhaler	3 inhalers
		60 blisters/inhaler	1 inhaler	3 inhalers
	250/50 mcg	14 blisters/inhaler*	1 inhaler	3 inhalers
		60 blisters/inhaler	1 inhaler	3 inhalers
	500/50 mcg	14 blisters/inhaler*	1 inhaler	3 inhalers
		60 blisters/inhaler	1 inhaler	3 inhalers
Advair [®] (fluticasone propionate/salmeterol aerosol)	45/21 mcg	60 inhalations/canister (8 g)*	8 grams (1 inhaler)	24 grams (3 inhalers)
		120 inhalations/canister (12 g)	12 grams (1 inhaler)	36 grams (3 inhalers)
	115/21 mcg	60 inhalations/canister (8 g)*	8 grams (1 inhaler)	24 grams (3 inhalers)
		120 inhalations/canister (12 g)	12 grams (1 inhaler)	36 grams (3 inhalers)
	230/21 mcg	60 inhalations/canister (8 g)*	8 grams (1 inhaler)	24 grams (3 inhalers)
		120 inhalations/canister (12 g)	12 grams (1 inhaler)	36 grams (3 inhalers)
AirDuo [®] (fluticasone propionate/salmeterol powder)	55/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
	113/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
	232/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
AirDuo (fluticasone propionate/salmeterol powder, generic)	55/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
	113/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
	232/14 mcg	60 actuations/canister	1 inhaler	3 inhalers
Breo [®] (fluticasone vilanterol powder, generic)	100/25 mcg	14 inhalations (28 blisters)/canister*	28 blisters (1 inhaler)	84 blisters (3 inhalers)
		30 inhalations (60 blisters)/canister	60 blisters (1 inhaler)	180 blisters (3 inhalers)
	200/25 mcg	14 inhalations (28 blisters)/canister*	28 blisters (1 inhaler)	84 blisters (3 inhalers)
		30 inhalations (60 blisters)/canister	60 blisters (1 inhaler)	180 blisters (3 inhalers)
Dulera [®] (mometasone furoate/fumarate aerosol)	50/5 mcg	120 inhalations/canister (13 g)	1 inhaler (13 grams)	3 inhalers (39 grams)
	100/5 mcg	60 inhalations/canister (8.8g)*	1 inhaler (9 grams)	3 inhalers (27 grams)
		120 inhalations/canister (13 g)	1 inhaler (13 grams)	3 inhalers (39 grams)
	200/5 mcg	60 inhalations/canister (8.8 g)*	1 inhaler (9 grams)	3 inhalers (27 grams)
		120 inhalations/canister (13 g)	1 inhaler (13 grams)	3 inhalers (39 grams)
Symbicort [®] (budesonide/formoterol fumarate inhalation aerosol, authorized generic)	80/4.5 mcg	60 inhalations/canister (6.9 g)*	7 grams (1 inhaler)	21 grams (3 inhalers)
		120 inhalations/canister (10.2 g)	11 grams (1 inhaler)	31 grams (3 inhalers)
	160/4.5 mcg	60 inhalations/canister (6 g)*	6 grams (1 inhaler)	18 grams (3 inhalers)
		120 inhalations/canister (10.2 g)	11 grams (1 inhaler)	31 grams (3 inhalers)

* Institutional pack.

CRITERIA

Budesonide/formoterol 80/4.5 mcg and 160/4.5 mcg inhalation aerosol (Symbicort, authorized generic)

1. If the patient has asthma and is using budesonide/formoterol (Symbicort, authorized generic) as a reliever therapy, approve the requested quantity not to exceed 2 inhalers per dispensing at retail or 4 inhalers per dispensing at home delivery.

All other corticosteroid/long-acting beta₂-agonist combination inhalers

No overrides recommended.

REFERENCES

1. Advair Diskus[®] inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair[®] HFA inhalation aerosol [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
3. Symbicort[®] inhalation aerosol [prescribing information]. Wilmington, DE: AstraZeneca; December 2017.
4. Dulera[®] inhalation aerosol [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
5. Breo[®] Ellipta[®] inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
6. AirDuo[®] RespiClick[®] inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; July 2021.
7. AirDuo[®] Digihaler[®] inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; July 2021.
8. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2022. Accessed on December 28, 2022. Available at: <http://www.ginasthma.org>.