

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
INTERIM MEETING
Addendum March 7, 2017**

I. UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

A. Proton Pump Inhibitors (PPIs)

Background—Following the February 2017 DoD P&T Committee meeting, the Pharmacy Operations Division became aware of a contract cancellation that would significantly impact MHS expenditures for the PPI Drug Class. An interim meeting was held to determine the clinical and cost-effectiveness, and UF status of the PPIs. The PPIs were previously evaluated for UF status at the May 2007 meeting. Current automated prior authorization (PA) (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), pantoprazole, or rabeprazole applies to new users presenting with a prescription for a nonformulary PPI.

Relative Clinical Effectiveness Conclusion—At the May 2007 meeting, the P&T Committee reviewed evidence across a wide range of disease states and, in summary, concluded that PPIs appear very similar with regard to efficacy, safety, and tolerability. Recent updates to the safety of the PPIs were presented at the November 2016 P&T Committee meeting. There have been three drug safety communications from the U.S. Food and Drug Administration relating to long-term safety concerns with the PPIs as a class. The P&T Committee did not find new clinical evidence that would alter the conclusion from 2007 that the PPIs are highly therapeutically interchangeable. Risks of long-term use (>1 year) without a clear indication for use could outweigh the benefits of the PPIs. Deprescribing should be considered for appropriate patients.

Relative Cost-Effectiveness Analysis and Conclusion—The current costs for the PPIs were evaluated. Nexium brand is exponentially more expensive than therapeutically equivalent generic PPIs.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) esomeprazole (Nexium brand and generics) be designated nonformulary and non step-preferred. Nonformulary PPIs would be subject to the requirement that they generally be available only in the Mail Order Pharmacy, regardless of generic status. The formulary recommendation is as follows:

- UF and Step-Preferred:
 - omeprazole (Prilosec generics)
 - pantoprazole (Protonix generics)
 - rabeprazole tablets (Aciphex generics)

- UF and Non Step-Preferred:
 - omeprazole 40 mg capsule (Prilosec)
 - rabeprazole sprinkles (Aciphex sprinkles)

 - NF and Non Step-Preferred:
 - esomeprazole (Nexium brand and generics)
 - esomeprazole strontium
 - dexlansoprazole (Dexilant)
 - lansoprazole (Prevacid)
 - omeprazole/sodium bicarbonate (Zegerid)

 - This recommendation includes step therapy (automated PA), which requires a trial of omeprazole, pantoprazole, and rabeprazole in new and current users presenting with a prescription for esomeprazole, and in new users presenting with a prescription for one of the other nonformulary PPIs.

 - As part of this recommendation, the current Tier 1 copayment for Nexium will move to the Tier 3 nonformulary copayment at the Retail Network and Mail Order Pharmacy.
2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing esomeprazole from the BCF and adding pantoprazole to the BCF. Refer to the addendum signed by RADM C. Chinn for VADM R.C. Bono, Director, Defense Health Agency, on March 20, 2017.

 3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) MN criteria for esomeprazole (Nexium), consistent with the other nonformulary PPIs. No changes to the current MN criteria for the other nonformulary PPIs were recommended. See Appendix B for the full criteria.

 4. **COMMITTEE ACTION: AUTOMATED (STEP THERAPY) AND MANUAL PA CRITERIA**—Existing automated PA (step therapy) requires a trial of omeprazole, Nexium, pantoprazole, and rabeprazole prior to use of a nonformulary PPI.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) modifying the existing step therapy and manual PA criteria to require all new and current users of esomeprazole to try omeprazole, pantoprazole, and rabeprazole first. See Appendix C for the full criteria.

5. **COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD**—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee’s recommendation, the effective date will be no later than June 28, 2017.

Director, DHA, Decision:

Approved

Disapproved

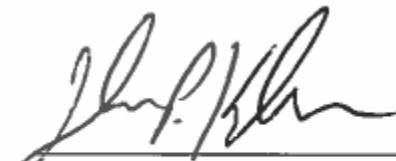
Approved, but modified as follows:

Appendix A—Table of Medical Necessity Criteria

Appendix B—Table of Prior Authorization Criteria

**Appendix C—Table of Implementation Status of UF Recommendations/Decisions
Summary**

SUBMITTED BY



John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.



RADM Colin Chinn, MC, USN
Acting Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director, DHA

31 MAR 2017

Date

Appendix A—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> • esomeprazole (Nexium) <p>Proton Pump Inhibitors (PPIs)</p>	<ul style="list-style-type: none"> • Use of ALL formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from ALL formulary agents • All formulary agents result or are likely to result in therapeutic failure <p>Formulary alternatives: omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics)</p>

Appendix B—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • esomeprazole (Nexium) <p>Proton Pump Inhibitors (PPIs)</p>	<p>PA criteria apply to all new and current users of esomeprazole (Nexium).</p> <p><u>Automated PA criteria:</u> The patient has filled a prescription for omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics) at any Military Health Service (MHS) pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order), during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA criteria:</u> A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if:</p> <ul style="list-style-type: none"> • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response. • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects. • Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

Appendix C—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications (NF) MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Mar 2017 Interim	Proton Pump Inhibitors (PPIs)	UF class review	<p><u>Step-Preferred:</u></p> <ul style="list-style-type: none"> ▪ omeprazole (Prilosec generics); excludes 40 mg branded product ▪ pantoprazole (Protonix, generics) 	<p><u>UF and Step-Preferred:</u></p> <ul style="list-style-type: none"> ▪ rabeprazole tabs (Aciphex generics) <p><u>UF and Non Step-Preferred:</u></p> <ul style="list-style-type: none"> ▪ omeprazole 40 mg cap (Prilosec) ▪ rabeprazole sprinkles (Aciphex sprinkles) 	<p><u>NF and Non Step-Preferred:</u></p> <ul style="list-style-type: none"> ▪ esomeprazole (Nexium brand and generic) ▪ esomeprazole strontium ▪ dexlansoprazole (Dexilant) ▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid) 	Pending signing of the minutes / BCF change at signing and NF no later than 90 days	See comments	<ul style="list-style-type: none"> ▪ Nexium removed from the BCF and made NF and non step-preferred ▪ Pantoprazole generic added to the BCF ▪ All new and current users of Nexium must try omeprazole, pantoprazole, and rabeprazole first (See Appendix C)