

MTF Formulary Management
Ophthalmic-1s: Antihistamine Mast Cell Stabilizers (AH/MCS) Subclass
 Defense Health Agency Pharmacy Operations Division

Bottom Line

- **Generic olopatadine 0.1% (Patanol generic) remains on the Basic Core Formulary (BCF).**
- **Update Jan 2018:** A new Joint National Contract awarded for olopatadine 0.1% from Golden State, effective Jan 28, 2018, is at a substantially reduced price of \$4.25/5 mL bottle.
- **Olopatadine 0.7% (Pazeo) is now Uniform Formulary (UF), along with azelastine (Optivar generic) and epinastine (Elestat generic).**
- **Olopatadine 0.2% (Pataday) moves from UF to Nonformulary (NF) status. Cost-effective generic Pataday formulations are not yet commercially available.**
- **Prior Authorization (PA) applies to the class – see below.**
- **The 16,000 Military Treatment Facility (MTF) patients with prior/current prescriptions for Pataday will need to be converted to one of the UF products; conversion to generic olopatadine will result in considerable cost avoidance.**
- **There is a high degree of therapeutic interchangeability with the AH/MCS drugs.**

UF Decision: The Director, DHA, approved the recommendations from the May 2017 DoD P&T Committee meeting on July 27, 2017. Implementation will occur by November 1, 2017.

Uniform Formulary (UF) Agents		Nonformulary (NF) Agents
BCF drugs – MTFs <u>must</u> have on formulary	MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<ul style="list-style-type: none"> • olopatadine 0.1% (Patanol generic) 	<ul style="list-style-type: none"> • azelastine (Optivar generic) • epinastine (Elestat generic) • olopatadine 0.7% (Pazeo) 	<ul style="list-style-type: none"> • alcaftadine 0.25% (Lastacraft) • bepotastine 1.5% (Bepreve) • emedastine 0.05% (Emadine) • olopatadine 0.2% (Pataday)

Formulary Management Issues and Prior Authorization

- Allergic conjunctivitis is a highly seasonal condition, and Military Health System (MHS) utilization for the class reflects this variability. Peak usage of the AH/MCS occurs in the month of March.
- Currently, Pataday accounts for 39% of MTF utilization, with olopatadine 0.1% comprising 35% of the market share. Pataday will move to NF status, and patients currently receiving Pataday will need to change to one of the formulary AH/MCS drugs.
- Manual Prior Authorization (PA) applies to the nonformulary drugs in the class (Lastacraft, Bepreve, Emadine, and Pataday). All **new and current** users of a nonformulary product require manual PA in order to stay on the nonformulary drug. PA criteria requirements include the following:
 - The patient must have tried and failed two formulary drugs (olopatadine 0.1%, Pazeo, azelastine or epinastine) in the past 90 days, or
 - The patient has experienced intolerable adverse effects from two formulary products (olopatadine, azelastine or epinastine), or
 - The patient is pregnant (Lastacraft and Emadine are pregnancy category B).
- The price of generic olopatadine 0.1% continues to fall, making this drug a cost-effective AH/MCS.
- The over-the-counter (OTC) product ketotifen (Zaditor, generics) is not part of the TRICARE pharmacy benefit, and the formulary recommendation does not apply to OTC formulations.

Clinical Summary

- The AH/MCS have both antihistamine properties that provide relief of ocular itching and hyperemia along with mast cell stabilizing properties that prevent early phase release of inflammatory mediators. Onset of action occurs within minutes of administration.

- The AH/MCS are the standard of care for treating the signs and symptoms of allergic conjunctivitis.
- Clinical practice guidelines from the American Academy of Ophthalmology and the American Optometric Association recommend the AH/MCS products as first-line therapy for treatment of acute and chronic allergic conjunctivitis. The guidelines do not place preference on any one product.
- A 2015 Cochrane review of topical treatments for allergic conjunctivitis showed that AH/MCS agents were clinically superior to placebo; that olopatadine may be more effective than ketotifen; and, that there is insufficient evidence to discern which topical ophthalmic agent is the most effective in the class.
- A 2016 meta-analysis compared olopatadine with placebo, epinastine, ketotifen, and alcaftadine. Olopatadine showed clinical superiority to placebo; there was no statistically significant difference in ocular symptoms when olopatadine was compared with epinastine and ketotifen; and, olopatadine was inferior to alcaftadine. These differences among products may not be clinically relevant.
- Comparator studies of the olopatadine products show that olopatadine 0.1% and 0.2% are comparable in efficacy. The olopatadine 0.7% formulation only showed a statistically significant reduction in ocular itching at 24 hours following administration, when the next daily dose is due; these results did not meet the threshold for clinical relevance.

Overall Conclusion

- There was no new evidence to change the previous conclusions from the August 2010 DoD P&T Committee meeting, which determined that there was insufficient evidence to suggest clinically relevant differences in efficacy between the AH/MCSs.
- The newest olopatadine 0.7% QD formulation (Pazeo) was statistically superior to olopatadine 0.2% in reducing itchiness and redness, but this change did not translate into a meaningful clinical difference.

References

- DoD P&T Committee minutes:
<http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes>
- Current/future drug classes under review by the DoD P&T Committee:
<http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee>
- TRICARE Formulary Search Tool:
<http://www.express-scripts.com/tricareformulary>
- Prior Authorization/Medical Necessity forms:
See Formulary Search Tool above.
- Formulary Management Documents and Executive Summaries available at:
<http://www.health.mil/DoDPTResources>
- Point of contact for additional information:
dha.jbsa.pharmacy.list.poduf@mail.mil

AH/MCS Price Comparison at MTF	
Drug	MTF Cost/Month (May 2017)
Basic Core Formulary	
Olopatadine 0.1% (Patanol generic)	\$ Most Cost-Effective
Uniform Formulary	
Azelastine (Optivar generic)	\$ Less Cost-Effective
Epinastine (Elestat generic)	\$ Less Cost-Effective
Olopatadine 0.2% (Pazeo)	\$ Less Cost-Effective
Nonformulary	
Alcaftadine (Lastacraft)	\$\$\$\$ Least Cost-Effective
Bepotastine (Bepreve)	\$\$\$\$ Least Cost-Effective
Emedastine (Emadine)	\$\$\$\$ Least Cost-Effective
Olopatadine 0.2% (Pataday)	\$\$\$\$ Least Cost-Effective
Legend: \$ = "Most Cost-Effective" represents Rx's with the <u>lowest cost</u> and best clinical efficacy \$ = "Less Cost-Effective" represents <u>higher cost</u> Rx's with similar clinical efficacy \$ = "Less 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	