

MTF Formulary Management for Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)

Defense Health Agency Pharmacy Operations Division

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Bottom-line

- Advair Diskus and Advair HFA inhaler remain the BCF agents; they are the most cost effective products.
- Reserve use of ICS / LABA combos for patients with persistent asthma uncontrolled on long-term asthma control therapy such as inhaled corticosteroids.
- Prior Authorization and Step Therapy now apply to new and current users of Symbicort, Dulera and Breo-Ellipta older than age 12 – see below.

Uniform Formulary Decision: The Director, DHA approved the recommendations from the February 2014 DoD P&T Committee meeting on May 12, 2014, with an implementation date of July 9, 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*
Fluticasone/Salmeterol (Advair Diskus and Advair HFA)	(See BCF)	Fluticasone/vilanterol (Breo Ellipta) Budesonide/formoterol (Symbicort) Mometasone/formoterol (Dulera)
* Step therapy applies to all patients >12 years–must try Advair Diskus or Advair HFA before one of the other inhalers.		

Clinical Summary

Asthma

- Advair and Symbicort are highly therapeutically interchangeable for asthma; head-to-head trials and systematic reviews show no clinically relevant differences in efficacy.
- For Dulera, there are no head-to-head trials with another ICS/LABA in asthma; clinically relevant differences in efficacy with the other ICS/LABAs are not expected.
- For Breo Ellipta, there is only limited data in patients with asthma, and it is not FDA-approved for this indication.

COPD

- Advair Diskus, Symbicort, and Breo Ellipta are all FDA-approved for maintenance treatment of COPD. Only Advair Diskus and Breo Ellipta are specifically approved for decreasing COPD exacerbations. Symbicort has data from observational studies showing decreases in COPD exacerbations.
- For Advair and Symbicort, there is insufficient evidence to conclude that there are clinically relevant differences in efficacy for COPD.
- Breo Ellipta offers the convenience of once-a-day dosing in COPD. However, the long-term safety of the LABA component vilanterol is not known. One large trial (SUMMIT) evaluating mortality as a primary endpoint is underway.
- Dulera is not approved for COPD; two small trials have shown benefit in improving spirometric endpoints in COPD.

Pediatrics

- Advair Diskus is the only drug approved for asthma in children down to the age of 4; however, for this age range, a metered dose inhaler (MDI) with a spacer is more commonly used. Advair also has the advantage of availability in both a MDI (Advair HFA) and dry powder inhaler (Advair Diskus).
- Symbicort and Dulera are approved for patients down to the age of 12.

Safety

- For safety, a systematic review did not show clinically relevant differences between Advair and Symbicort in asthma. Advair Diskus, Advair HFA, Symbicort, Dulera, and Breo Ellipta all contain the same black box warnings and precautions. All drugs containing a LABA carry a black box warning for an increased risk of death in asthma.
- All the products now have dose counters.

MHS Utilization

- MHS data shows that asthma represents the majority of ICS/LABA use (67%), followed by COPD (37%), with 17% of beneficiaries having ICD-9 codes other than asthma or COPD (e.g., viral infections, bronchitis).

Prior Authorization and Step Therapy apply to this class

- Prior authorization and step therapy apply to new and current users of the ICS/LABAs. All patients must try Advair Diskus or Advair HFA prior to receiving Symbicort, Dulera or Breo-Ellipta, due to the significant cost avoidance.
- Step therapy does not apply to children ≤12 years.
- Existing users of Symbicort, Dulera or Breo-Ellipta older than 12 years are not grandfathered. All new and current users of the non-preferred ICS/LABAs must try Advair first, unless the patient has had an inadequate response to Advair, intolerable adverse effects, contraindication or has previously responded to the non-formulary ICS/LABA and changing to Advair would incur unacceptable risk.

References

- DoD P&T Committee minutes are available at 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 can be downloaded at http://pec.ha.osd.mil/forms_criteria.php?submenuheader=1
- Point Of Contact: For more information usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil

ICS/LABA Price Comparison at MTF	
Drug & Dosage Form	MTF cost/month (Feb 2014)
Basic Core Formulary	
fluticasone/salmeterol (Advair Diskus & Advair HFA)	\$ "Most Cost-Effective"
Non-Formulary	
budesonide/formoterol (Symbicort)	\$\$\$ "Less Cost-Effective"
mometasone/formoterol (Dulera)	\$\$\$ "Less Cost-Effective"
fluticasone/vilanterol (Breo-Ellipta)	\$\$\$\$ "Least Cost-Effective"
Legend:	
\$	= "Most Cost-Effective" = Represents Rx's with the <u>lowest cost</u> and similar clinical efficacy
\$\$	= "Less Cost-Effective" - Represents higher cost Rx's similar clinical efficacy
\$\$\$	= "Lesser Cost-Effective" Represents <u>next higher cost</u> Rx's with similar clinical efficacy
\$\$\$\$	= "Least Cost-Effective" Represents Rx's with the <u>highest cost</u> with similar clinical efficacy