Drug Monograph

Drug/Drug Class:	**Luzu™ (luliconazole) cream/ azole antifungal**
Prepared for:	MO HealthNet
Prepared by:	Xerox Heritage, LLC

☒ New Criteria ☐ Revision of Existing Criteria

Executive Summary

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms & Manufacturer:	Luzu™ is available as a 1% topical cream containing luliconazole. Manufactured for: Medicis, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 Manufactured by: DPT Laboratories, Ltd., San Antonio, TX 78215
Summary of Findings:	Luzu™ is a topical azole antifungal cream approved for the treatment of adults with athlete's foot (interdigital tinea pedis), jock itch (tinea cruris), or ringworm (tinea corporis) caused by Trichophyton rubrum and Epidermophyton floccosum. It is the first topical antifungal agent approved with a once daily 1-week course of treatment for tinea cruris and tinea corporis,
Status Recommendation:	☐ Prior Authorization (PA) Required ☐ Open Access ☐ Fiscal Edit ☒ PDL Edit
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Preferred Agent ☐ Appropriate Indications ☒ Under Solicitation

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction[1]

Topical fungal infections, while common, can be difficult to treat. An additional treatment option, with a shorter duration, can be helpful in resolving infections completely.

Dosage Form(s) [1]

Luzu™ is available as a 1% topical cream containing luliconazole.

Manufacturer [1]

Manufactured for: Medicis, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807
Manufactured by: DPT Laboratories, Ltd., San Antonio, TX 78215

Indication(s) [1]

Luzu™ is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by Trichophyton rubrum and Epidermophyton floccosum in adults.

Clinical Efficacy [1] (mechanism of action/pharmacology, comparative efficacy)

Luzu™ is an azole antifungal that appears to inhibit the conversion of lanosterol to ergosterol by inhibiting the enzyme lanosterol demethylase. This results in accumulation of lanosterol and a decreased amount of ergosterol in fungal cell membranes.

Pharmacokinetics

Protein Binding	Luliconazole is > 99% protein bound.

Luzu™ 1% cream was evaluated in 3 randomized, double-blind, placebo-controlled, clinical trials. In patients with tinea cruris (n=256), Luzu completely cleared the infection at 3 weeks post-treatment in 21% of patients compared with 4% of patients who received placebo. In 2 trials of patients with interdigital tinea pedis (n=423), Luzu completely cleared the infection at 4 weeks post-treatment in 26% of patients compared with 2% of patients who received placebo in study 1, and 14% compared with 3%, respectively, in study 2.

TINEA CRURIS

STUDY DESIGN	Randomized, double-blind, vehicle-controlled, multicenter study (n=256).
INCLUSION CRITERIA	Adults with a clinical and culture confirmed diagnosis of tinea cruris.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients (mean age, 40 years) were randomized to Luzu™ 1% cream or vehicle applied once daily for 7 days.
RESULTS	Overall treatment success, defined as complete clearance (clinical cure and mycological cure) at 3 weeks post-treatment, occurred in 21% of patients who received Luzu™ (n=165) and 4% of patients who received placebo (n=91). Treatment was effective, defined as a negative KOH and culture with only mild erythema and/or scaling but no pruritus, in 43% with Luzu™ and 19% with placebo. Clinical cure (ie, absence of erythema, scaling, and pruritus) was achieved in 24% and 7%, while mycological cure (ie, negative KOH and fungal culture) was achieved in 78% and 45% of the Luzu™ and placebo groups, respectively.
SAFETY	Not specified.

INTERDIGITAL TINEA PEDIS

STUDY DESIGN	Two randomized, double-blind, vehicle-controlled, multicenter studies (n=423).
INCLUSION CRITERIA	Adults with a clinical and culture confirmed diagnosis of interdigital tinea pedis.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients (mean age, 41 years) were randomized to Luzu™ 1% cream or vehicle applied once daily for 14 days.
RESULTS	Overall treatment success, defined as complete clearance (clinical cure and mycological cure) at 4 weeks post-treatment, occurred in 26% of patients with Luzu™ (n=106) versus 2% of patients with placebo (n=103) in study 1, and 14% (n=107) versus 3% (n=107), respectively, in study 2. Treatment was effective (defined as negative KOH and culture with only mild erythema and/or scaling but no pruritus) in 48% of the Luzu™ group

	and 10% of the placebo group in study 1 and 33% and 15%, respectively, in study 2. Clinical cure (ie, absence of erythema, scaling, and pruritus) was achieved in 29% and 8% of Luzu™ and placebo patients, respectively, in study 1, and 15% and 4%, respectively, in study 2. Mycological cure (ie, negative KOH and fungal culture) was achieved in 62% and 18% of Luzu™ and placebo patients, respectively, in study 1, and 56% and 27%, respectively, in study 2.
SAFETY	Not specified.

Contraindications (1)

- None

Warnings and Precautions (1)

- None

Adverse Effects (1)

Application site reactions (n=616), occurred in < 1% of patients.

Drug Interactions (1)

- No interaction studies have been performed

Dosage and Administration (1)

Apply a sufficient amount to cover affected skin and approximately 1 inch of the immediate surrounding area(s) once daily for 1 week for tinea cruris or tinea corporis, and once daily for 2 weeks for interdigital tinea pedis.

Cost

GENERIC NAME	BRAND NAME	MANUFACTURER	STRENGTH	COST/ PACKAGE
Luliconazole cream	Luzu	Valeant	1%, 60 g tube	$ 379.80

*WholesaleAcquisitionCost

Conclusion

Luzu™ is a topical azole antifungal cream approved for the treatment of adults with athlete's foot (interdigital tinea pedis), jock itch (tinea cruris), or ringworm (tinea corporis) caused by Trichophyton rubrum and Epidermophyton floccosum. It is the first topical antifungal agent approved with a once daily 1-week course of treatment for tinea cruris and tinea corporis, while

other agents require 2 weeks of treatment. Interdigital tinea pedis still requires 2 weeks of treatment. The most common adverse effects are mild application site reactions.

Recommendation

This drug is being considered for inclusion in the state specific Preferred Drug List (PDL).

References

Product Information: Luzu™, luliconazole cream. Valeant Pharmaceuticals, Bridgewater, NJ, 11/2013.

Prepared by: Katie Wilbers, PharmD
Date: May 14, 2014

