



## Uniform Formulary Medical Necessity Criteria for Macrolide/Ketolide Antibiotics

**Drug Class** - Macrolide/ketolide antibiotics

**Background** - After evaluating the relative clinical and cost effectiveness of the macrolide/ketolide antibiotics, the DoD P&T Committee recommended that the following medications be designated as non-formulary: telithromycin (Ketek) and azithromycin sustained release suspension (Zmax). This recommendation has been approved by the Director, TMA.

**Effective Date:** 22 March 2006

Patients currently using a nonformulary macrolide/ketolide product may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost shares, and Therapeutic Alternatives for Macrolide/Ketolide Antibiotics\*, \*\*

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail Network (up to a 30-day supply)
Non-Formulary (Tier 3)	Telithromycin (Ketek) Azithromycin sustained release suspension (Zmax)	Not available**	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)	Azithromycin Erythromycin Clarithromycin	\$0	Generic cost share applies	Generic cost share applies
<p>* 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.</p> <p>** 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.</p>				

### Medical Necessity Criteria for Ketek (telithromycin) and Zmax (azithromycin sustained release suspension)

The non-formulary cost share for Ketek (telithromycin) may be reduced to the formulary cost share if:

1. Use of ALL of the formulary macrolide antibiotics (azithromycin, clarithromycin, and erythromycin) is contraindicated.
2. The patient has experienced significant adverse effects from ALL of the formulary macrolide antibiotics (azithromycin, clarithromycin, and erythromycin), and is not expected to experience these effects with Ketek.
3. Use of ALL of the formulary macrolide antibiotics (azithromycin, clarithromycin, and erythromycin) has resulted in therapeutic failure or is likely to result in therapeutic failure (e.g., due to lack of activity against a particular organism) AND Ketek therapy is appropriate.
4. The patient cannot be treated with formulary macrolide antibiotics due to a recent history of documented multi-resistant *S. pneumoniae* (MDRSP) and use of other formulary antibiotics (e.g., fluoroquinolones, high dose aminopenicillins) is not appropriate.

The non-formulary cost share for the nonformulary azithromycin product Zmax (sustained release suspension) may be reduced to the formulary cost share if:

1. Use of all other azithromycin products (250 or 500 mg tablets or immediate release suspension) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient), and treatment with Zmax sustained release suspension is not contraindicated.

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the November 2005 meeting & approved by the Director, TMA on 19 Jan 2006. For more information, please see the [November 2005 DoD P&T Committee minutes](#).

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