Clinical Policy: Calcipotriene/Betamethasone Dipropionate Foam (Enstilar)

Reference Number: IL.ERX.PMN.181
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar®) is a combination topical product of a vitamin D analog and a corticosteroid.

FDA Approved Indication(s)
Enstilar is indicated for the topical treatment of plaque psoriasis (PsO) in patients 18 years of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions that Enstilar is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO;
2. Age ≥ 12 years;
3. Failure of a medium to ultra high potency topical corticosteroid (*see Appendix B*) unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of calcipotriene, unless contraindicated or clinically significant adverse effects are experienced
5. Dose does not exceed 60 g every 4 days (7 canisters per month).

Approval duration: One month

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 gm every 4 days (7 canisters per month).

Approval duration: Up to one month of total treatment *(a single continuous course of therapy up to 4 weeks is recommended)*

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PsO: plaque psoriasis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcipotriene (Dovonex®) cream, ointment, solution	Apply topically to the affected area(s) BID	100 g/week
Ultra High Potency Topical Corticosteroids		
clobetasol propionate 0.05% (Temovate®, Temovate E®) cream, ointment, gel, solution	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
diflorasone diacetate 0.05% (Apexicon®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
diflorasone 0.05% (Apexicon E®) cream	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium/Medium to High Potency Topical Corticosteroids		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
fluticasone propionate 0.05% (Cutivate®) cream		
mometasone furoate 0.1% (Elocon®) cream, lotion, ointment		
triamcinolone acetonide 0.1%, 0.25%,0.5% (Aristocort®, Kenalog®) cream, ointment		

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
None reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Calcipotriene 0.005% and betamethasone dipropionate 0.064% (Enstilar)	Apply topically to affected areas QD for up to 4 weeks. Avoid use on face, groin, axillae, or if skin atrophy is present at the treatment site.	60 g/4 days

VI. Product Availability

Foam: 60 g, 100 g

VII. References

1. Enstilar Prescribing Information. Parsippany, NJ: LEO Laboratories Ltd; July2019. Available at: http://www.leo-pharma.us/Files/Billeder/Enstilar%20USPI%20- Rev%20July%202019.pdf.

Accessed August 4, 2020.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the managementand treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009 Apr;60(4):643- 59.
3. Menter A, Corduro KM, Davis DMR, et al. Joint American Academy of DermatologyNational Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol. 2020;82(6):1445-1486.
4. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 4, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.