Clinical Policy: Plaque Psoriasis – Topical Therapy (Enstilar, Sernivo, Taclonex)

Reference Number: CP.CPA.255
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Commercial

Revision Log

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

Description
The following are topical corticosteroids requiring prior authorization: Calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex®), Calcipotriene 0.005% and betamethasone dipropionate foam (Enstilar®), betamethasone dipropionate 0.05% spray (Sernivo®).

FDA approved indication
Taclonex ointment is indicated for topical treatment of plaque psoriasis in patients 12 years of age and older.

Enstilar is indicated for topical treatment of plaque psoriasis in patients 18 years of age and older.

Sernivo is indicated for treatment of mild to moderate plaque psoriasis in patients 18 years of age and older.

Limitation of use: Do not use on face, axillae, or groin. Do not use if skin atrophy is present at the treatment site.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Enstilar, Sernivo, and Taclonex are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of psoriasis;
2. Failure of a medium to ultra high potency topical corticosteroid unless contraindicated or clinically significant adverse effects are experienced;
3. For patients 18 years of age and older: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: calcipotriene (Dovonex®), calcitriol (Vectical®) or Tazorac® (tazarotene).
4. Dose does not exceed:

a. Enstilar: 60 gm every 4 days;
b. Taclonex:
   i. Patients ages 12 to 17 years - 60 gm/week;
   ii. Patient ≥ 18 years: 100 gm/week;
c. Sernivo: 120 mL every 4 weeks.

Approval duration: One month

B. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has not received more than 4 weeks of therapy;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed:
   a. Enstilar: 60 gm every 4 days;
   b. Taclonex:
      i. Patients ages 12 to 17 years - 60 gm/week;
      ii. Patient ≥ 18 years: 100 gm/week;
   c. Sernivo: 120 mL every 4 weeks.

Approval duration: Up to one month of total treatment (a single continuous course of therapy up to 4 weeks is recommended. Patient should stop therapy once psoriasis is under control).

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.CPA.09 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 – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: food and drug administration
gm: gram
mL: milliliters

Appendix B: General Information

- As stated in the prescribing information for Taclonex, patients 18 years and older should not use more than 100 grams per week and patients 12 to 17 years should not use more than 60 grams per week.
- As stated in the prescribing information for Enstilar and Taclonex, treatment of more than 30% body surface area is not recommended.
- As stated in all prescribing information, treatment is up to 4 weeks of therapy. Therapy must be discontinued when control is achieved.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
calcipotriene (Dovonex) cream, ointment, solution	apply topically to the affected area(s) BID	Limit dosage to 100 gm/week
calcitriol (Vectical) ointment	apply topically to the affected area(s) BID	Limit dosage to 200 gm/week
Tazorac (tazarotene) gel, cream	apply topically to the affected area(s) HS	Once daily application
Ultra High Potency		
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®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency		
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 (brand not available) 0.05% ointment		

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
desoximetasone (Topicort®) 0.25%, 0.05% cream, ointment, gel		
diflorasone 0.05% (Apexicon E®) cream		
fluocinonide acetonide 0.05% (brand not available) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium/Medium to High Potency		
betamethasone dipropionate 0.05% (brand not available) 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% (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.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose

calcipotriene 0.005% and betamethasone dipropionate 0.064% (Enstilar)	Apply topically to affected area(s) QD for up to 4 weeks Treatment of more than 30% body surface area is not recommended.	60 gm foam every 4 days topically;
betamethasone dipropionate 0.05% (Sernivo)	Apply topically to affected area(s) QD for up to 4 weeks	N/A
calcipotriene 0.005% and betamethasone dipropionate 0.064% (Taclonex)	Apply topically to affected skin areas BID for up to 4 weeks Treatment of more than 30% body surface area is not recommended.	Patients 18 years and older: 100 gm foam per week topically; Patients 12 to 17 years should not use more than 60 grams per week

VI. Product Availability

Drug	Availability
calcipotriene 0.005% and betamethasone dipropionate 0.064% (Enstilar)	Foam: 60 gm, 100 gm
betamethasone dipropionate 0.05% (Sernivo)	Spray: 60 mL, 120 mL
calcipotriene 0.005% and betamethasone dipropionate 0.064% (Taclonex)	Ointment: 60 gm, 100 gm

VII. References

1. Taclonex Ointment [Prescribing Information]. Parsippany, NJ: LEO Laboratories Ltd; December 2014.
2. Enstilar [Prescribing Information]. Parsippany, NJ: LEO Laboratories Ltd; November 2016.
3. 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.
4. DRUGDEX® System[Internet database]. Greenwood Village, Colorado, Truven Health Analytics. Available at: http://www.micromedexsolutions.com/ Accessed May 10, 2017.
5. Sernivo [Prescribing Information]. San Antonio, TX: DPT Laboratories; February 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	05.10.17	11.17

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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