



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, generic)
 - 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 [including Breyna[®]])

REVIEW DATE: 01/17/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

All of the inhaled corticosteroid (ICS) and long-acting beta₂-agonist (LABA) combination inhalers are indicated for the **treatment of asthma**.¹⁻⁷ Age indications vary and are outlined on Table 1.

- 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)	Dose Form	Available Strength (s)	Doses per Package	Asthma Dosing/ Age Indications	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.	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	4 to 11 years of age: One inhalation of 100/50 mcg BID.	
Advair® HFA (fluticasone propionate/salmeterol inhalation aerosol, authorized generic)	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

Brand (generic)	Dosage Form	Available Strength(s)	Doses per Package	Asthma Dosing/ Age Indications	COPD Dosing
AirDuo® Digihaler™ (fluticasone propionate/ salmeterol inhalation powder)	DPI w/ a built in electron ic module	55/14 mcg	60 actuations/c anister	≥ 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/c anister		
		232/14 mcg	60 actuations/c anister		
AirDuo RespiClick® (fluticasone propionate/ salmeterol inhalation powder, authorized generic)	DPI	55/14 mcg	60 actuations/c anister	≥ 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/c anister		
		232/14 mcg	60 actuations/c anister		
Breo® Ellipta® (fluticasone furoate/vilanterol inhalation powder, authorized generic)	DPI	50/25 mcg	30 inhalations (60 blisters)/can ister	≥ 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. <i>12 to 17 years of age:</i> One inhalation of 100/25 mg QD. <i>5 to < 12 years of age:</i> One inhalation of 50/25 mcg QD.	One inhalation of 100/25 mcg QD
		100/25 mcg	14 inhalations (28 blisters)/can ister* 30 inhalations (60 blisters)/can ister		
		200/25 mcg	14 inhalations (28 blisters)/can ister* 30 inhalations (60 blisters)/can ister		
Dulera® (mometasone)	pMDI	50/5 mcg	120 inhalations/c anister	≥ 12 years of age: Two inhalations BID (initial dose based on	NA

Brand (generic)	Dosage Form	Available Strength(s)	Doses per Package	Asthma Dosing/ Age Indications	COPD Dosing
furoate/for moterol fumarate inhalation aerosol)		100/5 mcg	60 inhalations/c anister* 120 inhalations/c anister	asthma severity and previous therapy). • Max dose: Two inhalations of 200/5 mcg BID.	
		200/5 mcg	60 inhalations/c anister* 120 inhalations/c anister	<i>5 to < 12 years of age:</i> Two inhalations BID of 50/5mcg.	
Symbicort® (budesonid e/ formoterol fumarate inhalation aerosol, generic [including Breyna])	pMDI	80/4.5 mcg	60 inhalations/c anister* 120 inhalations/c anister	<i>≥ 12 years of age:</i> Two inhalations BID (initial dose based on asthma severity and previous therapy). • Max dose: Two inhalations of 160/4.5 mcg BID.	Two inhalation s of 160/4.5 mcg BID
		160/4.5 mcg	60 inhalations/c anister* 120 inhalations/c anister	<i>≥ 6 years of age:</i> Two inhalations of 80/4.5 mcg BID.	

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 (2023) recommends low-dose ICS/formoterol as the preferred initial asthma reliever therapy and subsequently as maintenance and reliever therapy, if necessary. The two ICS/LABA combination inhalers containing and ICS with formoterol that are available in the US are budesonide/formoterol inhalation aerosol (Symbicort, generic [including Breyna]) and Dulera. For this “off-label” use, ICS/formoterol products may be dosed at 1 to 2 inhalations as needed for asthma symptoms at a maximum dose of 54 mcg of formoterol per day.⁹ An override to quantity limits is provided for patients using the product “as needed”, providing an extra inhaler (i.e., 2 inhalers at retail or 4 inhalers at home delivery) to accommodate the increased dosing.

POLICY STATEMENT

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.

Drug Quantity Limits

Brand (generic)	Strength	Package Size(s)	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx	
Advair Diskus® (fluticasone propionate/ salmeterol inhalation powder, generic [including Wixela 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® HFA (fluticasone propionate/ salmeterol inhalation aerosol, authorized generic)	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® Digihaler™ (fluticasone propionate/ salmeterol inhalation 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 RespiClick® (fluticasone propionate/ salmeterol inhalation powder, authorized 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® Ellipta® (fluticasone furoate/ vilanterol inhalation)	50/25 mcg	30 inhalations (60 blisters)/canister	60 blisters (1 inhaler)	180 blisters (3 inhalers)	
	100/25 mcg	14 inhalations (28 blisters)/canister*	28 blisters (1 inhaler)	84 blisters (3 inhalers)	

Brand (generic)	Strength	Package Size(s)	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
powder, authorized generic)		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)

Drug Quantity Limits (continued)

Brand (generic)	Strength	Package Size(s)	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Dulera® (mometasone furoate/formoterol fumarate inhalation aerosol)	50/5 mcg	120 inhalations/canister (13 g)	1 inhaler (13 grams)	3 inhalers (39 grams)
		60 inhalations/canister (8.8g)*	1 inhaler (9 grams)	3 inhalers (27 grams)
	200/5 mcg	120 inhalations/canister (13 g)	1 inhaler (13 grams)	3 inhalers (39 grams)
		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)
		60 inhalations/canister (8.8 g)*	1 inhaler (9 grams)	3 inhalers (27 grams)
Symbicort® (budesonide/formoterol fumarate inhalation aerosol, generic [including Breyna])	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.

Pulmonary – Corticosteroid/Long-Acting Beta2-Agonist Combination Inhalers Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Budesonide/formoterol 80/4.5 mcg and 160/4.5 mcg inhalation aerosol (Symbicort, generic [including Breyna])

1. If the patient has asthma and is using budesonide/formoterol (Symbicort, generic [including Breyna]) 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.

Dulera 50/5 mcg and 100/5 mcg inhalation aerosol

1. If the patient has asthma and is using Dulera 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; May 2023.
6. AirDuo[®] RespiClick[®] inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; September 2022.
7. AirDuo[®] Digihaler[®] inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; September 2022.
8. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2023. Accessed on January 5, 2024. Available at: <http://www.ginasthma.org>.
9. Micromedex[®] Healthcare Series. Thomson Reuters (Healthcare) Inc. Available at: <http://www.thomsonhc.com>. Accessed on January 5, 2024. Search terms: Dulera and Symbicort.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Existing quantity limits for the Corticosteroid/Long-Acting Beta ₂ -Agonist were previously in place. Policy created to provide override for budesonide/formoterol 80/4.5 mcg and 160/4.5 mcg inhalation aerosol (Symbicort, authorized generic) for a patient who has asthma and is using this product as a reliever therapy.	01/11/2023
Annual Revision	<p>Authorized generic to Advair HFA was added to the policy. Existing quantity limits for Advair HFA apply to the authorized generic product.</p> <p>Authorized generic to Symbicort was removed from the policy (obsolete). Generics to Symbicort (including Breyndra) were added. Existing quantity limits and overrides for Symbicort apply to the generic products.</p> <p>Dulera 50/5 mcg and 100/5 mcg inhalation aerosol: A new override was added for a patient to obtain 2 inhalers per dispensing at home delivery or 4 inhalers per dispensing at retail if they have asthma and are using this product as a reliever therapy.</p>	01/17/2024

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