Drug Quantity Management – Per Days
Topical Calcipotriene Products

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Product Identifier(s)

Effective 1/1/23 to 2/27/23: 109332

Effective 2/28/23: 60890

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Dovonex® (calcipotriene 0.005% cream – generic)
- Sorilux® (calcipotriene 0.005% foam)
- calcipotriene 0.005% ointment – generic only
- calcipotriene 0.005% solution – generic only
- Enstilar® (calcipotriene/betamethasone 0.005%/0.064% foam)
- Taclonex® (calcipotriene/betamethasone 0.005%/0.064% ointment – generic)
- Taclonex® (calcipotriene/betamethasone 0.005%/0.064% suspension – generic)
- Wynzora® (calcipotriene/betamethasone 0.005%/0.064% cream)

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of topical calcipotriene products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per 30 Days*	Home Delivery Maximum Quantity per 90 Days
Dovonex® (calcipotriene 0.005% topical cream, generic)	• Apply a thin layer to affected area(s) BID and rub in gently and completely. Safety and efficacy have been demonstrated in individuals treated for 8 weeks.	60 gram tube 120 gram tube	120 grams	360 gram
Sorilux® (calcipotriene 0.005% foam)	• Apply a thin layer BID to the affected areas and rub in gently and completely.	60 gram canister	120 grams	360 grams
calcipotriene 0.005% ointment, generic only	• Apply a thin layer QD or BID and rub in gently and completely.	60 gram tube 120 gram tube	120 grams	360 grams
calcipotriene 0.005% solution [scalp], generic only	• Apply to lesions only BID and rub in gently and completely. Safety and efficacy have been demonstrated in individuals treated for 8 weeks.	60 mL bottle	120 mL	360 mL
Enstilar® (calcipotriene 0.005% and betamethasone dipropionate 0.064% foam)	• Apply to affected area(s) QD for up to 4 weeks. • Discontinue when control is achieved. • Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site. • Do not exceed 60 g every 4 days.	60 gram can	60 grams	180 grams

Drug Quantity Limits (continued)

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per 30 Days*	Home Delivery Maximum Quantity per 90 Days
Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment, generic)	• Apply an adequate layer to the affected area(s) QD for up to 8 weeks. Rub in gently and completely. • Discontinue treatment when control is achieved. • Individuals ≥ 18 years of age should not use > 100 g/week. • Individuals 12 to 17 years of age should not use > 60 g/week. • Treatment of > 30% BSA is not recommended.	60 gram tube 100 gram tube	60 grams	180 grams
Taclonex® (calcipotriene 0.005% and betamethasone	• Apply to affected area(s) on scalp and body QD for up to 8 weeks. • Discontinue treatment when control is achieved.	60 gram bottle	60 grams	180 grams

dipropionate topical suspension 0.064%,)	• Individuals ≥ 18 years of age should not use > 100 g/week. • Individuals 12 to 17 years of age should not use > 60 g/week.	120 gram bottle		
Wynzora® (calcipotriene 0.005% and betamethasone dipropionate 0.064% cream)	• Apply to affected area(s) QD for up to 8 weeks. Rub in gently. • Do not use > 100 g/ week. • Discontinue therapy when control is achieved.	60 gram tube	60 grams	180 grams

*This is enough drug to cover approximately 8% of the body surface area when applying two times daily for one month (single-entity calcipotriene products) or 8% of the body when applying once daily for one month (calcipotriene/betamethasone combination products); BID – Twice daily; QD – Once daily; BSA – Body surface area.

Criteria

Cigna covers quantities of topical calcipotriene products as medically necessary if the individual is using the product for plaque psoriasis (FDA-approved indication) and meets one of the following criteria:

Dovonex 0.005% cream (generic), Sorilux foam, calcipotriene 0.005% ointment,

1. If the individual needs to treat greater than 8% of body surface area, approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery.

Calcipotriene 0.005% solution

1. If the individual needs to treat greater than 8% of body surface area, approve the requested quantity not to exceed 240 mL per 30 days at retail and 720 mL per 90 days at home delivery.

Enstilar foam, Taclonex 0.005%/0.064% ointment (generic), Taclonex 0.005%/0.064% suspension (generic), Wynzora

1. If the individual needs to treat greater than 8% of body surface area, approve the requested quantity not to exceed 120 grams per 30 days at retail and 360 grams per 90 days at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

1. No overrides are recommended for use in compounded formulations.

Background

Overview

The topical vitamin D analog products are indicated for the treatment of **plaque psoriasis**. The specific indications are as follows:[1-9]

- Calcipotriene cream and ointment are indicated for the treatment of **plaque psoriasis of the body in adults**.
- Calcipotriene solution is indicated for the treatment of **plaque psoriasis of the scalp in adults**.
- Dovonex cream is indicated for the treatment of **plaque psoriasis in adults**.
- Enstilar foam is indicated for the topical treatment of **plaque psoriasis in patients ≥ 12 years** of age.
- Calcipotriene foam 0.005% (authorized generic) and Sorilux foam are indicated for the topical treatment of **plaque psoriasis of the scalp and body in adults and pediatric patients ≥ 4 years** of age.
- Taclonex ointment is indicated for the topical treatment of **plaque psoriasis in patients ≥ 12 years** of age.
- Wynzora cream is indicated for the topical treatment of **plaque psoriasis in patients ≥ 18 years** of age.

Dosing/Availability
The single-entity calcipotriene products are to be applied to the affected area two times daily (BID).[1-4] The calcipotriene/betamethasone combination products are applied to the affected area once daily (QD).[5-8] Refer to the Drug Quantity Limits table for additional dosing and availability information.

Application Information
When determining the amount of a topical product to apply, a standard measure, the fingertip unit (FTU), is often used.[9] One FTU is the amount of product that is squeezed out of a standard tube along an adult's fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total body surface area (BSA). Therefore, it is assumed that 1 g of a topical product would provide enough product for one application to approximately 4% of the patient's BSA. For children, an FTU is still the amount of product that will fit on an adult's index fingertip. The amount of BSA that the application will cover depends on the size of the child.

In a 2014 article regarding the prevalence of psoriasis among adults in the US defined severity as mild, moderate or severe according to the amount of BSA affected.[10] Psoriasis is considered mild when < 3% of the body is affected, moderate when 3% to 10% of the body is affected, and severe when > 10% of the body is affected.

Based on the FTU method, the quantity limits below provide enough topical calcipotriene to cover approximately 8% of the patient's BSA when applying two times daily for 30 days at retail or 90 days at home delivery and enough topical calcipotriene/betamethasone to cover approximately 8% of the patient's BSA when applying once daily for 30 days at retail or 90 days at home delivery.

References

1. Dovonex® 0.005% cream [prescribing information]. Madison, NJ: LEO; June 2017.
2. Sorilux® 0.005% foam [prescribing information]. Greenville, NC: Mayne: November 2019.
3. Calcipotriene 0.005% ointment [prescribing information]. Hawthorne, NY: Taro; November 2011.
4. Calcipotriene 0.005% solution [prescribing information]. Bridgewater, NJ: Amneal; December 2018.
5. Enstilar® foam [prescribing information]. Madison, NJ: LEO, August 2021.
6. Taclonex® ointment [prescribing information]. Madison, NJ: LEO; March 2020.
7. Taclonex® suspension [prescribing information]. Parsippany, NJ: LEO; August 2020.
8. Wynzora® cream [prescribing information]. Dover, DE: MC2 Therapeutics; November 2020.
9. Eichenfeld LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. *J Am Acad Dermatol*. 2014;71:116-132.
10. Helmick CG, Lee-Han H, Hirsch SC, et al. Prevalence of Psoriasis Among Adults in the US. *Am J Prev Med*. 2014; 47(1): 37-45.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. **Calcitriene (calcipotriene 0.005% ointment):** Brand was removed, this product is obsolete. The generic product remains in the policy. **Dovonex 0.005% cream (generics), Sorilux 0.005% foam, calcipotriene 0.005% ointment:** Override criteria were updated to allow overrides for patients treating > 8% body surface area, previously > 9% body surface area. **Calcipotriene 0.005% solution:** Override criteria were updated to allow overrides for patients treating > 8% body surface area, previously > 9% body surface area.	10/05/2022

	Enstilar 0.005% foam, Taclonex 0.005%/0.064% ointment (generics), Taclonex 0.005%/0.064% suspension (generic), Wynzora. Override criteria were updated to allow overrides for patients treating > 8% body surface area, previously > 18% body surface area.	