

5.90.015

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	June 26, 2015
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**Last Review Date:** March 8, 2024

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## Ertaczo

### Description

#### Ertaczo (sertaconazole)

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#### 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).

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#### 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** if the conditions indicated below are met.

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Ertaczo may be considered **investigational** 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. Suspected infection of **ONE** of the following fungal species:
  - a. *Trichophyton rubrum*
  - b. *Trichophyton mentagrophytes*
  - c. *Epidermophyton floccosum*
2. Inadequate treatment response, intolerance, or contraindication to a topical or oral antifungal legend medication (e.g., fluconazole, terbinafine, ketoconazole, etc.)
3. **NOT** immunocompromised

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## Prior – Approval *Renewal* Requirements

**Age** 12 years of age or older

### Diagnosis

Patient must have the following:

Interdigital Tinea Pedis

**AND ALL** of the following:

1. Suspected infection of **ONE** of the following fungal species:
  - a. *Trichophyton rubrum*
  - b. *Trichophyton mentagrophytes*
  - c. *Epidermophyton floccosum*

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## 2. **NOT** immunocompromised

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Quantity** 60 units

**Duration** 1 month

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#### 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: Bausch Health US, LLC; December 2020.

### 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
September 2017	Annual review
September 2018	Annual review

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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
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.90.015
September 2023	Annual review. Per SME, revised requirement for laboratory documentation of a fungal infection to “suspected infection”, added examples of legend drugs, removed requirement for continuation: “NOT used in a previously treated location within the last 12 months”
March 2024	Annual review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**