

MTF Formulary Management for Inhaled Corticosteroids (ICS)

Defense Health Agency Pharmacy Operations Division

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Bottom-line

- Flovent Diskus and Flovent HFA inhaler remain the BCF agents.
- Asmanex Twisthaler is no longer on the BCF; it moves to Non-Formulary.
- Prior Authorization (Step Therapy) now applies to new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan and Asmanex Twisthaler older than age 12 – see below.
- Budesonide nebulized solution (Pulmicort) was reviewed in 2009; it remains on the UF and is not subject to step therapy.

Uniform 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
<u>Step-preferred:</u> Fluticasone (Flovent Diskus and Flovent HFA)	(See BCF)	<u>Non step-preferred:*</u> Beclomethasone (QVAR) Budesonide (Pulmicort Flexhaler) Ciclesonide (Alvesco) Flunisolide (Aerospan) Mometasone (Asmanex Twisthaler)
* Step therapy applies to all new patients >12 years–must try Flovent Diskus or Flovent HFA before one of the other inhalers.		

Prior Authorization and Step Therapy information

- Prior authorization (step therapy) criteria apply to all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler who are older than 12 years of age, due to significant cost avoidance and high degree of therapeutic interchangeability with the class.
- Flovent Diskus and Flovent HFA are the step preferred products.
- Step therapy does not apply to children ≤ 12 years.
- A new user is a patient who has been prescribed a non-step preferred ICS (QVAR, Pulmicort Flexhaler, Alvesco, Aerospan or Asmanex Twisthaler) and does not have a prescription for the non step-preferred medication in their drug profile during the last 180 days.
- Existing users of QVAR, Pulmicort Flexhaler, Alvesco, and Asmanex Twisthaler older than 12 years are “grandfathered”. All new users of the non-preferred ICS must try Flovent Diskus or Flovent HFA first, unless the patient has had the following:
 - an inadequate response to Flovent
 - intolerable adverse effects to Flovent (for example, the patient has a history of adrenal suppression and the request is for Alvesco)
 - contraindication to Flovent
 - has previously responded to the non-formulary ICS and changing to Flovent would incur unacceptable risk
 - there is no formulary alternative for the following: the patient is pregnant and requires Pulmicort Flexhaler

Clinical Summary

Asthma

- There is no new evidence that substantively changes the conclusions for the class review completed in 2009.
- In patients with asthma, there is fair-to-moderate evidence that ICS agents do not differ with regard to symptom control, need for rescue medication, and exacerbations.

COPD

- There is insufficient evidence to conclude there are clinically relevant differences in efficacy among the ICS products for treating COPD. The ICS products are not indicated for COPD treatment.

Pediatrics

- Flovent Diskus and Flovent HFA are approved for patients down to the age of 4.

Safety

- In terms of safety, there is insufficient evidence to determine whether there are clinically relevant differences among the ICS products in terms of minor adverse events or systemic adverse events.
- Based on limited data, ciclesonide (Alvesco) is an alternative for patients with adrenal suppression caused by an ICS.
- For pregnant patients, budesonide (Pulmicort Flexhaler) is the only product with a pregnancy category B rating.

Other Factors

- All the products except Alvesco have dose counters.
- Existing MTF utilization: currently there are approximately 2,000 Asmanex Twisthaler Rxs dispensed monthly (15% market share, compared to 83% with Flovent).
- A new HFA formulation of Asmanex (Asmanex HFA) was just approved by the FDA and will be reviewed as a new drug at an upcoming meeting.

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.jbsa.medcom-ameddcs.list.pecuf2@mail.mil

ICS Price Comparison at MTF	
Drug & Dosage Form	MTF cost/month (May 2014)
Basic Core Formulary	
Fluticasone (Flovent Diskus and Flovent HFA)	\$ Most Cost-Effective
Non-Formulary	
Ciclesonide (Alvesco)	\$\$\$ Less Cost-Effective
Flunisolide (Aerospan)	\$\$\$ Less Cost-Effective
Mometasone (Asmanex Twisthaler)	\$\$\$ Less Cost-Effective
Beclomethasone (QVAR)	\$\$\$\$ Least Cost-Effective
Budesonide (Pulmicort Flexhaler)	\$\$\$\$ Least Cost-Effective