Clinical Policy Title:	luliconazole
Policy Number:	RxA.610
Drug(s) Applied:	Luzu®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Luliconazole cream (Luzu®), 1% is an azole antifungal. It is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum and Epidermophyton floccosum.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
luliconazole cream (Luzu®)	Tinea pedis	Apply to affected and immediate surrounding area(s) once daily for 2 weeks	Varies
	Tinea cruris, tinea corporis	Apply to affected and immediate surrounding area(s) once daily for 1 week	Varies

Dosage Forms

- Cream (1%): 60 g

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Tinea Infections (must meet all)**:**

1. Diagnosis of tinea pedis, tinea cruris, or tinea corporis;
2. Member meets once of the following (a or b)
   a. Age ≥ 12 years for tinea pedis and tinea cruris;
   b. Age ≥ 2 years for tinea corporis;
3. Failure of two formulary topical azole antifungal products (e.g., clotrimazole, ketoconazole, econazole), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one tube (60 g) per month.

Approval duration
Commercial: 1 month
Medicaid: 1 month

II. Continued Therapy Approval

A. Tinea Infections

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration
Commercial: Not applicable
Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clotrimazole cream (Lotrimin® AF), ointment (Alevazol®)	Apply to affected area Twice daily	Varies
econazole cream, foam (Ecoza®)	Apply to affected area Once daily	Varies
ketoconazole cream	Apply to affected and immediate surrounding area once daily	Varies
miconazole spray (Lotrimin® AF)	Apply to affected area twice daily	Varies
oxiconazole cream, lotion (Oxistat®)	Apply to affected area 1-2 times per day	Varies
sulconazole cream, solution (Exelderm®)	Tinea corporis/tinea cruris: apply to affected and surrounding area 1 – 2 times daily Tinea pedis (cream): apply to affected area twice daily	Varies

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

APPENDIX D: General Information

- The exact mechanism of action is unknown; however, luliconazole may exert its antifungal activity by disrupting normal fungal cell membrane permeability. Luliconazole and other azole antifungal agents inhibit lanosterol desmethylase in susceptible fungi, which leads to a decrease in ergosterol concentration and accumulation of lanosterol.
- Avoid ocular exposure to luliconazole; do not administer by ophthalmic administration. If ocular exposure occurs, treat by immediately flushing the affected eye with cool, clean water.

References

1. Luzu® Prescribing Information. Bridgewater, NJ: Bausch Health US, LLC; April 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a7016010-ce43-4c09-8d21-aeb697ffed31. Accessed October 14, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Available at: http://www.micromedexsolutions.com. Accessed October 14, 2021.
3. Luliconazole, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed October 14, 2021.
4. Clinical Pharmacology. Tampa, FL: Elsevier, 2020. Available at: http://www.clinicalkey.com. Accessed October 14, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title table was updated. Line of Business Policy Applies to was updated to “All lines of business”. 2. Dosing regimen was updated “QD” is changed to “once daily”. 3. Commercial and Medicaid approval duration rephrased from 4 weeks to 1 month for initial. 4. Appendix B was updated: Pre table phrase was updated to “Below are suggested therapeutic alternatives..” 5. “QD” changed to “once daily” in therapeutic alternative. 6. Appendix B: Discontinued brands were removed. 7. Appendix D General information was added. 8. References was reviewed and updated.	10/02/2020	12/07/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A.2 was updated	10/14/2021	12/07/2021

to include age criteria as per indications Tinea pedis, Tinea cruris and tinea corporis. 3. Appendix B was updated to remove "sertaconazole cream, clotrimazole athletes Foot" generics as these were not available in US. 4. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 5. References were reviewed and updated.		