



Therapeutic Class ReviewSM

Respiratory – ciclesonide (Alvesco[®])

December 2008

Key Points

New Product for Review:

ciclesonide (Alvesco[®]) [Sepracor/Altana]

Dossier Provided by Manufacturer: Yes

Dossier Evaluation: (2)

- 1 - Dossier missing significant clinical trial(s).
- 2 - Mfg. provided all relevant trials; Missing pharmacoeconomic model.
- 3 - Mfg. provided all relevant trials and information.

Executive Summary

- Ciclesonide (Alvesco[®]) was approved by the U.S. Food and Drug Administration (FDA) on January 10, 2008, and was launched in the third quarter 2008. Ciclesonide (Alvesco):
 - is the seventh ICS treatment option available to control asthma in adults and adolescents (12 years and older).
 - has been available outside the U.S. since 2004.
 - is a prodrug that is metabolized by esterases in the lungs to the active metabolite (des-ciclesonide).
- National and international guidelines recommend the following as first-line options to control asthma symptoms:
 - ICS products are the preferred long-term maintenance therapy for adults and children with mild, moderate and severe persistent asthma.^[11]
 - ICS may be titrated when administered alone; or
 - A long-acting beta agonist (LABA) may be added to an ICS.
- There is no reliable evidence that any one inhaled corticosteroid is safer or more effective than another.

Evidence

- It is well recognized that adding LABA to an ICS improves lung function (FEV₁) and reduces rates of asthma exacerbations over ICS treatment alone.
- Systematic reviews have not identified any significant differences between the different ICS products.
- There is no reliable evidence that ICS products are effective for chronic obstructive pulmonary disease (COPD).^[20]
- There is no reliable evidence regarding any differences in safety between the ICS products because of large variations in study populations and dosing regimens studied in the trials.
- Considerations in Subpopulations:
 - **Pediatrics:** The safety and effectiveness of ciclesonide (Alvesco) in children under 12 years of age have not been established
 - **Geriatrics:** Clinical studies of ciclesonide (Alvesco) did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger patients.
 - **Gender, Race:** Specific studies to examine the effects of gender and race on the pharmacokinetics of ciclesonide (Alvesco) have not been conducted.

Decision

Ciclesonide (Alvesco) is non-preferred/non-formulary because:

- There is no reliable evidence to show that ciclesonide (Alvesco) is superior to other available ICS products.
- There are multiple preferred/formulary options available that provide a better value and meet the needs of Regence members.

Products

Drug Products	FDA approval ^a	Patent Expiration(s) ^c	FDA approved indications	Usual Dose/Route	Potential Off-label Uses ^d
beclomethasone dipropionate (QVAR [®]) ⁵	9/2000	11/2009	<ul style="list-style-type: none"> • Asthma • 5 years and older 	2-3 puffs BID Metered dose inhaler	COPD
budesonide (Pulmicort Flexhaler [™]) ⁶	6/1997	1/2018 (3/2007-1/2018)	<ul style="list-style-type: none"> • Asthma • 6 years and older 	2-3 puffs BID Dry powder inhaler	COPD
ciclesonide (Alvesco) ¹	1/2008	7/2010 – 5/2018	<ul style="list-style-type: none"> • Asthma • 12 years and older 	1-2 inhalations BID	COPD, asthma in pediatrics less than 12
flunisolide (Aerobid [®] , Aerobid [®] -M) ⁷	8/1984	6/2007	<ul style="list-style-type: none"> • Asthma • 6 years and older 	2-4 puffs BID Metered dose inhaler	COPD
fluticasone propionate (Flovent [®] HFA) ⁴	11/1997	9/2014	<ul style="list-style-type: none"> • Asthma • 4 years and older 	220mcg BID-TID Metered dose inhaler	COPD, chronic bronchitis
mometasone furoate	3/2005	6/2012	<ul style="list-style-type: none"> • Asthma 	1 -2 puffs QD	COPD

(Asmanex [®]) ⁸			• 12 years and older	- BID Dry powder inhaler	
triamcinolone acetonide (Azmacort [®]) ⁹	4/1982	-	• Asthma • 12 years of age and older	3-5 puffs QID, not to exceed 16 puffs/day Metered dose inhaler	COPD
budesonide/ formoterol (Symbicort [®]) ²⁹	9/2006	12/2012	• Asthma • 12 years and older	1-2 puffs BID Metered dose inhaler	COPD, asthma in pediatrics less than 12
fluticasone/salmetero 1 (Advair [®] Diskus [®]) ³¹	8/2000	8/2008	• Asthma • 4 years and older • COPD associated with chronic bronchitis	1 puff BID Dry powder inhaler	Extrinsic asthma prophylaxis
fluticasone/salmeterol (Advair [®] HFA) ³⁰	6/2006	8/2008		2 puffs BID Metered dose inhaler	Extrinsic asthma prophylaxis

^a Date applies to approval date for the original brand name medication where there are now generics available.

^c Based on patents listed in Orange Book as of 11/21/2008.

^d As listed in © 1974 - 2008 Thomson MICROMEDEX database or as referenced.

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