



## Uniform Formulary Medical Necessity Criteria for Proton Pump Inhibitors

**Drug Class** - Proton Pump Inhibitors (PPIs). This class includes six products: esomeprazole (Nexium), omeprazole, omeprazole/sodium bicarbonate (Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), rabeprazole (Aciphex), and dexlansoprazole (Dexilant/Kapidex).

**Background** - After evaluating the relative clinical and cost effectiveness of the PPIs, the DoD P&T Committee recommended that the following medications be designated as non-formulary on the Uniform Formulary. This recommendation has been approved by the Director, TMA.

- Aciphex (rabeprazole)
- Prevacid (lansoprazole)
- Protonix (pantoprazole)
- Zegerid (omeprazole/sodium bicarbonate)
- Dexilant [ *formerly named Kapidex*] (dexlansoprazole)

**Effective Date:** 24 Oct 2007; 28 Sept 2009

Patients currently using a non-formulary agent may wish to consult their doctor to consider a formulary alternative. Both omeprazole and Nexium (esomeprazole) are available at the generic cost share.

### Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Proton Pump Inhibitors<sup>1-5</sup>

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) cost share for up to a 90 day supply	Mail Order cost share for up to a 90 day supply	Retail Network cost share for up to a 30 day supply
Non-Formulary (Tier 3)	Aciphex (rabeprazole) Prevacid (lansoprazole) <sup>5</sup> Protonix (pantoprazole) Zegerid (omeprazole/sodium bicarbonate) Dexilant [ <i>formerly Kapidex</i> ] (dexlansoprazole)	Not available <sup>2</sup>	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	-	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic (Tier 1)	Generic omeprazole <sup>3</sup> Nexium (esomeprazole) <sup>4</sup>	\$0	Generic cost share applies	Generic cost share applies

1. Active duty cost share always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.

2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is

established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

3. [Mandatory generic policy](#) applies to both formulary and non-formulary medications.
4. Although Nexium (esomeprazole) is a branded product, the DoD P&T Committee recommended that it be made available at a generic cost share based on its similar clinical and cost effectiveness compared to generic omeprazole.
5. Prevacid is available in oral suspension and orally disintegrating tablet formulations and has been approved by the FDA for children as young as 1 year of age. The formulary PPI Nexium is also available as an oral suspension, but is not FDA-approved for pediatric use in children younger than 12 years of age. The only other PPI with a liquid formulation is Zegerid, which has not been studied in children.

### Special Notes

[Step therapy / prior authorization \(PA\)](#) requirements apply to all non-formulary drugs in this class, effective 24 Oct 2007. The medical necessity form may NOT be used to meet PA requirements.

### Medical Necessity Criteria for Aciphex, Prevacid, Protonix, Zegerid, and Kapidex

The non-formulary cost share for Aciphex, Prevacid, Protonix, Zegerid or Dexilant/ Kapidex may be reduced to the formulary cost share IF the patient meets any of the following criteria:

1. Use of ALL of the following formulary alternatives is contraindicated (e.g., due to hypersensitivity): omeprazole (Prilosec, generics) and esomeprazole (Nexium).
2. The patient has experienced significant adverse effects with ALL of the following formulary alternatives: omeprazole (Prilosec, generics) and esomeprazole (Nexium).
3. Use of ALL of the following formulary alternatives has resulted in therapeutic failure: omeprazole (Prilosec, generics) and esomeprazole (Nexium).
4. **Prevacid only** - The patient is younger than 12 years of age.

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the May 2007 meeting & approved by the Director, TMA on 24 Jul 2007. Kapidex criteria recommended by the DoD Pharmacy & Therapeutics Committee at the May 2009 meeting & approved by the Director, TMA on 17 Aug 2009. For more information, please see the [May 2007 DoD P&T Committee minutes](#).

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TRICARE Management Activity,  
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Skyline 5, Suite 810, 5111 Leesburg Pike,  
Falls Church, VA 22041-3206

