

## Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

### Therapeutic Class:

Nasal Preparations

### Overview:

Seven corticosteroid nasal sprays are currently marketed in the United States. Flunisolide and fluticasone propionate are available generically. Omnaris® (ciclesonide) was approved in November 2007 for use in both seasonal and perennial allergic rhinitis. Nasacort®, Nasacort® HFA, Nasalide®, Vancenase®, and Rhinocort® aerosol metered nasal spray have been discontinued. Originally, several of these agents were marketed as metered dose spray preparations that were associated with many local adverse effects. Several of these agents have now been reformulated as aqueous sprays. Most patients better tolerate these new formulations. The mechanism of action of nasal steroid sprays is not completely understood, but is thought to involve multiple cell types and mediators involved in inflammation. Clinical trials have demonstrated all agents to be similar in terms of efficacy and safety. Additionally, the available nasal steroid products are equally effective in relieving the symptoms of allergic rhinitis. Only Nasonex® is indicated for the treatment of nasal polyps in patients 18 years of age and older. Fluticasone propionate nasal spray is available in a 0.05mg/spray. Azelastine (Astelin®), an anti-histamine preparation, was shown to be as efficacious as a nasal corticosteroid combined with a non-sedating anti-histamine in one study. Azelastine and its metabolite, desmethylazelastine, are H<sub>1</sub>-receptor antagonists. Azelastine also inhibits histamine release from mast cells. Astelin® is indicated for the treatment of SAR in patients 5 years of age and older, and for treatment of vasomotor rhinitis in patients 12 years of age and older. Other available nasal antihistamines include Patanase® (olopatadine), indicated for SAR in patients 12 years of age and older, and Astepro™ (azelastine) indicated for the treatment of both SAR and PAR in patients 12 years of age and older. Ipratropium bromide (Atrovent®), a nasal anticholinergic preparation, is also available for the treatment of rhinorrhea associated with the common cold or with allergic or non-allergic perennial rhinitis. In one study, ipratropium bromide was as effective as beclomethasone in the control of rhinorrhea.

Generic Name	Trade Name	Allergic Rhinitis	Non-Allergic Rhinitis	Manufacturer
Beclomethasone	Beconase AQ®	≥ 6 Years of Age (SAR and PAR)	Yes	Glaxo SmithKline
Ciclesonide	Omnaris®	≥ 6 Years of Age (SAR) ≥ 12 Years of Age (PAR)	No	Nycomed
Flunisolide	Nasarel®	≥ 6 Years of Age (SAR and PAR)	No	IVAX, Apotex
Fluticasone	Flonase® (fluticasone propionate)	≥ 4 Years of Age (SAR and PAR)	Yes	Glaxo SmithKline, various

	Veramyst™ (fluticasone furoate)	≥2 years of Age (SAR and PAR)	No	Glaxo SmithKline
Budesonide	Rhinocort Aqua™	≥ 6 Years of Age (SAR and PAR)	No	AstraZeneca
Mometasone	Nasonex®	≥ 2 Years of Age (SAR and PAR)	No	Schering
Triamcinolone	Nasacort® AQ	≥ 2 Years of Age (SAR and PAR)	No	Aventis
Azelastine HCl	Astelin®*	≥ 5 Years of Age (SAR and PAR)	Yes	MedPointe
	Astepro™*	≥ 12 Years of Age (SAR and PAR)	No	Meda
Ipratropium	Atrovent®*	≥ 6 Years of Age (PAR)	Yes	Boehringer Ingelheim
Olopatadine	Patanase®	≥ 12 Years of Age (SAR)	No	Alcon

SAR = Seasonal Allergic Rhinitis, PAR = Perennial Allergic Rhinitis

\*Although not corticosteroids, Astelin®, Astepro, and Atrovent® nasal sprays are included with this review.

## Summary:

Intranasal corticosteroids include the following agents:

- beclomethasone (Beconase AQ®)
- ciclesonide (Omnaris®)
- flunisolide (Nasarel®)
- fluticasone (Flonase®, Veramyst™)
- budesonide (Rhinocort Aqua™)
- mometasone (Nasonex®)
- triamcinolone (Nasacort AQ®)

Azelestine (Astelin®, Astepro™), olopatadine (Patanase®), and ipratropium (Atrovent®) are other agents used for allergic rhinitis. Selection of a preferred agent should be based on adverse events, patient tolerability, and ease of administration.