

## 5.90.15

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	June 26, 2015
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**Last Review Date:** March 12, 2021

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## 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

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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*

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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

1. Ertaczo [package Insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; November 2017.

## Policy History

Date	Action
June 2015	Addition to PA
September 2015	Annual review
December 2016	Annual editorial review and reference update. Policy number change from 5.14.15 to 5.90.15

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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
September 2020	Annual review
March 2021	Annual review

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**