

Federal Employee Program. Federal Employee Program® 750 9th St NW Washington, D.C. 20001 202.942.1000 Fax 202.942.1125

5.90.014

Section: Prescription Drugs Effective Date: April 1, 2024

Subsection: Topical Products Original Policy Date: June 5, 2015

Subject: Exelderm Page: 1 of 4

Last Review Date: March 8, 2024

Exelderm

Description

Exelderm (sulconazole nitrate)

Background

Exelderm is used to treat skin infections such as jock itch (tinea cruris) and ringworm (tinea corporis). This medication is also used to treat a skin condition known astinea (pityriasis versicolor), a fungal infection that causes a lightening or darkening of the skin of the neck, chest, arms, or legs. Sulconazole is an azole antifungal that works by preventing the growth of fungus (1).

Regulatory Status

FDA-approved indications: Exelderm is an azole antifungal indicated for the treatment of tinea tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*, and for the treatment of tinea versicolor. Effectiveness has not been proven in tinea pedis (athlete's foot) (1).

Safety and effectiveness of Exelderm in pediatric patients has not been established (1).

Related policies

Ecoza, Ertaczo, 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.

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

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

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

- 1. Tinea Cruris
 - a. Suspected infection of **ONE** of the following fungal species
 - i. Trichophyton rubrum
 - ii. Trichophyton mentagrophytes
 - iii. Epidermophyton floccosum
 - iv. Microsporum canis
- 2. Tinea Corporis
 - a. Suspected infection of **ONE** of the following fungal species
 - i. Trichophyton rubrum
 - ii. Trichophyton mentagrophytes
 - iii. Epidermophyton floccosum
 - iv. Microsporum canis
 - 3. Tinea Versicolor

AND the following for **ALL** indications:

a. Inadequate treatment response, intolerance, or contraindication to a legend topical or oral antifungal medication (e.g., fluconazole, terbinafine, ketoconazole, etc.)

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

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

- 1. Tinea Cruris
 - a. Suspected infection of **ONE** of the following fungal species

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i. Trichophyton rubrum

- ii. Trichophyton mentagrophytes
- iii. Epidermophyton floccosum
- iv. Microsporum canis
- 2. Tinea Corporis
 - a. Suspected infection of **ONE** of the following fungal species
 - i. Trichophyton rubrum
 - ii. Trichophyton mentagrophytes
 - iii. Epidermophyton floccosum
 - iv. Microsporum canis
- 3. Tinea Versicolor

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 1 month

Prior - Approval Renewal Limits

Same as above

Rationale

Summary

Exelderm is an antifungal cream used topically to treat skin infections such as jock itch (tinea cruris) and ringworm (tinea corporis). This medication is also used to treat a skin condition known as pityriasis (tinea versicolor). Safety and effectiveness of Exelderm in pediatric patients has not been established (1).

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

References

1. Exelderm [package Insert]. San Antonio, TX; Sun Pharmaceutical Industries, Inc.; June 2018.

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Policy History	
Date	Action
June 2015	Addition to PA
December 2016	Annual editorial review and reference update Addition of age to renewal section Policy number change from 5.14.14 to 5.90.14
September 2017	Annual editorial review and reference update
September 2018	Annual editorial review and reference update Removal of the diagnosis of tinea pedis (athlete's foot) from initiation and renewal criteria per package insert.
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual editorial review. Rearranged criteria requirements for clarity. Changed policy number to 5.90.014
September 2023	Annual review. Per SME, revised requirement for laboratory documentation of 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
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.