

# Texas Vendor Drug Program

## Drug Use Criteria: Aerosolized Agents - Metered-Dose Inhalers (MDIs): Anti-Inflammatory Drugs

### Publication History

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2. Revised **April 2021**; March 2019; March 2017; November 2015; March 2014; August 2012; June 2012; August 2010; July 2010; July 2007; February 2003; January 2002; January 2001; March 2000; January 2000; February 1999; March 1998; August 1997; February 1997.

**Notes:** All criteria may be applied retrospectively. 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 that may be included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.***

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**TEXAS**  
Health and Human  
Services

Medical and  
Social Services

# 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 time 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

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Maximum Recommended Dosage</b>
ciclesonide (Alvesco®)	inhalation aerosol: 80 mcg/actuation	<i>prior therapy with bronchodilators alone:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/day
		<i>prior therapy with ICS, oral corticosteroids:</i> 8 (4 actuations twice daily); total dose = 640 mcg/day
	inhalation aerosol: 160 mcg/actuation	<i>prior therapy with bronchodilators alone:</i> 2 actuations/day in divided doses (1 actuation twice daily); total dose = 320 mcg/day
		<i>prior therapy with ICS, oral corticosteroids:</i> <i>160 mcg/actuation:</i> 4 (2 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	<i>no previous ICS:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 176 mcg/day
	inhalation aerosol: 110 mcg/actuation	<i>prior therapy with bronchodilators alone, ICS:</i> 16 actuations/day in divided doses (8 actuations twice daily); total dose = 1760 mcg/day
	inhalation aerosol: 220 mcg/actuation	<i>prior therapy with bronchodilators alone, ICS:</i> 8 actuations/day in divided doses (4 actuations twice daily); total dose = 1760 mcg/day
		<i>prior therapy with oral corticosteroids:</i> 8 (4 actuations twice daily); total dose = 1760 mcg/day

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Maximum Recommended Dosage</b>
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
<b>fluticasone propionate (ArmonAir Digihaler®)</b>	<b>inhalation powder: 55 mcg/actuation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg</b>
	<b>inhalation powder: 113 mcg/actuation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg</b>
	<b>inhalation powder: 232 mcg/actuation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg</b>
mometasone HFA (Asmanex HFA®)	inhalation aerosol: 100 mcg/actuation	<i>prior therapy with medium- dose ICS:</i> 4 actuations/day (2 actuations twice daily); total dose = 400 mcg/day
	inhalation aerosol: 200 mcg/actuation	<i>prior therapy high-dose ICS, oral corticosteroids:</i> 4 actuations/day (2 actuations twice daily); total dose = 800 mcg/day^
mometasone (Asmanex Twisthaler®)	inhalation powder: 110 mcg/actuation	<i>prior therapy with bronchodilators alone, ICS:</i> 4 actuations/day (4 actuations once daily in evening or 2 actuations twice daily); total dose = 440 mcg/day
		<i>prior therapy with oral corticosteroids:</i> 8 actuations/day in divided doses (4 actuations twice daily); total dose = 880 mcg/day

Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
	inhalation powder: 220 mcg/actuation	<i>prior therapy with bronchodilators alone, ICS:</i> 2 actuations/day (2 actuations once daily in evening or 1 actuation twice daily); total dose = 440 mcg/day
		<i>prior therapy with oral corticosteroids:</i> 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®) is approved for patients 12 years of age and older, **mometasone/formoterol inhalation aerosol (Dulera®) is FDA-approved for use as maintenance therapy for asthma in patients 5 years of age and older**, and 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 and **maintenance therapy for asthma**. Additionally, a triple therapy inhaler containing fluticasone, umecclidinium and vilanterol (Trelegy Ellipta®) has now been approved for COPD **and asthma** management. 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®, <b>Wixela Inhub®</b> )	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

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
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
		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
asthma	<b>fluticasone propionate/ salmeterol (AirDuo Digihaler®)</b>	<b>inhalation powder: 55 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg/28 mcg/day</b>
		<b>inhalation powder: 113 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg/28 mcg/day</b>
		<b>inhalation powder: 232 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg/28 mcg/day</b>
asthma	<b>fluticasone furoate/ umeclidinium/ vilanterol (Trelegy Ellipta®)</b>	<b>inhalation powder: 100 mcg/ 62.5 mcg/ 25 mcg/inhalation</b>	<b>1 actuation/day; total dose = 100 mcg/62.5 mcg/ 25 mcg/day</b>
COPD			1 actuation/day; total dose = 100 mcg/62.5 mcg/ 25 mcg/day
asthma		<b>inhalation powder: 200 mcg/ 62.5 mcg/ 25 mcg/inhalation</b>	<b>1 actuation/day; total dose = 200 mcg/62.5 mcg/ 25 mcg/day</b>

Treatment Indication	Drug Name	Dosage Form/ Strength	Maximum Recommended Dosage
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	<i>patients on medium-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 400 mcg/20 mcg/day</i>
		inhalation aerosol: 200 mcg mometasone/5 mcg formoterol/actuation	<i>patients on high-dose inhaled corticosteroids: 4 actuations/day in divided doses (2 actuations twice daily); total dose = 800 mcg/20 mcg/day</i>

*Number of maximum actuations per day based on dose of salmeterol and formoterol, and independent of inhaled corticosteroid dose*

## 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**

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

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Patient Age/Maximum Recommended Dosage</b>
	dry powder inhaler: 200 mcg/actuation	<i>adolescents 12-17 years:</i> 1 actuation once daily; total dose = 200 mcg/day*
fluticasone propionate HFA (Flovent HFA®)	inhalation aerosol: 44 mcg/actuation	<i>children 4-11 years:</i> <i>regardless of prior therapy:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 176 mcg/day
	inhalation aerosol: 110 mcg/actuation	<i>adolescents 12-17 years:</i> <i>prior therapy with bronchodilators alone, ICS:</i> 16 actuations/day in divided doses (8 actuations twice daily); total dose = 1760 mcg/day
	inhalation aerosol: 220 mcg/actuation	<i>adolescents 12-17 years:</i> <i>prior therapy with bronchodilators alone, ICS:</i> 8 actuations/day in divided doses (4 actuations twice daily); total dose = 1760 mcg/day
fluticasone propionate (Flovent Diskus®)	dry powder inhaler: 50 mcg/actuation	<i>children 4-11 years:</i> <i>regardless of prior therapy:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 200 mcg/day
	dry powder inhaler: 100 mcg/actuation	<i>children 4-11 years:</i> <i>regardless of prior therapy:</i> 2 actuations/day in divided doses (1 actuation twice daily); total dose = 200 mcg/day  <i>adolescents 12-17 years:</i> total dose = 2000 mcg/day
	dry powder inhaler: 250 mcg/actuation	<i>adolescents 12-17 years:</i> 8 actuations/day in divided doses (4 actuations twice daily); total dose = 2000 mcg/day
<b>fluticasone propionate (ArmonAir Digihaler®)</b>	<b>dry powder inhaler: 55 mcg/actuation</b>	<b><i>adolescents 12-17 years:</i></b> <b><i>no current corticosteroid therapy:</i></b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg</b>
	<b>dry powder inhaler: 113 mcg/actuation</b>	<b><i>adolescents 12-17 years:</i></b> <b><i>prior treatment with ICS:</i></b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg</b>
	<b>dry powder inhaler: 232 mcg/actuation</b>	<b><i>adolescents 12-17 years:</i></b> <b><i>prior treatment with ICS:</i></b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg</b>
<b>mometasone HFA (Asmanex HFA®)</b>	<b>inhalation aerosol: 50 mcg/actuation</b>	<b><i>children 5-11 years:</i></b> <b><i>regardless of prior therapy:</i></b> <b>4 actuations/day (2 actuations twice daily); total dose = 200 mcg/day</b>

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Patient Age/Maximum Recommended Dosage</b>
	inhalation aerosol: 100 mcg/actuation	<i>adolescents 12-17 years: prior therapy with medium-dose ICS: 4 actuations/day (2 actuations twice daily); total dose = 400 mcg/day</i>
	inhalation aerosol: 200 mcg/actuation	<i>adolescents 12-17 years: prior therapy with high-dose ICS, oral corticosteroids: 4 actuations/day (2 actuations twice daily); total dose = 800 mcg/day<sup>^</sup></i>
mometasone (Asmanex Twisthaler®)	inhalation powder: 110 mcg/actuation	<i>children 4-11 years: 1 actuation/day once daily in evening; total dose = 110 mcg/day</i>
	inhalation powder: 220 mcg/actuation	<i>adolescents 12-17 years: prior therapy with bronchodilators alone, ICS: 1 actuation twice daily or 2 actuations once daily; total dose = 440 mcg/day</i>  <i>prior therapy with oral corticosteroids: 4 actuations/day (2 actuations twice daily); total dose = 880 mcg/day</i>

*\*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*

*<sup>^</sup>prednisone should be tapered slowly, beginning at least one week after mometasone use*

Combined therapy with inhaled ICS and long-acting beta<sub>2</sub>-agonists is only FDA-approved for use in asthma treatment in children **≥ 5 years of age**; combined ICS/ long-acting beta<sub>2</sub>-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**

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Patient Age/Maximum Recommended Dosage</b>
budesonide/ formoterol (Symbicort®)	inhalation aerosol: 80 mcg/4.5 mcg/ actuation	<i>6 to 11 years of age:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 320 mcg/18 mcg/day
		<i>12-17 years of age:</i> 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	<i>12-17 years of age:</i> 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	<i>12-17 years of age:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 180 mcg/84 mcg/day
	inhalation aerosol: 115 mcg/21 mcg/ actuation	<i>12-17 years of age:</i> 4 actuations/day in divided doses (2 actuations twice daily); total dose = 460 mcg/84 mcg/day
	inhalation aerosol: 230 mcg/21 mcg/ actuation	<i>12-17 years of age:</i> 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	<i>4-11 years of age:</i> 2 actuations/day (1 actuation twice daily); total dose = 200 mcg/100 mcg/day

<b>Drug Name</b>	<b>Dosage Form/ Strength</b>	<b>Patient Age/Maximum Recommended Dosage</b>
	inhalation powder: 100 mcg/50 mcg/ actuation	<i>12-17 years of age:</i> 2 actuations/day (1 actuation twice daily); total dose = 200 mcg/100 mcg/day
	inhalation powder: 250 mcg/50 mcg/ actuation	<i>12-17 years of age:</i> 2 actuations/day (1 actuation twice daily); total dose = 500 mcg/100 mcg/day
	inhalation powder: 500 mcg/50 mcg/ actuation	<i>12-17 years of age:</i> 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	<i>12-17 years of age:</i> 2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg/28 mcg/day
	113 mcg fluticasone/14 mcg salmeterol/ actuation	<i>12-17 years of age:</i> 2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg/28 mcg/day
	232 mcg fluticasone/14 mcg salmeterol/ actuation	<i>12-17 years of age:</i> 2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg/28 mcg/day
<b>fluticasone propionate/ salmeterol (AirDuo Digihaler®)</b>	<b>55 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>≥ 12 years of age:</b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 110 mcg/28 mcg/day</b>
	<b>inhalation powder: 113 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>≥ 12 years of age:</b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 226 mcg/28 mcg/day</b>
	<b>inhalation powder: 232 mcg fluticasone/ 14 mcg salmeterol/ inhalation</b>	<b>≥ 12 years of age:</b> <b>2 actuations/day in divided doses (1 actuation twice daily); total dose = 464 mcg/28 mcg/day</b>
<b>mometasone/ formoterol (Dulera®)</b>	<b>inhalation aerosol: 50 mcg/5 mcg/ actuation</b>	<b>5-11 years of age:</b> <b>4 actuations/day in divided doses (2 actuations twice daily); total dose = 200 mcg/ 20 mcg/ day</b>

Drug Name	Dosage Form/ Strength	Patient Age/Maximum Recommended Dosage
	inhalation aerosol: 100 mcg/5 mcg/ actuation	<i>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</i>
	200 mcg/5 mcg/ actuation	<i>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</i>

*Number of maximum actuations per day based on dose of salmeterol and formoterol, and independent of inhaled corticosteroid dose*

## 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 beta<sub>2</sub>-agonists are summarized in Tables 5 and 6. Fluticasone is available as both the furoate and propionate salts; fluticasone propionate is available as **four** 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. New fluticasone/salmeterol inhalation powder formulations have also been approved for asthma management (AirDuo RespiClick® and **AirDuo Digihaler®**) 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<sup>+</sup> 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) <sup>+</sup>
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)
fluticasone furoate dry powder inhaler 50 mcg/actuation 30 blisters	30	30
100 mcg/actuation <b>14 blisters</b>	<b>14</b>	<b>14</b>
30 blisters	30	30
200 mcg/actuation <b>14 blisters</b>	<b>14</b>	<b>14</b>
30 blisters	30	30
fluticasone propionate HFA aerosol 44 mcg/actuation (10.6 g canister)	120	30 days (child)

<b>Drug Name</b>	<b># of Actuations Per Canister</b>	<b>Days' Supply (based on maximum dose per day)<sup>†</sup></b>
110 mcg/actuation (12 g canister)	120	7.5 days (adults, adolescents)
220 mcg/actuation (12 g canister)	120	15 days (adults, adolescents)
fluticasone propionate dry powder inhaler 50 mcg/actuation <i>60 blisters</i>	60	15 days (child)
100 mcg/actuation <i>60 blisters</i>	60	30 days (child)
250 mcg/actuation <b>28 blisters</b>  <i>60 blisters</i>	<b>28</b>  60	<b>3.5 days (adults, adolescents)</b>  7.5 days (adults, adolescents)
fluticasone propionate dry powder inhaler ( <b>Digihaler®</b> ) 55 mcg/actuation	60	30 days (adults, adolescents)
113 mcg/actuation	60	30 days (adults, adolescents)
232 mcg/actuation	60	30 days (adults, adolescents)
mometasone inhalation aerosol <b>50 mcg/actuation</b>	<b>120</b>	<b>30 days (child)</b>
100 mcg/actuation	120	30 days (adults, adolescents)
200 mcg/actuation	120	30 days (adults, adolescents)
mometasone inhalation powder 110 mcg/actuation	30	30 (child) BD alone, ICS: 7.5 days (adults, adolescents) OCS: 3.75 days (adults, adolescents)



Drug Name	# of Actuations Per Canister	Days' Supply (based on maximum dose per day) <sup>+</sup>
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)

<sup>+</sup>calculated based on canister size and maximum dose allowed per day (summarized in Tables 1 & 3)

\*for more than 2 inhalations daily

BD = bronchodilator; ICS = inhaled corticosteroids; OCS = oral corticosteroids

**Table 6. Days' Supply<sup>+</sup> 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) <sup>+</sup>
budesonide/formoterol inhalation aerosol# 80 mcg/4.5 mcg/actuation	60 120	15 30
160 mcg/4.5 mcg/actuation	60 120	15 30
fluticasone propionate/ salmeterol xinafoate inhalation aerosol^ 45 mcg fluticasone/21 mcg salmeterol / actuation	120 60	30 15
115mcg fluticasone/21 mcg salmeterol/ actuation	120 60	30 15

<b>Drug</b>	<b># of Actuations Per Canister</b>	<b>Days' Supply (based on maximum dose per day)<sup>+</sup></b>
<i>230 mcg fluticasone/21 mcg salmeterol/actuation</i>	120 60	30 15
fluticasone propionate/salmeterol inhalation powder* <i>100 mcg fluticasone/50 mcg salmeterol/actuation</i>	<b>14 blisters</b> 60 blisters	<b>7</b> 30
<i>250 mcg fluticasone/50 mcg salmeterol/actuation</i>	<b>14 blisters</b> 60 blisters	<b>7</b> 30
<i>500 mcg fluticasone/50 mcg salmeterol/actuation</i>	<b>14 blisters</b> 60 blisters	<b>7</b> 30
fluticasone/salmeterol inhalation powder <i>55 mcg/14 mcg/actuation</i>	60	30
<i>113 mcg/14 mcg/actuation</i>	60	30
<i>232 mcg/14 mcg/actuation</i>	60	30
fluticasone furoate/ umeclidinium/ vilanterol inhalation powder~ <i>100 mcg/62.5 mcg/25 mcg/actuation</i> 28 blisters <i>(one strip contains fluticasone, one strip contains umeclidinium and vilanterol)</i>	14	14
60 blisters <i>(one strip contains fluticasone, one strip contains umeclidinium and vilanterol)</i>	30	30
<b><i>200 mcg/62.5 mcg/25 mcg/actuation</i></b> <b>28 blisters</b> <b><i>(one strip contains fluticasone, one strip contains umeclidinium and vilanterol)</i></b>	<b>14</b>	<b>14</b>
<b>60 blisters</b> <b><i>(one strip contains fluticasone, one strip contains umeclidinium and vilanterol)</i></b>	<b>30</b>	<b>30</b>

Drug	# of Actuations Per Canister	Days' Supply (based on maximum dose per day) <sup>+</sup>
fluticasone furoate/vilanterol inhalation powder <sup>\$</sup>		
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 <sup>#</sup>		
<b>50 mcg/5 mcg/actuation</b>	<b>120</b>	<b>30</b>
100 mcg/5 mcg/actuation	<b>60</b> 120	<b>15</b> 30
200 mcg/5 mcg/actuation	<b>60</b> 120	<b>15</b> 30

<sup>+</sup>calculated based on canister size and maximum allowed dose per day (summarized in Tables 2 & 4)

<sup>\*</sup>Salmeterol inhalation powder, alone or in combination with fluticasone as Advair Diskus®, may be used in children  $\geq 4$  years of age

<sup>#</sup>Budesonide/formoterol indicated in children **6 years of age and older** and mometasone/formoterol inhalation aerosols is indicated for **children 5 years of age and older**

<sup>^</sup>Fluticasone/salmeterol inhalation aerosol only indicated for children  $\geq 12$  years of age

<sup>\$</sup> 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.

**When using single maintenance and reliever therapy (SMART), the “2020 Focused Updates to the Asthma Management Guidelines” recommends using a single inhaled corticosteroid (ICS)/ long acting beta<sub>2</sub>-agonist combination inhaler as the preferred therapy as opposed to using a separate ICS inhaler. Additionally, the guidelines recommend intermittent use of a single ICS inhaler for patients 12 years of age and older with mild persistent asthma in certain situations when the patient is not already using ICS controller therapy.**

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 <sup>+</sup>
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 <sup>+</sup>
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 <sup>^</sup>	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 <sup>+</sup>
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)

<sup>+</sup>CP = Clinical Pharmacology

COPD = chronic obstructive pulmonary disease; ECG = electrocardiogram; MAOIs = monoamine oxidase inhibitors; TCAs = tricyclic antidepressants

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