



Effective Date..... 1/15/2024
Next Review Date..... 1/15/2025
Coverage Policy Number IP0181

Topical Adapalene Products

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Related Coverage Resources

- Clascoterone – (IP0173)
Topical Acne – Non-Retinoid Products (IP0166)
Topical Azelaic Acid Products – (IP0172)
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Topical Tazarotene Products – (IP0174)
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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions to the following topical adapalene products:

- adapalene (generic formulations)
Differin® (adapalene)
Epiduo® (adapalene/benzoyl peroxide)
Epiduo® Forte (adapalene/benzoyl peroxide)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for product in below table:

Employer Group Non-Covered Product and Criteria:

Non-Covered Product	Criteria
adapalene 0.1% swab	<p>Adapalene 0.1% swab is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets the following criteria:</p> <p>A. Documentation of failure, contraindication or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> i. adapalene 0.1% cream, 0.3% gel, or 0.1% lotion (may require prior authorization) ii. tazarotene 0.1% cream iii. tretinoin cream, gel, or microgel (may require prior authorization)
Differin cream (adapalene 0.1% cream)	<p>Differin cream is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets ALL of the following criteria:</p> <p>A. Documentation of trial of adapalene 0.1% cream (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p> <p>B. Documentation of failure, contraindication or intolerance to BOTH of the following:</p> <ul style="list-style-type: none"> i. tazarotene 0.1% cream ii. tretinoin cream, gel, or microgel (may require prior authorization)
Differin lotion (adapalene 0.1% lotion)	<p>Differin lotion is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets the following criteria:</p> <p>A. Documentation of failure, contraindication or intolerance to ALL of the following:</p> <ul style="list-style-type: none"> i. ONE generic formulation of differin ii. tazarotene 0.1% cream iii. tretinoin cream, gel, or microgel (may require prior authorization)
Differin gel (adapalene 0.3% gel)	<p>Differin gel is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets ALL of the following criteria:</p> <p>A. Documentation of trial of adapalene 0.3% gel (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p> <p>B. Documentation of failure, contraindication or intolerance to BOTH of the following:</p> <ul style="list-style-type: none"> i. tazarotene 0.1% cream ii. tretinoin cream, gel, or microgel (may require prior authorization)

Non-Covered Product	Criteria
Epiduo (adapalene/benzoyl peroxide 0.1%-2.5% gel)	<p>Epiduo is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets ALL of the following criteria:</p> <ul style="list-style-type: none"> A. Documentation of trial of <u>adapalene/benzoyl peroxide 0.1%-2.5% gel</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Documentation of failure, contraindication or intolerance to BOTH of the following: <ul style="list-style-type: none"> i. tazarotene 0.1% cream ii. tretinoin gel (may require prior authorization)
Epiduo Forte (adapalene/benzoyl peroxide 0.3%-2.5% gel)	<p>Epiduo Forte is considered medically necessary when the following are met:</p> <p>Acne Vulgaris. Individual meets ALL of the following criteria:</p> <ul style="list-style-type: none"> A. Documentation of trial of <u>adapalene/benzoyl peroxide 0.3%-2.5% gel</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Documentation of inability to use topical adapalene 0.3% gel (may require prior authorization) with topical benzoyl peroxide concurrently

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of topical adapalene products are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered not medically necessary.

Under many benefit plans, services are not covered when they are performed solely for the purpose of altering appearance or self-esteem, or to treat psychological symptomatology or psychosocial complaints related to one's appearance.

Background

OVERVIEW

All of these products are indicated for use in the management of **acne vulgaris**.^{1,2} Some of the benzoyl peroxide-containing products are available over-the-counter (OTC) and these products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris.

The topical products for treatment of acne are available in multiple formulations.^{1,2} Creams and lotions may be best for dry or sensitive skin and gels or foams may be best for more oily skin (although newer aqueous gels may also be suitable for sensitive skin).³

Acne treatment guidelines do not prefer any of the specific brand name agents over similar products available as generics for the treatment of acne.³ Acne management should focus on preventing formation of microcomedones and minimizing the potential for visible acne lesions.^{1,2} The combination of a topical retinoid and benzoyl peroxide remains the preferred approach for almost all patients with acne. Unlike other topical antibiotics, benzoyl peroxide has not been associated with the development of antibiotic resistance.

References

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: <http://fco.factsandcomparisons.com/lco/action/home> Accessed on August 31, 2023. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twynéo.
2. Clinical Pharmacology © 2023. Available at <https://www.clinicalkey.com/pharmacology/> Accessed on August 31, 2023. Search terms: benzoyl peroxide and sulfur/sulfacetamide.
3. Thiboutot DM, Dreno B, Abanmi A, et al. Practical management of acne for clinicians: an international consensus from the Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol*. 2018;78:S1-S23.

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