

Clinical Policy Title:	luliconazole cream
Policy Number:	RxA.610
Drug(s) Applied:	Luzu®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
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.

I. Initial Approval Criteria

A. Tinea Infections (must meet all):

1. Diagnosis of tinea pedis, tinea cruris, or tinea corporis;
2. Age 2 years or more;
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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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, Athletes Foot), ointment (Alevazol [®])	Apply to affected area BID	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 (Lotrimin AF)	Apply to affected area BID	Varies
oxiconazole cream, lotion (Oxistat [®])	Apply to affected area Once daily – BID	Varies
Ertaczo [®] (sertaconazole cream)	Tinea pedis: apply to affected area BID	Varies
Exelderm [®] (sulconazole cream, solution)	<i>Tinea corporis/tinea cruris:</i> apply to affected and surrounding area Once daily – BID <i>Tinea pedis (cream):</i> apply to affected area BID	Varies

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

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: <http://www.luzurx.com>. Accessed October 02, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 02, 2020.
3. Luliconazole, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed October 02, 2020.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: <http://www.clinicalkey.com>. Updated January 14, 2020. Accessed October 02, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 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