

Texas Vendor Drug Program

Drug Use Criteria: Aerosolized Agents - Metered-Dose Inhalers: Anti-Inflammatory Drugs

Publication History

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Notes: Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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TEXAS
Health and Human
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1 Dosage

Because asthma is comprised of both inflammatory and bronchoconstrictive components, asthma treatment plans include routine use of inhaled corticosteroids (ICS) to manage inflammatory processes in asthma patients requiring chronic treatment. Higher ICS doses may contribute to a decrease in linear growth velocity in children, but adult height does not appear to be significantly inhibited following ICS use in childhood. All ICS doses may contribute to decreased bone formation in children and bone mineral density in adults. Close monitoring of growth and bone formation markers in children and fracture risk in adults is warranted with long-term ICS use. The lowest effective ICS dose should be utilized for the shortest required period.

1.1 Adults

Maximum recommended adult orally inhaled doses for available aerosolized corticosteroids as individual agents are summarized in Table 1. Prescribed dosages exceeding these recommendations will be reviewed.

Table 1. Maximum Daily Recommended Adult Doses for ICS as Monotherapy in Asthma

Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
beclomethasone dipropionate HFA (QVAR® Redihaler)	inhalation aerosol: 40 mcg/actuation	16 actuations/day in divided doses (8 actuations twice daily); total dose = 640 mcg/day
	inhalation aerosol: 80 mcg/actuation	8 actuations/day in divided doses (4 actuations twice daily); total dose = 640 mcg/day
budesonide (Pulmicort Flexhaler®)	inhalation powder: 90 mcg/actuation	16 actuations/day in divided doses (8 actuations twice daily); total dose = 1440 mcg/day
	inhalation powder: 180 mcg/actuation	8 actuations/day in divided doses (4 actuations twice daily); total dose = 1440 mcg/day
ciclesonide (Alvesco®)	inhalation aerosol: 80 mcg/actuation	prior therapy with bronchodilators alone: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/day
		prior therapy with ICS, oral corticosteroids: 8 (4 actuations twice daily); total dose = 640 mcg/day

Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
	inhalation aerosol: 160 mcg/actuation	prior therapy with bronchodilators alone: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 320 mcg/day
		prior therapy with ICS, oral corticosteroids: 160 mcg/actuation: 4 (2 actuations twice daily); total dose = 640 mcg/day
flunisolide HFA (Aerospan®)	aerosol solution: 80 mcg/actuation	8 actuations/day in divided doses (4 actuations twice daily); total dose = 640 mcg/day
fluticasone furoate (Arnuity® Ellipta®)	dry powder inhaler: 100 mcg/actuation	1 actuation once daily; total dose = 100 mcg/day*
	dry powder inhaler: 200 mcg/actuation	1 actuation once daily; total dose = 200 mcg/day*
fluticasone propionate HFA (Flovent® HFA)	inhalation aerosol: 44 mcg/actuation	no previous ICS: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 176 mcg/day
	inhalation aerosol: 110 mcg/actuation	prior therapy with bronchodilators alone, ICS: 16 actuations/day in divided doses (8 actuations twice daily); total dose = 1760 mcg/day
	inhalation aerosol: 220 mcg/actuation	prior therapy with bronchodilators alone, ICS: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 1760 mcg/day
		prior therapy with oral corticosteroids: 8 (4 actuations twice daily); total dose = 1760 mcg/day
fluticasone propionate (Flovent® Diskus)	inhalation powder: 100 mcg/actuation	total dose = 2000 mcg/day
	inhalation powder: 250 mcg/actuation	8 actuations/day in divided doses (4 actuations twice daily); total dose = 2000 mcg/day
fluticasone propionate (ArmonAir™ RespiClick®)	inhalation powder: 55 mcg/actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg
	inhalation powder: 113 mcg/actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg
	inhalation powder: 232 mcg/actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg
mometasone HFA (Asmanex® HFA)	inhalation aerosol: 100 mcg/actuation	prior therapy with medium-dose ICS: 4 actuations/day (2 actuations twice daily); total dose = 400 mcg/day
	inhalation aerosol: 200 mcg/actuation	prior therapy high-dose ICS, oral corticosteroids: 4 actuations/day (2 actuations twice daily); total dose = 800 mcg/day^

Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
mometasone (Asmanex® Twisthaler®)	inhalation powder: 110 mcg/actuation	prior therapy with bronchodilators alone, ICS: 4 actuations/day (4 actuations once daily in evening or 2 actuations twice daily); total dose = 440 mcg/day
		prior therapy with oral corticosteroids: 8 actuations/day in divided doses(4 actuations twice daily); total dose = 880 mcg/day
	inhalation powder: 220 mcg/actuation	prior therapy with bronchodilators alone, ICS: 2 actuations/day (2 actuations once daily in evening or 1 actuation twice daily); total dose = 440 mcg/day
		prior therapy with oral corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 880 mcg/day

- * initial fluticasone furoate dose in patients not on ICS is 100 mcg once/day; if 100 mcg not effective, dose should be increased to 200 mcg once/day
- ^ prednisone should be tapered slowly, beginning at least one week after mometasone use

ICS combined with LABAs are FDA-approved for use in adults and children as asthma maintenance therapy: fluticasone propionate/salmeterol metered aerosol (Advair® HFA) and mometasone/formoterol inhalation aerosol (Dulera®) are FDA-approved for use as maintenance therapy for asthma in patients 12 years of age and older, while fluticasone propionate/salmeterol inhalation powder (Advair Diskus®) is FDA-approved for use in asthma maintenance in patients 4 years of age and older. A newer fluticasone/salmeterol inhalation powder (AirDuo RespiClick®) that provides additional dosage strengths has been approved for use in asthma patients 12 years and older. Budesonide/formoterol inhalation aerosol (Symbicort®) and Advair Diskus® are FDA-approved for use in adults as COPD maintenance therapy. The newer combination agent, fluticasone/vilanterol (Breo® Ellipta®), is indicated for use in adults as maintenance therapy for COPD but are not FDA-approved for use in asthma. Additionally, a triple therapy inhaler containing fluticasone, umeclidinium and vilanterol (Trelegy® Ellipta®) has now been approved for COPD management to treat airway obstruction and reduce exacerbations. Advair Diskus® 250 mcg/50 mcg is the only fluticasone/salmeterol dose approved for use in adult patients with COPD, while budesonide/formoterol (Symbicort®) 160 mcg/4.5 mcg is the only recommended strength for COPD.

The maximum recommended orally inhaled doses for available aerosolized corticosteroids as combination therapy is summarized in Table 2. Prescribed dosages exceeding these recommendations will be reviewed.

Table 2. Maximum Adult Daily Recommended Doses for ICS as Combination Therapy for Asthma and COPD

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
asthma	budesonide/ formoterol (Symbicort®)	inhalation aerosol: 80 mcg/4.5 mcg/ actuation	4 actuations/day (2 actuations twice daily); total dose = 320 mcg/18 mcg/day
asthma		inhalation aerosol: 160 mcg/4.5 mcg/ actuation	4 actuations/day (2 actuations twice daily); total dose = 640 mcg/18 mcg/day
chronic obstructive pulmonary disease (COPD)			4 actuations/day (2 actuations twice daily); total dose = 640 mcg/18 mcg/day
asthma	fluticasone propionate/ salmeterol xinafoate (Advair® HFA)	inhalation aerosol: 45 mcg fluticasone/21 mcg salmeterol/ actuation	4 actuations/day (2 actuations twice daily); total dose = 180 mcg/84 mcg/day
		inhalation aerosol: 115 mcg fluticasone/21 mcg salmeterol/ actuation	4 actuations/day (2 actuations twice daily); total dose = 460 mcg/84 mcg/day
		inhalation aerosol: 230 mcg fluticasone/21 mcg salmeterol/ actuation	4 actuations/day (2 actuations twice daily); total dose = 920 mcg/84 mcg/day
asthma	fluticasone propionate/ salmeterol (Advair Diskus®)	inhalation powder: 100 mcg fluticasone/50 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 200 mcg/100 mcg/day
asthma		inhalation powder: 250 mcg fluticasone/50 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 500 mcg/100 mcg/day
COPD			2 actuations/day in divided doses (1 actuation twice daily); total dose = 500 mcg/100 mcg/day
asthma		inhalation powder: 500 mcg fluticasone/50 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 1000 mcg/100 mcg/day
asthma	fluticasone propionate/ salmeterol (AirDuo RespiClick®)	inhalation powder: 55 mcg fluticasone/14 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg/28 mcg/day

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
		inhalation powder: 113 mcg fluticasone/14 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg/28 mcg/day
		inhalation powder: 232 mcg fluticasone/14 mcg salmeterol/ actuation	2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg/28 mcg/day
COPD	fluticasone furoate/ umeclidinium/ vilanterol (Trelegy® Ellipta®)	inhalation powder: 100 mcg/ 62.5 mcg/ 25 mcg/inhalation	1 actuation/day; total dose = 100 mcg/62.5 mcg/ 25 mcg/day
asthma	fluticasone furoate/ vilanterol (Breo® Ellipta®)	inhalation powder: 100 mcg fluticasone/25 mcg vilanterol/ actuation	1 actuation/day; total dose = 100 mcg/25 mcg/day
		200 mcg fluticasone/ 25 mcg vilanterol/actuation	1 actuation/day; total dose = 200 mcg/25 mcg/day
COPD		inhalation powder: 100 mcg fluticasone/25 mcg vilanterol/ actuation	1 actuation/day; total dose = 100 mcg/25 mcg/day
asthma	mometasone/ formoterol (Dulera®)	inhalation aerosol: 100 mcg mometasone/5 mcg formoterol/ actuation	patients on medium-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 400 mcg/20 mcg/day
		inhalation aerosol: 200 mcg mometasone/ 5 mcg formoterol/ actuation	patients on high-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 800 mcg/20 mcg/day

- # Budesonide/formoterol, fluticasone/salmeterol inhalation aerosol only indicated for children greater than or equal to 12 years of age
- + Number of maximum actuations per day based on dose of salmeterol and formoterol, and independent of inhaled corticosteroid dose
- † Mometasone/formoterol inhalation aerosol only indicated for children greater than or equal to 12 years of age

1.2 Pediatrics

ICS as individual agents are FDA-approved for use in pediatric asthma management in children as young as 4 years of age. Pediatric therapy initiation differs by age for individual agents and is summarized in Table 3. Prescribed dosages exceeding these recommendations will be reviewed.

Table 3. Maximum Recommended Pediatric Doses for ICS as Monotherapy in Asthma

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
beclomethasone dipropionate HFA (QVAR® Redihaler)	inhalation aerosol: 40 mcg/actuation	children 4-11 years: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 160 mcg/day
		adolescents 12-17 years: 16 actuations/day in divided doses (8 actuations twice daily); total dose = 640 mcg/day
	inhalation aerosol: 80 mcg/actuation	children 4-11 years: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 160 mcg/day
		adolescents 12-17 years: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 640 mcg/day
budesonide (Pulmicort Flexhaler®)	inhalation powder: 90 mcg/actuation	children, adolescents 6-17 years: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 720 mcg/day
	inhalation powder: 180 mcg/actuation	children, adolescents 6-17 years: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 720 mcg/day
ciclesonide (Alvesco®)	inhalation aerosol: 80 mcg/actuation	adolescents 12-17 years: prior therapy with bronchodilators alone: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/day
		prior therapy with ICS, oral corticosteroids: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 640 mcg/day
	inhalation aerosol: 160 mcg/actuation	adolescents 12-17 years: prior therapy with bronchodilators alone: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 320 mcg/day
		prior therapy with ICS, oral corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 640 mcg/day
flunisolide (Aerospan®)	aerosol solution: 80 mcg/actuation	children 6-11 years: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/day
		adolescents 12-17 years: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 640 mcg/day
fluticasone furoate (Arnuity® Ellipta®)	dry powder inhaler: 50 mcg/actuation	children 5-11 years: 1 actuation once daily; total dose = 50 mcg/day
	dry powder inhaler: 100 mcg/actuation	adolescents 12-17 years: 1 actuation once daily; total dose = 100 mcg/day*
	dry powder inhaler: 200 mcg/actuation	adolescents 12-17 years: 1 actuation once daily; total dose = 200 mcg/day*

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
fluticasone propionate HFA (Flovent® HFA)	inhalation aerosol: 44 mcg/actuation	children 4-11 years: regardless of prior therapy: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 176 mcg/day
	inhalation aerosol: 110 mcg/actuation	adolescents 12-17 years: prior therapy with bronchodilators alone, ICS: 16 actuations/day in divided doses (8 actuations twice daily); total dose = 1760 mcg/day
fluticasone propionate (Flovent® Diskus®)	inhalation aerosol: 220 mcg/actuation	adolescents 12-17 years: prior therapy with bronchodilators alone, ICS: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 1760 mcg/day
	dry powder inhaler: 50 mcg/actuation	children 4-11 years: regardless of prior therapy: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 200 mcg/day
	dry powder inhaler: 100 mcg/actuation	children 4-11 years: regardless of prior therapy: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 200 mcg/day adolescents 12-17 years: total dose = 2000 mcg/day
	dry powder inhaler: 250 mcg/actuation	adolescents 12-17 years: 8 actuations/day in divided doses (4 actuations twice daily); total dose = 2000 mcg/day
fluticasone propionate (ArmonAir™RespiClick)	dry powder inhaler: 55 mcg/actuation	adolescents 12-17 years: no current corticosteroid therapy: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg
	dry powder inhaler: 113 mcg/actuation	adolescents 12-17 years: prior treatment with ICS: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg
	dry powder inhaler: 232 mcg/actuation	adolescents 12-17 years: prior treatment with ICS: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg
mometasone HFA (Asmanex® HFA)	inhalation aerosol: 100 mcg/actuation	adolescents 12-17 years: prior therapy with medium-dose ICS: 4 actuations/day (2 actuations twice daily); total dose = 400 mcg/day
	inhalation aerosol: 200 mcg/actuation	adolescents 12-17 years: prior therapy with high-dose ICS, oral corticosteroids: 4 actuations/day (2 actuations twice daily); total dose = 800 mcg/day^
mometasone (Asmanex® Twisthaler)	inhalation powder: 110 mcg/actuation	children 4-11 years: 1 actuation/day once daily in evening; total dose = 110 mcg/day

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
	inhalation powder: 220 mcg/actuation	adolescents 12-17 years: prior therapy with bronchodilators alone, ICS: 1 actuation twice daily or 2 actuations once daily; total dose = 440 mcg/day prior therapy with oral corticosteroids: 4 actuations/day (2 actuations twice daily); total dose = 880 mcg/day

- * initial fluticasone furoate dose in patients not on ICS is 100 mcg once/day; if 100 mcg not effective, dose should be increased to 200 mcg once daily
- ^ prednisone should be tapered slowly, beginning at least one week after mometasone use

Combined therapy with inhaled ICS and long-acting beta2-agonists is only FDA-approved for use in asthma treatment in children greater than or equal to 12 years of age; combined ICS/ long-acting beta2-agonist therapy as inhalation powder is FDA-approved for use in asthma management in children 4 years of age and older. Maximum recommended orally inhaled doses for available aerosolized corticosteroids as combination therapy are summarized in Table 4. Prescribed dosages exceeding these recommendations will be reviewed.

Table 4. Maximum Pediatric Recommended Doses for ICS as Combination Therapy for Asthma

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
budesonide/ formoterol (Symbicort®)	inhalation aerosol: 80 mcg/4.5 mcg/ actuation	6 to 11 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/18 mcg/day
		12-17 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/18 mcg/day
	inhalation aerosol: 160 mcg/4.5 mcg/actuation	12-17 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 640 mcg/18 mcg /day
fluticasone propionate/ salmeterol xinafoate (Advair® HFA)	inhalation aerosol: 45 mcg/21 mcg/ actuation	12-17 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 180 mcg/84 mcg/day

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
	inhalation aerosol: 115 mcg/21 mcg/ actuation	12-17 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 460 mcg/84 mcg/day
	inhalation aerosol: 230 mcg/21 mcg/ actuation	12-17 years of age: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 920 mcg /84 mcg/day
fluticasone propionate/ salmeterol (Advair Diskus®)	inhalation powder: 100 mcg/50 mcg/ actuation	4-11 years of age: 2 actuations/day (1 actuation twice daily); total dose = 200 mcg/100 mcg/day
	inhalation powder: 100 mcg/50 mcg/ actuation	12-17 years of age: 2 actuations/day (1 actuation twice daily); total dose = 200 mcg/100 mcg/day
	inhalation powder: 250 mcg/50 mcg/ actuation	12-17 years of age: 2 actuations/day (1 actuation twice daily); total dose = 500 mcg/100 mcg/day
	inhalation powder: 500 mcg/50 mcg/ actuation	12-17 years of age: 2 actuations/day (1 actuation twice daily); total dose = 1000 mcg/100 mcg/day
fluticasone propionate/ salmeterol (AirDuo RespiClick®)	inhalation powder: 55 mcg fluticasone/14 mcg salmeterol/ actuation	12-17 years of age: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg/28 mcg/day
	113 mcg fluticasone/14 mcg salmeterol/ actuation	12-17 years of age: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg/28 mcg/day
	232 mcg fluticasone/14 mcg salmeterol/ actuation	12-17 years of age: 2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg/28 mcg/day
mometasone/ formoterol (Dulera®)	inhalation aerosol: 100 mcg/5 mcg/ actuation	12-17 years of age: patients on medium-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 400 mcg/20 mcg/day

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
	200 mcg/5 mcg/ actuation	12-17 years of age: patients on high-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 800 mcg/20 mcg/day

- #Budesonide/formoterol, fluticasone/salmeterol inhalation aerosol only indicated for children greater than or equal to 12 years of age
- +Number of maximum actuations per day based on dose of salmeterol and formoterol, and independent of inhaled corticosteroid dose
- † Mometasone/formoterol inhalation aerosol only indicated for children greater than or equal to 12 years of age

2 Duration of Therapy

ICS, both as individual agents and as combination therapy, are FDA-approved for managing chronic asthma and COPD and may be continued indefinitely, as both COPD and asthma are chronic, lifelong processes. However, days supply per canister is limited based on the number of actuations per canister combined with the maximum recommended dose per day. Recommended days supply for available ICS as monotherapy or combined with long-acting beta2-agonists are summarized in Tables 5 and 6. Fluticasone is available as both the furoate and propionate salts; fluticasone propionate is available as three different formulations in three dosage strengths per formulation. Each dosage strength is associated with a maximum recommended dose (cited in Tables 1 and 3) which is used in combination with the number of actuations per drug canister to calculate days supply. A new fluticasone/salmeterol inhalation powder has also been approved for asthma management (AirDuo RespiClick®) with three different dosage formulations available; days supply can be calculated using dosages provided in Tables 2 and 4. Combined therapy with fluticasone furoate and vilanterol is available as two blister strips, with fluticasone in one strip and vilanterol in the second strip; similarly, triple therapy with fluticasone furoate, umeclidinium, and vilanterol is available as two blister strips, with fluticasone in one strip and umeclidinium and vilanterol in the second strip. Excessive use of ICS may be identified based on refill frequency. Inappropriate supply of ICS will be reviewed by monitoring refill requests.

Table 5. Days Supply+ for Available ICS as Monotherapy When Maximum Doses are Utilized (Adults and Children)

Drug Name	# of Actuations Per Canister	Days Supply (based on maximum dose per day)+
beclomethasone dipropionate HFA aerosol 40 mcg/actuation (10.6 g canister)	120	7.5 days (adult, adolescent) 30 days (child)
80 mcg/actuation (10.6 g canister)	120	15 days (adult, adolescent) 60 days (child)
budesonide inhalation powder 90 mcg/actuation	60	-- (adult) ~ 7.5 days (child)
180 mcg/actuation	120	15 days (adult) 30 days (child)
ciclesonide inhalation aerosol 80 mcg/actuation	60	BD alone: 15 days (adult, adolescents) ICS, OCS: 7.5 days (adults, adolescents)
160 mcg/actuation	60	BD alone: 30 days (adult, adolescents) ICS, OCS: 15 days (adults, adolescents)
flunisolide aerosol solution 80 mcg/actuation (5.1 g canister)	60	15 days (child) ~ 7.5 days (adolescent, adult)
80 mcg/actuation (8.9 g canister)	120	30 days (child) 15 days (adolescent, adult)
fluticasone furoate dry powder inhaler 50 mcg/actuation 30 blisters	30	30
100 mcg/actuation 30 blisters	30	30
200 mcg/actuation 30 blisters	30	30
fluticasone propionate HFA aerosol 44 mcg/actuation (10.6 g canister)	120	30 days (child)
110 mcg/actuation (12 g canister)	120	7.5 days (adults, adolescents)
220 mcg/actuation (12 g canister)	120	15 days (adults, adolescents)

Drug Name	# of Actuations Per Canister	Days Supply (based on maximum dose per day) +
fluticasone propionate dry powder inhaler (Diskus®) 50 mcg/actuation 60 blisters	60	15 days (child)
100 mcg/actuation 60 blisters	60	30 days (child)
250 mcg/actuation 60 blisters	60	7.5 days (adults, adolescents)
fluticasone propionate dry powder inhaler (RespiClick®) 55 mcg/actuation	60	30 (adults, adolescents)
113 mcg/actuation	60	30 (adults, adolescents)
232 mcg/actuation	60	30 (adults, adolescents)
mometasone inhalation aerosol 100 mcg/actuation	120	30 (adults, adolescents)
200 mcg/actuation	120	30 (adults, adolescents)
mometasone inhalation powder 110 mcg/actuation	7	7 (child)
	30	30 (child) BD alone, ICS: 7.5 days (adults, adolescents) OCS: 3.75 days (adults, adolescents)
mometasone inhalation powder 220 mcg/actuation 14 doses	14	BD alone, ICS: 7 days (adult, adolescents) OCS: 3.5 days (adults, adolescents)
30 doses	30	BD alone, ICS: 15 days (adult, adolescents) OCS: 7.5 days (adults, adolescents)
60 doses	60	BD alone, ICS: 30 days (adults, adolescents) OCS: 15 days (adults, adolescents)
120 doses	120	BD alone, ICS: 60 days (adults, adolescents) OCS: 30 days (adults, adolescents)

- + Calculated based on canister size and maximum dose allowed per day (summarized in Tables 1 and 3)
- * For more than 2 inhalations daily
- BD = bronchodilator
- ICS = inhaled corticosteroids
- OCS = oral corticosteroids

Table 6. Days Supply⁺ for Available ICS as Combination Therapy When Maximum Doses are Utilized (Adults and Children)

Drug	# of Actuations Per Canister	Days Supply (based on maximum dose per day) +
budesonide/formoterol inhalation aerosol# 80 mcg/4.5 mcg/actuation	60	15
	120	30
160 mcg/4.5 mcg/actuation	60	15
	120	30
fluticasone propionate/ salmeterol xinafoate inhalation aerosol^ 45 mcg fluticasone/21 mcg salmeterol / actuation	120	30
	60	15
115mcg fluticasone/21 mcg salmeterol/ actuation	120	30
	60	15
230 mcg fluticasone/21 mcg salmeterol/ actuation	120	30
	60	15
fluticasone propionate/salmeterol inhalation powder* 100 mcg fluticasone/50 mcg salmeterol/ actuation 28 blisters 60 blisters	28	14
	60	30
250 mcg fluticasone/50 mcg salmeterol/ actuation 28 blisters 60 blisters	28	14
	60	30
500 mcg fluticasone/50 mcg salmeterol/ actuation 28 blisters 60 blisters	28	14
	60	30
fluticasone/salmeterol inhalation powder 55 mcg/14 mcg/actuation	60	30
113 mcg/14 mcg/actuation	60	30
232 mcg/14 mcg/actuation	60	30

Drug	# of Actuations Per Canister	Days Supply (based on maximum dose per day) +
fluticasone furoate/ umeclidinium/ vilanterol inhalation powder~ 100 mcg/62.5 mcg/25 mcg/actuation 28 blisters (one strip contains fluticasone, one strip contains umeclidinium and vilanterol)	14	14
60 blisters (one strip contains fluticasone, one strip contains umeclidinium and vilanterol)	30	30
fluticasone furoate/vilanterol inhalation powder\$ 100 mcg/25/mcg/actuation 28 blisters (one strip contains fluticasone, one strip contains vilanterol)	14	14
60 blisters (one strip contains fluticasone, one strip contains vilanterol)	30	30
200 mcg/25 mcg/actuation 28 blisters (one strip contains fluticasone, one strip contains vilanterol)	14	14
60 blisters (one strip contains fluticasone, one strip contains vilanterol)	30	30
mometasone furoate/formoterol inhalation aerosol# 100 mcg/5 mcg/actuation	120	30
200 mcg/5 mcg/actuation	120	30

- + calculated based on canister size and maximum allowed dose per day (summarized in Tables 2 and 4)
- * Salmeterol inhalation powder, alone or in combination with fluticasone, may be used in children greater than or equal to 4 years of age
- # Budesonide/formoterol and mometasone/formoterol inhalation aerosols only indicated for children greater than 12 years of age
- ^ Fluticasone/salmeterol inhalation aerosol only indicated for children greater than 12 years of age
- \$ Fluticasone/vilanterol powder not indicated for use in children

3 Duplicative Therapy

Concurrent use of inhaled corticosteroids with systemic corticosteroids may result in augmented adverse effects, especially when high doses of inhaled corticosteroids are utilized.

The concomitant use of two or more inhaled corticosteroids for the treatment of asthma is not recommended and will be reviewed.

4 Drug-Drug Interactions

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. Drug interactions considered clinically relevant for inhaled corticosteroids with or without beta agonists are summarized in Table 7. Only those drug-drug interactions classified as clinical significance level 1 or those considered life-threatening which have not yet been classified will be reviewed.

Table 7. ICS Drug-Drug Interactions

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level+
budesonide, budesonide/salmeterol, fluticasone, fluticasone/salmeterol, fluticasone/vilanterol, mometasone, mometasone/formoterol	strong CYP3A4 inhibitors (e.g., azole antifungals, erythromycin, clarithromycin, protease inhibitors)	potential for increased steroid concentrations with risk for excessive adrenal suppression and Cushing syndrome development	concurrent administration not recommended by Advair HFA®/Advair Diskus®, Flovent® Diskus by manufacturers; Flovent® HFA not recommended with ritonavir; for all others, adjunctively administer combination cautiously; monitor patients for signs/symptoms of corticosteroid excess	budesonide, mometasone: 3-moderate; fluticasone: 2-major (CP) budesonide: major, moderate; fluticasone: major (DrugReax)
steroids	quinolones	increased potential for serious tendonitis, tendon rupture with concurrent therapy	closely monitor patients requiring combination therapy; discontinue quinolone if tendon pain develops	3-moderate (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level+
systemic steroids	bupropion	potential increased seizure risk due to systemic steroid-induced lowering of seizure threshold	utilize only recommended bupropion dosages; initiate bupropion therapy with low doses and titrate slowly when combination therapy warranted; closely monitor patients for seizure development	major (DrugReax)
budesonide/formoterol, fluticasone/salmeterol, fluticasone/vilanterol, mometasone/formoterol	MAOIs* (including linezolid)	concurrent administration of MAOIs with beta agonists may increase risk of tachycardia, hypomania, or agitation due to potentiation of effects on vascular system	administer combination cautiously or within 2 weeks of MAOI discontinuation; observe patients for adverse effects	major (DrugReax) 1-severe (CP)
budesonide/formoterol, fluticasone/salmeterol, fluticasone/vilanterol, mometasone/formoterol	TCAs^	concurrent administration of TCAs with beta agonists may potentiate effects on cardiovascular system and increase risk of adverse events	cautiously administer TCAs and beta agonists together, including within 2 weeks of TCA discontinuation; monitor patients and observe for changes in blood pressure, heart rate and ECG	moderate (DrugReax) moderate (CP)
budesonide/formoterol, fluticasone/salmeterol, fluticasone/vilanterol, mometasone/formoterol	beta blockers	concurrent administration may decrease effectiveness of beta-adrenergic blocker or beta-2 agonists like formoterol, salmeterol	combination not recommended in asthma/COPD patients; if adjunctive therapy necessary, utilize cardioselective beta blocker (e.g., atenolol, bisoprolol)	major (DrugReax) 2-major (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level+
budesonide/ formoterol, fluticasone/ salmeterol, fluticasone/ vilanterol, mometasone/ formoterol	diuretics	potential for worsening of diuretic-associated hypokalemia and/or ECG changes with beta-agonist concurrent administration, especially with high beta-agonist doses	administer combination cautiously; monitoring potassium levels may be necessary	3-moderate (CP)

- +CP = Clinical Pharmacology
- COPD = chronic obstructive pulmonary disease
- ECG = electrocardiogram
- MAOIs = monoamine oxidase inhibitors
- TCAs = tricyclic antidepressants

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