

Clinical Policy: Calcipotriene/Betamethasone Dipropionate Foam (Enstilar)

Reference Number: CP.PMN.181

Effective Date: 12.01.18

Last Review Date: 11.20

Line of Business: Commercial, HIM, 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 12 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 Centene Corporation[®] 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 \geq 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 one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: calcipotriene, calcitriol, or tazarotene;
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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Plaque Psoriasis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

- 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):

- Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 1 month (whichever is less); or

- Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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

- 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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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
calcitriol (Vectical [™]) ointment	Apply topically to the affected area(s) BID	200 g/week
tazarotene (Tazorac [®]) gel, cream	Apply topically to the affected area(s) QHS	Once daily application
Ultra-High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolene [®] , Alphatrex [®]) ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
clobetasol propionate 0.05% (Temovate [®] , Temovate E [®])		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon [®]) ointment		
halobetasol propionate 0.05% (Ultravate [®]) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolone [®] , Diprolene [®] AF) cream, lotion	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
betamethasone dipropionate 0.05% ointment		
desoximetasone (Topicort [®]) 0.25%, 0.05% cream, ointment, gel		
diflorasone 0.05% (Apexicon E [®]) cream		
fluocinonide acetone 0.05% cream, ointment, gel, solution		
triamcinolone acetone 0.5% (Aristocort [®] , Kenalog [®]) cream, ointment		
Medium/Medium to High Potency Topical Corticosteroids		
betamethasone dipropionate 0.05% cream	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
desoximetasone 0.05% (Topicort [®]) cream, ointment, gel		
fluocinolone acetone 0.025% (Synalar [®]) cream, ointment		
fluticasone propionate 0.05% (Cutivate [®]) cream		
mometasone furoate 0.1% (Elocon [®]) cream, lotion, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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, skin treatment site with atrophy present, or with occlusive dressing unless directed by a healthcare provider.	60 g/4 days

VI. Product Availability

Foam (60 g, 100 g): 0.005% calcipotriene/0.064% betamethasone dipropionate

VII. References

1. Enstilar Prescribing Information. Parsippany, NJ: LEO Laboratories Ltd; July 2019. 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 management and 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 Dermatology-National 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: adapted from previously approved policy CP.CPA.255 (retired) and Medicaid line of business added; age requirement added; no significant changes; references reviewed and updated.	08.14.18	11.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: revised age limit to 12 years and older per FDA pediatric extension; no significant changes; references reviewed and updated.	08.13.19	11.19
4Q 2020 annual review: HIM line of business added; references reviewed and updated.	08.04.20	11.20

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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