

Pharmacy Policy Bulletin

Title: Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®)

Policy #: Rx.01.9

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®) is indicated for the topical treatment of psoriasis vulgaris in adults 18 years of age and older.

The use of calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

▶ Description:

Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®) is a combination of calcipotriene and betamethasone dipropionate. Calcipotriene is a synthetic analog of vitamin D3. Calcipotriene inhibits keratinocyte proliferation and induces terminal differentiation of keratinocytes which reverses the abnormal keratinocyte change in psoriasis. Betamethasone dipropionate is a steroid that induces phospholipase A2 inhibitory proteins. These proteins inhibit the release of arachidonic acid, which is the precursor to inflammatory mediators such as prostaglandins and leukotrienes.

▶ Policy:

Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®) is approved when **both** of the following inclusion criteria are met:

- Documentation of psoriasis vulgaris in adults 18 years of age or older
- Documentation of the trial and failure of/intolerance to concurrent use of calcipotriene (Dovonex®) and a topical betamethasone product

▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ References:

Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed December 3, 2010.

Calcipotriene and betamethasone dipropionate (Taclonex®/Taclonex Scalp®). In: Drugdex [online through Micromedex Healthcare

Series]. Greenwood Village, CO: Thomson Micromedex. Accessed December 3, 2010.

Dovonex [package insert]. Rockaway, NJ: Warner Chilcott; 2007.

Kaufmann R, Bibby AJ, Bissonnette R, et al. A new calcipotriol/betamethasone dipropionate formulation (Daviobet) is an effective once daily treatment for psoriasis vulgaris. *Dermatology*. 2002;205(4):389-393.


Papp KA, Guenther L, Boyden B, et al. Early onset of action and efficacy of a combination of calcipotriene and betamethasone dipropionate in the treatment of psoriasis. *J Am Acad Dermatol*. 2003;48(1):48-54.

Patel B, Siskin S, Krazmien R, Lebwohl M. Compatibility of calcipotriene with other topical medications. *J Am Acad Dermatol*. 1998;38(6 Pt 1):1010-1011.

Taclonex [package insert]. Rockaway, NJ: Warner Chilcott; July 2008.

Taclonex Scalp® Topical Suspension [package insert]. Rockaway, NJ: Warner Chilcott; 2008. Also available online at: <http://www.taclonex.com/flash/TaclonexScalpPI.pdf>. Site no longer active.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Taclonex/Taclonex Scalp	Calcipotriene and betamethasone dipropionate

Cross References:

Policy Version Number:	1.00
P&T Approval Date:	November 10, 2011
Policy Effective Date:	February 01, 2012
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