



## Uniform Formulary Medical Necessity Criteria for Topical Antifungals

**Drug Class** - Topical Antifungals

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

**Effective Date:** 17 Aug 2005

- Ciclopirox (Loprox)
- Econazole (Spectazole)
- Oxiconazole (Oxistat)
- Sertaconazole (Ertaczo)
- Sulconazole (Exelderm)

**Effective Date:** 21 Feb 2007

- Miconazole 0.25% / zinc oxide 15% (Vusion)

Patients currently using a non-formulary topical antifungal may wish to consult their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost shares, and Therapeutic Alternatives for Topical Antifungals\*

Uniform Formulary Status	Medication		MTF (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail (up to a 30-day supply)
	Brand name	Generic Name			
Non-Formulary (Tier 3)	Ertaczo Exelderm Loprox Oxistat Spectazole Vusion	sertaconazole sulconazole ciclopirox oxiconazole econazole miconazole 0.25% / zinc oxide 15%***	Not available**	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	Mentax Naftin Nizoral	butenafine naftifine ketoconazole	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic	-	clotrimazole	\$0	Generic cost	Generic cost

(Tier 1)	- - -	ketoconazole miconazole nystatin		share applies	share applies
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\* 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.

\*\* 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.

\*\*\* Miconazole 0.25% / zinc oxide 15% (Vusion) is FDA-indicated for the adjunctive treatment of diaper dermatitis (diaper rash) only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent children 4 weeks of age and older. Other topical antifungals commonly used for diaper rash include higher concentrations of miconazole (2%), clotrimazole, and nystatin, often used in conjunction with zinc oxide ointment, an over-the-counter skin protectant.

### Special Notes

- Some topical antifungals listed above are also available as over-the-counter products, which are not covered by TRICARE. Visit the Formulary Search Tool page to find if a specific product is over-the-counter.
- Brand-name topical antifungal products that have generic equivalents are not covered by TRICARE. Visit the Formulary Search Tool page to find if a specific product is over-the-counter.
- The non-formulary cost share applies to all products designated as non-formulary. Approval of medical necessity for such products reduces the cost share to the formulary.
- The following medical necessity criteria do not apply to Penlac Nail Lacquer (ciclopirox topical solution), which is available at the formulary cost share; however, prior authorization is required for Penlac.

### Medical Necessity Criteria

**Ciclopirox (Loprox), oxiconazole (Oxistat), sertaconazole (Ertaczo), and sulconazole (Exelderm) -**  
The \$22 non-formulary cost share may be reduced to the \$9 formulary cost share if the patient has tried ALL of the formulary alternatives or has a clinical reason(s) for not trying ALL of the alternatives, based on the following criteria:

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The formulary agent is not available in the desired formulation.
3. The formulary agent caused or is likely to cause significant burning, itching, redness or other significant adverse effects.
4. An adequate treatment course with the formulary agent resulted in therapeutic failure.
5. The formulary agent is not effective for the treatment of the specific condition. For example, nystatin is not effective for the treatment of tinea pedis, corporis, cruris, or versicolor.

**Miconazole 0.25% / zinc oxide 15% ( Vusion) -** The \$22 non-formulary cost share may be reduced to the \$9 formulary cost share if the patient has tried ALL of the formulary alternatives or has a clinical reason(s) for not trying ALL formulary alternatives, based on the following criteria. Formulary alternatives include higher concentrations of miconazole (2%), clotrimazole, and nystatin, which are often used in conjunction with zinc oxide ointment, an over-the-counter skin protectant.

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from the formulary agent.
3. The formulary agent is not available in the desired formulation.

Criteria for ciclopirox, oxiconazole, sertaconazole, and sulconazole recommended by the DoD Pharmacy & Therapeutics Committee at the May 2005 meeting & approved by the Director, TMA on 14 July 2005.

Criteria for miconazole 0.25%/zinc oxide 15% recommended by the DoD Pharmacy & Therapeutics Committee at the November 2006 meeting & approved by the Director, TMA on 17 January 2007. For more information, please see the [May 2005 and November 2006 DoD P&T Committee minutes](#).

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