



## Prior Authorization Approval Criteria

### *Extina (ketoconazole foam 2%)*

|                                  |  |
|----------------------------------|--|
| <b>Generic name:</b>             | Ketoconazole   |
| <b>Brand name:</b>               | Extina   |
| <b>Medication class:</b>         | Topical antifungal   |
| <b>FDA-approved uses:</b>        | Topical application in the treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. |
| <b>Available dosage forms:</b>   | 2% ketoconazole foam in 50g and 100g aluminum containers.  |
| <b>Usual dose range:</b>         | Applied to the affected areas twice daily for four weeks.  |
| <b>Duration of therapy:</b>      | Four weeks.  |
| <b>Approximate monthly cost:</b> | 50g container \$149.50; 100g container \$299.00<br><i>(based on AWP 2008)</i>  |

**Criteria for use** *(bullet points below are all inclusive unless otherwise noted):*

- Clinically diagnosed seborrheic dermatitis.
- Failed/ intolerant to at least two different formulations of topical ketoconazole (cream, gel or shampoo).
- Failed/ intolerant to at least one over the counter product to treat seborrheic dermatitis.
- Must be 12 years of age or older.

**Contraindications:** None known.

**Not approved if:**

- Patient does not meet the above-stated criteria
- For convenience or preference.
- Being used for a fungal infection\*.

**Continuation of therapy**

- Physician must provide updates on the stability of the tumor.
- If tumor progression is noted therapy may not be continued.

**Special considerations:**

No data to prove it is better than other formulations of topical ketoconazole.  
Safety and efficacy of Extina foam for treatment of fungal infections have not been established.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/18/08