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5.90.015

Section: Prescription Drugs Effective Date: April 1, 2025

Subsection: Topical Products Original Policy Date: June 26, 2015

Subject: Ertaczo Page: 1 of 4

Last Review Date: March 7, 2025

### 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** 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

# 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

# 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
September 2024 Annual review
March 2025 Annual review

**Keywords** 

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.