

Clinical Policy Title:	betamethasone dipropionate spray
Policy Number:	RxA.489
Drug(s) Applied:	Sernivo™
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Betamethasone dipropionate 0.05% spray (Sernivo™) is a topical corticosteroid. It is indicated for the treatment of mild to moderate plaque psoriasis (PsO) in patients 18 years of age or older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
betamethasone dipropionate spray 0.05% (Sernivo™)	Mild to moderate plaque psoriasis	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

Dosage Forms

- Spray: 60 mL, 120 mL

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 ≥ 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

Commercial: 1 month

Medicaid: 1 month

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

II. Continued Therapy Approval

A. Plaque Psoriasis (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously 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 120 mL every 4 weeks.

Approval duration

Commercial: Up to 1 month of total treatment (a single continuous course of therapy up to 28 days is recommended)

Medicaid: Up to 1 month of total treatment (a single continuous course of therapy up to 28 days is recommended)

III. Appendices

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	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	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		
diflorasone diacetate 0.05% ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
halobetasol propionate 0.05% cream, ointment		
High Potency Topical Corticosteroids		
betamethasone dipropionate 0.05% ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
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% 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
- Boxed Warning(s):
 - None

APPENDIX D: General Information

- Sernivo™ Spray can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during or after treatment. High potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and use in pediatric patients may predispose to HPA axis suppression. Use of topical corticosteroids may require periodic evaluation for HPA axis suppression. Modify use if HPA axis suppression develops.

References

1. Sernivo™ Prescribing Information. San Antonio, TX: Encore Dermatology; March 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=21ca2c66-4ad1-4b6a-9c81-77d89eeb9edd&type=display>. Accessed September 03, 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. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed September 03, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020
Policy was reviewed <ol style="list-style-type: none"> 1. Clinical policy title was updated 2. Line of Business Policy Applies to was updated to "All lines of business". 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance...". 4. Appendix B (Therapeutic alternatives) updated to remove inactive products. 5. Appendix D Added. 6. References were reviewed and updated. 	09/03/2020	12/07/2020