RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Betamethasone Dipropionate Spray (Sernivo)**
Policy Number: **RxA.489**
Drug(s) Applied: **Betamethasone dipropionate 0.05% spray (Sernivo®)**
Last Review Date: **01/2020**
Line of Business: **Commercial, Medicaid**

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.

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

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: 1 month

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance 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.

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.

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Approval duration: Up to 1 month of total treatment (a single continuous course of therapy up to 4 weeks 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, 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		
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		

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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		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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% (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

References

1. Sernivo Prescribing Information. San Antonio, TX: DPT Laboratories; November 2018. Available at: http://www.sernivo.com/. Accessed August 6, 2019.

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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 6, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020

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