
5.90.014

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Topical Products	Original Policy Date:	June 5, 2015
Subject:	Exelderm	Page:	1 of 4

Last Review Date: September 6, 2024

Exelderm

Description

Exelderm (sulconazole nitrate)

Background

Exelderm is used to treat skin infections such as athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis). This medication is also used to treat a skin condition known as tinea (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 pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*, and for the treatment of tinea versicolor (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.

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Topical Products	Original Policy Date:	June 5, 2015
Subject:	Exelderm	Page:	2 of 4

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 Pedis
 - a. Suspected infection of **ONE** of the following fungal species:
 - i. *Trichophyton rubrum*
 - ii. *Trichophyton mentagrophytes*
 - iii. *Epidermophyton floccosum*
 - iv. *Microsporum canis*
4. 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

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Topical Products	Original Policy Date:	June 5, 2015
Subject:	Exelderm	Page:	3 of 4

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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 1 month

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Topical Products	Original Policy Date:	June 5, 2015
Subject:	Exelderm	Page:	4 of 4

Exelderm is an antifungal cream used topically to treat skin infections such as tinea pedis, tinea cruris, and 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]. Scottsdale, AZ; Journey Medical Corp.; March 2021.

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
September 2024	Annual editorial review and reference update. Per PI update, added indication of tinea pedis

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.