

5.90.010

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| Section: | Prescription Drugs | Effective Date: | October 1, 2023 |
| Subsection: | Topical Products | Original Policy Date: | January 1, 2015 |
| Subject: | Luzu | Page: | 1 of 4 |

Last Review Date: September 8, 2023

Luzu

Description

Luzu (Iuliconazole)

Background

Luzu (Iuliconazole) is a topical azole antifungal cream used to treat athlete's foot that is between the toes (interdigital tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*. Although the exact mechanism of action of Luzu is unknown, it appears to work by weakening the structure and function of the fungal cell membrane (1).

Regulatory Status

FDA-approved indications: Luzu is an azole antifungal indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum* (1).

Safety and effectiveness of Luzu in pediatric patients have been established (1).

Related policies

Ecoza, Ertaczo, Exelderm, Topical Antifungals, 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.

Luzu may be considered **medically necessary** if the conditions indicated below are met.

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Luzu may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

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

1. Interdigital Tinea Pedis
2. Tinea Cruris
3. Tinea Corporis

AND ALL of the following:

1. Suspected infection of **ONE** of the following fungal species:
 - a. *Trichophyton rubrum*
 - b. *Epidermophyton floccosum*
2. Inadequate treatment response, intolerance, or contraindication to a legend topical or oral antifungal medication (e.g., fluconazole, terbinafine, ketoconazole, etc.)

Prior – Approval *Renewal* Requirements

Diagnoses

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

1. Interdigital Tinea Pedis
2. Tinea Cruris
3. Tinea Corporis

AND ALL of the following:

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

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Pre - PA Allowance

None

Prior - Approval Limits

Quantity 60 units

Duration 1 month

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Luzu (luliconazole) is a topical azole antifungal cream used to treat interdigital tinea pedis, tinea cruris, and tinea corporis caused by *Trichophyton rubrum* and *Epidermophyton floccosum*. Although the exact mechanism of action of Luzu is unknown, it appears to work by weakening the structure and function of the fungal cell membrane. Safety and effectiveness of Luzu in pediatric patients have been established (1).

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

References

1. Luzu [package Insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.

Policy History

| Date | Action |
|----------------|---|
| December 2014 | Addition to PA and |
| March 2015 | Annual editorial review and reference update |
| December 2016 | Annual editorial review and reference update Added age limit to renewal criteria. Policy number changed from 5.14.10 to 5.90.10 |
| September 2017 | Annual editorial review |
| March 2018 | Removal of age from initiation and renewal criteria |
| June 2018 | Annual review |
| September 2019 | Annual review |
| December 2019 | Annual review. Addition of quantity limit of 60 units |

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| September 2020 | Annual review |
| June 2021 | Annual editorial review and reference update |
| June 2022 | Annual review |
| June 2023 | Annual review. Changed policy number to 5.90.010 |
| 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” |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.