



Horizon BCBSNJ
 Medical Necessity Guideline

Section Drugs
 Policy Number
 Effective Date 4/28/06
 Review Date 9/25/06, 11/12/07, 9/26/08, 5/12/09

SUBJECT:

DRUG CLASS Retinoid (topical)

BRAND NAME Differin (all topical)
 (Generic) (adapalene)

 Epiduo
 (adapalene/benzoyl peroxide)

IMPORTANT NOTE:

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

FDA-APPROVED INDICATIONS

Differin is indicated for the topical treatment of acne vulgaris.

CRITERIA FOR APPROVAL

1. Does the patient have the diagnosis of acne vulgaris?	Yes	No
--	-----	----

Guidelines for Approval	
Duration of Approval	12 months
Set 1	
Yes to question(s)	No to question(s)
1	None

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

BLACK BOX WARNINGS

None

RATIONALE

The intent of the criteria is to ensure patients follow selection elements noted in the labeling, guideline recommendations and acceptable compendia uses. Compendia refer to the use of Differin only for the FDA approved indication. Differin is indicated for the topical treatment of acne vulgaris. The criteria does not provide for cosmetic uses of this drug.^{1, 2, 3, 4, 5}

Safety and effectiveness in pediatric patients below the age of 12 have not been established.^{1, 2, 3}

The American Academy of Dermatology and the Institute for Clinical Systems Improvement have established guidelines for the treatment of acne vulgaris. Multiple treatment modalities are effective in the treatment of acne vulgaris. Topical agents alone may be indicated for mild cases of acne, whereas systemic agents are generally reserved for patients with moderate to severe cases. Patients with mild to moderate acne should be encouraged to try over-the-counter acne products containing an antibacterial or a keratolytic agent. Patients with moderate to severe acne may be treated with topical products such as antibacterial or keratolytic agent, or topical antibiotics. Oral antibiotics are also used in the treatment of moderate to severe acne. Combinations of any of these products may be used when monotherapy is inadequate.^{6, 7}

ADDITIONAL INFORMATION

Adapalene is a chemically stable, retinoid-like compound, Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinization, and inflammatory processes all of which represent important features in the pathology of acne vulgaris. Mechanistically, adapalene binds to specific retinoic acid nuclear receptors but does not bind to the cytosolic receptor protein. Although the exact mode of action of adapalene is unknown, it is suggested that topical adapalene may normalize the differentiation of follicular epithelial cells resulting in decreased microcomedone formation.

Dosage and Administration:

Differin Cream

Differin cream should be applied to affected areas of the skin, once daily at nighttime. A thin film of the cream should be applied to the skin areas where acne lesions appear, using enough to cover the entire affected areas lightly. A mild transitory sensation of warmth or slight stinging may occur shortly after the application of Differin cream.

Differin Gel

Differin gel should be applied once a day to affected areas after washing in the evening before retiring. A thin film of the gel should be applied, avoiding eyes, lips, and mucous membranes.

Differin Solution

1. Differin solution should be applied once a day to affected areas.
2. Before retiring in the evening, wash and dry areas to be treated.
3. Apply a thin film of medication to the affected areas. Avoid the eye, lips, and mucous membranes.

Pledget: Remove pledget from foil just before using. Discard pledget after single use. Do not use if seal is broken.

Glass bottle: Replace cap after each use.

During the early weeks of therapy, an apparent exacerbation of acne may occur. This is due to the action of the medication on previously unseen lesions and should not be considered a reason to discontinue therapy. Therapeutic results should be noticed after eight to twelve weeks of treatment.

CONTRAINDICATIONS/WARNINGS/PRECAUTIONS

Contraindications:

Use of Differin should be discontinued if hypersensitivity to any of the ingredients is noted. Patients with sunburn should be advised not to use the product until fully recovered.

Precautions:

If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued. Exposure to sunlight, including sunlamps, should be minimized during the use of adapalene. Patients, who normally experience high levels of sun exposure, and those with inherent sensitivity to sun, should be warned to exercise caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with adapalene.

Avoid contact with the eyes, lips, angles of the nose, and mucous membranes. The product should not be applied to cuts, abrasions, eczematous skin, or sunburned skin. As with other retinoids, use of “waxing” as a depilatory method should be avoided on skin treated with adapalene.

Certain cutaneous signs and symptoms such as erythema, dryness, scaling, burning, or pruritus may be experienced during treatment. These are most likely to occur during the first two to four weeks and will usually lessen with continued use of the medication. Depending upon the severity of adverse events, patients should be instructed to reduce the frequency of application or discontinue use.

Safety and effectiveness in pediatric patients below the age of 12 have not been established.

Drug Interactions:

As Differin has the potential to produce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or lime) should be approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with Differin. If these preparations have been used, it is advisable not to start therapy with Differin until the effects of such preparations in the skin have subsided.

REFERENCES

1. Differin Cream Product Information. Galderma Laboratories, L.P. Revised June 2004.
2. Differin Gel Product Information. Galderma Laboratories, L.P. Revised May 1996.
3. Differin Solution Product Information. Galderma Laboratories, L.P. Revised January 2000.
4. USPDI. Thompson MICROMEDEX. 2004.
5. AHFS Drug Information. 2004.
6. Mason C, Oftedahl G, Neely C, et al. Health Care Guideline: Acne Management. Institute for Clinical Systems Improvement. Second Edition; September 2003.
7. American Academy of Dermatology. Guidelines of Care for Acne Vulgaris. www.aad.org. Accessed 10/22/2004.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

This Horizon BCBSNJ Pharmacy Guideline is proprietary. It is to be used only as authorized by Horizon BCBSNJ and its affiliates. The contents of this Pharmacy Guideline are not to be copied, reproduced or circulated to other parties without the express written consent of Horizon BCBSNJ. The contents of this Pharmacy Guideline may be updated or changed without notice, unless otherwise required by law and/or regulation. However, benefit determinations are made in the context of Pharmacy Guidelines existing at the time of the decision and are not subject to later revision as the result of a change in Pharmacy Guideline.