

## **Clinical Policy: Betamethasone Dipropionate Spray (Sernivo)**

Reference Number: CP.PMN.182

Effective Date: 12.01.18

Last Review Date: 11.21

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Betamethasone dipropionate 0.05% spray (Sernivo<sup>®</sup>) is a topical corticosteroid.

### **FDA Approved Indication(s)**

Sernivo is indicated for the treatment of mild to moderate plaque psoriasis (PsO) in patients 18 years of age or 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<sup>®</sup> that Sernivo 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  $\geq$  18 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 120 mL every 4 weeks.

**Approval duration: 1 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.PA.154 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;
3. If request is for a dose increase, new dose does not exceed 120 mL every 4 weeks.

**Approval duration: Up to 1 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 Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. 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.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 policies – CP.CPA.09 for commercial, HIM.PA.154 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 <sup>®</sup> ) cream, ointment, solution	Apply topically to the affected area(s) BID	100 g/week
calcitriol (Vectical <sup>™</sup> ) ointment	Apply topically to the affected area(s) BID	200 g/week
tazarotene (Tazorac <sup>®</sup> ) gel, cream	Apply topically to the affected area(s) QHS	Once daily application
Ultra High Potency Topical Corticosteroids		
augmented betamethasone dipropionate 0.05% (Diprolene <sup>®</sup> , Alphatrex <sup>®</sup> ) 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 <sup>®</sup> , Temovate E <sup>®</sup> ) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon <sup>®</sup> ) ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
halobetasol propionate 0.05% (Ultravate <sup>®</sup> ) cream, ointment		
<b>High Potency Topical Corticosteroids</b>		
augmented betamethasone dipropionate 0.05% (Diprolone <sup>®</sup> , Diprolene <sup>®</sup> 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 <sup>®</sup> ) 0.25%, 0.05% cream, ointment, gel		
diflorasone 0.05% (Apexicon E <sup>®</sup> ) cream		
fluocinonide acetone 0.05% cream, ointment, gel, solution		
triamcinolone acetone 0.5% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		
<b>Medium/Medium to High Potency Topical Corticosteroids</b>		
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 <sup>®</sup> ) cream, ointment, gel		
fluocinolone acetone 0.025% (Synalar <sup>®</sup> ) cream, ointment		
fluticasone propionate 0.05% (Cutivate <sup>®</sup> ) cream		
mometasone furoate 0.1% (Elocon <sup>®</sup> ) cream, lotion, ointment		
triamcinolone acetone 0.1%, 0.25%, 0.5% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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
Betamethasone dipropionate 0.05% (Sernivo)	Apply spray topically to affected areas BID for up to 4 weeks. Avoid use on face, scalp, axilla, groin, or other intertriginous areas.	Not applicable

**VI. Product Availability**

Spray: 60 mL, 120 mL

**VII. References**

1. Sernivo Prescribing Information. San Antonio, TX: DPT Laboratories; March 2020. Available at: <http://www.sernivo.com/>. Accessed July 22, 2021.
2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed July 22, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy CP.CPA.255 (retired); age requirement added; no significant changes; references reviewed and updated.	08.14.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.08.19	11.19
4Q 2020 annual review: HIM line of business added; references reviewed and updated.	08.04.20	11.20
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	07.22.21	11.21

**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. 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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