Clinical Policy Title:	calcipotriene/betamethasone dipropionate foam
Policy Number:	RxA.116
Drug(s) Applied:	Enstilar®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All Line of Business

Background

Enstilar® is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid. It is indicated for the topical treatment of plaque psoriasis (PsO) in patients 12 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar®)	Plaque Psoriasis (PsO)	Apply topically to affected areas once daily for up to 4 weeks. Avoid use on face, groin, axillae, or if skin atrophy is present at the treatment site. Discontinue therapy when control is achieved.	60 g/4 days

Dosage Forms

- Topical Foam: 0.005% calcipotriene/0.064% betamethasone dipropionate

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of PsO;
2. Age 12 years of age or older;
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 contraindicated or clinically significant adverse effects are experienced: calcipotriene, calcitriol, or tazarotene;
5. Dose does not exceed 60 g every 4 days (7 canisters per month).

Approval Duration

Commercial: 1 month

Medicaid: 1 month

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
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

Commercial: 1 month

Medicaid: 1 month

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PsO: plaque psoriasis

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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®,) 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®) cream, ointment, gel, solution, foam		
diflorasone diacetate 0.05% ointment		

halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolene®, 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 acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% 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 acetonide 0.025% (Synalar®) cream, ointment		
fluticasone propionate 0.05% (Cutivate®) cream		
mometasone furoate 0.1% cream, lotion, ointment		
triamcinolone acetonide 0.1%, 0.25%,0.5% 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

- Contraindication(s):
  - None reported.

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information

- If hypercalcemia or hypercalciuria develop, discontinue treatment until parameters of calcium metabolism have normalized.
- Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Topical corticosteroid products may increase the risk of cataracts and glaucoma.

References

1. Enstilar® Prescribing Information. Parsippany, NJ: LEO Laboratories Ltd; October 2020. Available at: https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/Enstilar%20USPI%20-%20Clean%20-%20FDA%20Approved%20-%2016-Oct-2020.pdf. Accessed January 20, 2021.
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. Accessed January 20, 2021.
3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 20, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
1. Updated Appendix B 2. Updated References	04/29/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Drug(s) applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosing information was updated for indication. 5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 6. Initial approval and continued therapy approval	01/20/2021	03/09/2021

criteria updated for one month. 7. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 8. Inactive drugs Temovate E, Diprolene AF, Aristocort, Kenalog, Elocon removed from appendix B. 9. Appendix D added. 10. References were reviewed and updated. 11. Background updated to: Enstilar® is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid. It is indicated for the topical treatment of plaque psoriasis (PsO) in patients 12 years of age and older. 12. Dosing Regimen updated to include: Discontinue therapy when control is achieved. 13. Dosage Form update to: Topical Foam: 0.005% calcipotriene/0.064% betamethasone dipropionate		