Ertaczo

Description

Ertaczo (sertaconazole)

Background
Ertaczo cream is used on the skin (topical) to treat athlete’s foot that is between the toes (interdigital tinea pedis) caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes* and *Epidermophyton floccosum*, in people 12 years of age and older with normal immune systems (1).

Regulatory Status
FDA-approved indications: Ertaczo is an azole antifungal indicated for the treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older, caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* (1).

Safety and effectiveness of Ertaczo in pediatric patients under 12 years of age has not been established (1).

Related policies
Ecoza, Exelderm, Jublia, Kerydin, Luzu, Oxistat

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ertaczo may be considered medically necessary in patients 12 years of age or older with interdigital tinea pedis with laboratory and clinical documentation of one of the following
infections: *Trichophyton rubrum*, *Trichophyton mentagrophytes* and *Epidermophyton floccosum* and if the conditions indicated below are met.

Ertaczo is considered **investigational** in patients less than 12 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

12 years of age or older

**Diagnosis**

Patient must have the following:

Interdigital Tinea Pedis

**AND ALL** of the following:

1. Laboratory and clinical documentation of **ONE** of the following infections:
   a. *Trichophyton rubrum*
   b. *Trichophyton mentagrophytes*
   c. *Epidermophyton floccosum*

2. Inadequate treatment response, intolerance, or contraindication to a topical or oral antifungal legend medication

3. **NOT** immunocompromised

**Prior – Approval Renewal Requirements**

**Age**

12 years of age or older

**Diagnosis**

Patient must have **ONE** of the following:

Interdigital Tinea Pedis

**AND ALL** of the following:

1. Laboratory and clinical documentation of **ONE** of the infections:
   a. *Trichophyton rubrum*
   b. *Trichophyton mentagrophytes*
   c. *Epidermophyton floccosum*
2. **NOT** used in a previously treated location within last 12 months
3. **NOT** immunocompromised

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity** 60 units

**Duration** 1 month

**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**

Ertaczo is an antifungal cream used topically to treat interdigital tinea pedis caused by the following organisms *Trichophyton rubrum, Trichophyton mentagrophytes and Epidermophyton floccosum*. Safety and effectiveness of Ertaczo in pediatric patients under 12 years of age has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Ertaczo while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

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<td>June 2015</td>
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<td>September 2015</td>
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<td>December 2016</td>
<td>Annual editorial review and reference update. Policy number change from 5.14.15 to 5.90.15</td>
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September 2017    Annual review
September 2018    Annual review
September 2019    Annual review and reference update
December 2019     Annual review. Addition of quantity limit of 60 units

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.