

Clinical Policy: Betamethasone Dipropionate Spray (Sernivo)

Reference Number: CP.PMN.182

Effective Date: 12.01.18

Last Review Date: 11.18

Line of Business: Commercial, 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[®]) 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 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 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 contraindicated or clinically significant adverse effects are experienced: calcipotriene, calcitriol, or tazarotene;
5. Dose does not exceed 120 mL every 4 weeks.

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 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 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 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 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 and CP.PMN.53 for Medicaid.

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 [®]) cream, ointment, gel, solution | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|--|--|
| 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 acetonide 0.05% cream, ointment, gel, solution | | |
| triamcinolone acetonide 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 acetonide 0.025% (Synalar [®]) cream, ointment | | |
| fluticasone propionate 0.05% (Cutivate [®]) cream | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|----------------|-----------------------------|
| 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 |
|---|--|----------------|
| 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; February 2016. Available at: <http://sernivo.com/documents/sernivo-pi.pdf>. Accessed August 14, 2018.
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. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 14, 2018.

| 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 |

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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