

MTF Formulary Management for Inhaled Nasal Allergy Drugs

Defense Health Agency Pharmacy Operations Division

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Bottom-line

- Generic fluticasone (Flonase) remains the BCF choice.
- UF and step preferred drugs are generic fluticasone (Flonase), and the generics for flunisolide, azelastine 137 mcg, and ipratropium.
- **Nasonex is now Non Formulary; the price per inhaler will increase to \$76.96 (FSS price).** To maximize cost avoidance, we highly recommend moving patients older than age 4 from Nasonex to generic Flonase, unless the patient meets the prior authorization criteria below.
- Prior Authorization (Step Therapy) now applies to all new and current users of Nasonex, Beconase AQ, Omnaris, QNASL, Rhinocort Aqua, Veramyst, Zetonna, Astepro, Patanase, and Dymista older than age 4 –see below.
- Continue to maximize use of the nasal corticosteroids for allergic rhinitis, as they are the most clinically effective at reducing allergic rhinitis symptoms and are the most cost-effective subclass of the Nasal Allergy Drugs.

Formulary Decision: The Director, DHA approved the recommendations from the May 2014 DoD P&T Committee meeting in September 2014, with an implementation date of December 17, 2014.

Uniform Formulary (UF) drugs		Non-Formulary (NF) drugs
BCF drugs - MTFs <u>must</u> have on formulary	MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary*
<p><u>Step preferred:</u></p> <p>Nasal Steroids:</p> <ul style="list-style-type: none"> • Fluticasone propionate (Flonase generic) 	<p><u>Step preferred:</u></p> <p>Nasal Steroids:</p> <ul style="list-style-type: none"> • Flunisolide (Nasalide generic) <p>Antihistamines:</p> <ul style="list-style-type: none"> • Azelastine 137mcg (Astelin generic) <p>Anticholinergics:</p> <ul style="list-style-type: none"> • Ipratropium (Atrovent generic) 	<p><u>Non step-preferred*:</u></p> <p>Nasal Steroids:</p> <ul style="list-style-type: none"> • Beclomethasone (Beconase AQ) • Beclomethasone HFA (QNASL) • Budesonide (Rhinocort Aqua) • Ciclesonide 50 mcg (Omnaris) • Ciclesonide HFA 37 mcg (Zetonna) • Fluticasone furoate (Veramyst) • Mometasone (Nasonex) <p>Antihistamines:</p> <ul style="list-style-type: none"> • Azelastine 205mcg (Astepro) • Olopatadine (Patanase) <p>Antihistamine/Steroid Combo:</p> <ul style="list-style-type: none"> • Azelastine/Fluticasone (Dymista)
<p>* Step therapy applies to all new and current patients >4 years–must try generics to Flonase, Nasalide, Astelin or Atrovent before one of the other nasal inhalers.</p>		

Prior Authorization and Step Therapy information

- Prior authorization (step therapy) criteria apply to all new and current users of Beconase AQ, QNASL, Rhinocort Aqua, Omnaris, Zetonna, Veramyst, Nasonex, Astepro, Patanase and Dymista (the non step-preferred products) who are older than 4 years of age, due to the significant cost avoidance and high degree of therapeutic interchangeability with the class.
- The step preferred products are fluticasone propionate (generic Flonase), flunisolide (generic Nasarel), azelastine 137 mcg (generic Astelin), and ipratropium (generic Atrovent).
- Step therapy does not apply to children ≤4years.
- A new user is a patient who has been prescribed a non step-preferred Nasal Allergy Drug and does not have a prescription for the non step-preferred medication in their drug profile in the last 180 days.

Prior Authorization and Step Therapy information (continued)

- Existing users of non step-preferred Nasal Allergy Drugs older than 4 years are not “grandfathered”. All new and current users of the non step-preferred Nasal Allergy Drugs must try at least one preferred product (generic Flonase, Nasalide, Astelin or Atrovent) first, unless the patient has had the following with the step preferred drug which is not expected to occur with the non step-preferred Nasal Allergy Drug:
 - an inadequate response to one of the step-preferred Nasal Allergy Drugs
 - intolerable adverse effects to one of the step-preferred Nasal Allergy Drugs (for example, persistent epistaxis, significant nasal irritation, or pharyngitis)
 - contraindication
 - has previously responded to the non-formulary Nasal Allergy Drugs and changing to a preferred agent would incur unacceptable risk
 - there is no formulary alternative for the following:
 - for budesonide (Rhinocort Aqua): the patient is pregnant
 - for beclomethasone (Beconase AQ) and mometasone (Nasonex): the patient has nasal polyps and cannot be treated with one of the preferred products.

Clinical Summary

Nasal Corticosteroids

- There is no new evidence that substantively changes the previous conclusions from the August 2011 review.
- Nasal corticosteroids are 1st line agents for reducing allergic rhinitis symptoms - rhinorrhea, congestion, itching.
- None of the nasal corticosteroids have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over the other nasal corticosteroids
- Nasal steroid HFA aerosol formulations: ciclesonide (Zetonna) and beclomethasone (QNASL)
 - Advantages of HFA over aqueous formulations include no post nasal drip, longer retention in the nasal cavity, potentially better taste, once daily dosing, and inclusion of a dose counter.
 - Disadvantages of HFA over aqueous formulations include a higher incidence of epistaxis and burning, and FDA approval only for children older than 12 years.
- Fluticasone/azelastine (Dymista) is the first combination nasal corticosteroid/nasal antihistamine. It has not been compared with individual components given separately or with concomitant use of another nasal steroid/oral antihistamine.

Nasal Antihistamines

- The nasal antihistamines are generally less effective than nasal corticosteroids for treating allergic rhinitis, but may be used as 1st line therapy, and in non-allergic rhinitis.
- Nasal antihistamines have a quicker onset of effect than the nasal steroids. They are associated with a clinically significant effect on reducing nasal congestion.
- Somnolence with the nasal antihistamines is considered a class effect.

Nasal Anticholinergics

- Ipratropium is the only nasal anticholinergic; it has adequate safety in regards to treating rhinorrhea associated with seasonal allergic rhinitis.

Pregnancy/Pediatrics

- Budesonide (Rhinocort Aqua) and ipratropium are the only Nasal Allergy rated as pregnancy category B.
- Fluticasone propionate (Flonase) is approved in children down to the age of 4 years. Fluticasone furoate (Veramyst) and mometasone (Nasonex) are approved in children down to the age of 2 years.

Other Factors

- The only products approved for nasal polyps are Nasonex and Beconase AQ.
- **Generic Nasonex is anticipated in Fall 2014, but no generic formulations have been approved by the FDA (as of Sep-14). DHA will provide additional guidance when generic pricing permits UF status change.**
- A generic formulation of azelastine 205 mcg (Astepro) was approved in May 2014, but is not cost effective.
- Triamcinolone (Nasacort) is now OTC and was not part of the class review.
- An OTC formulation of full strength Flonase (50 mcg) was approved in July, 2014, but is not expected to reach the market until 2015.

References

- DOD P&T Committee minutes:
http://pec.ha.osd.mil/pt_minutes.php?submenuheader=5
- Current/future drug classes under review by the DOD P&T Committee:
http://pec.ha.osd.mil/PT_Committee.php?submenuheader=4
- TRICARE formulary search tool:
http://pec.ha.osd.mil/formulary_search.php?submenuheader=1
- Prior Authorization/Medical Necessity forms:
http://pec.ha.osd.mil/forms_criteria.php?submenuheader=1
- Point Of Contact for additional information:
usarmy.ibsa.medcom-ameddcs.list.pecuf2@mail.mil

Nasal Allergy Drugs Price Comparison at MTF	
Drug & Dosage Form	MTF cost/month (May 2014)
Basic Core Formulary	
Fluticasone (Flonase generic)	\$ Most Cost-Effective
Uniform Formulary	
Ipratropium (Atrovent)	\$ Most Cost-Effective
Flunisolide (Nasarel)	\$ Most Cost-Effective
Azelastine 137 mcg (Astelin)	\$\$ Less Cost-Effective
Non Formulary	
Mometasone (Nasonex)	\$\$\$\$ Least Cost-Effective
Fluticasone furoate (Veramyst)	\$\$\$\$ Least Cost-Effective
Azelastine 205 mcg (Astepro)	\$\$\$\$ Least Cost-Effective
Budesonide (Rhinocort Aqua)	\$\$\$\$ Least Cost-Effective
Beclomethasone HFA (QNASL)	\$\$\$\$ Least Cost-Effective
Ciclesonide 50 mcg (Omnaris)	\$\$\$\$ Least Cost-Effective
Olopatadine (Patanase)	\$\$\$\$ Least Cost-Effective
Ciclesonide HFA 37 mcg (Zetonna)	\$\$\$\$ Least Cost-Effective
Beclomethasone (Beconase AQ)	\$\$\$\$ Least Cost-Effective
Fluticasone/azelastine (Dymista)	\$\$\$\$ Least Cost-Effective