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Topical Acne – Non-Retinoid Products

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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 non-covered non-retinoid topical acne products:

- **Clindamycin-Containing Products**
 - Clindagel® (clindamycin phosphate 1% topical gel)
- **Dapsone Products**
 - Aczone® (dapsone 5% topical gel)
- **Minocycline Products**
 - Amzeeq™ (minocycline 4% topical foam)
- **Other Combination Products**
 - Acanya® (clindamycin phosphate/benzoyl peroxide 1.2%/2.5% gel)
 - BenzaClin® (clindamycin phosphate/benzoyl peroxide 1%/5% gel)
 - clindamycin phosphate/benzoyl peroxide 1.2%/3.75% topical gel
 - Neuac® (clindamycin phosphate/benzoyl peroxide 1.2%/5% kit)
 - Onexton™ (clindamycin phosphate/benzoyl peroxide 1.2%/3.75% topical gel)

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

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Employer Plans:

Product	Criteria
Clindamycin-Containing Products	
Clindagel 1% topical gel (clindamycin)	<p>Clindagel 1% topical gel is considered medically necessary when there is documentation of BOTH of the following:</p> <ol style="list-style-type: none"> 1. Trial of clindamycin phosphate 1% topical 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 2. Failure, contraindication, or intolerance to BOTH of the following: <ol style="list-style-type: none"> A. dapsone 5% topical gel B. erythromycin 2% topical gel
Dapsone Products	
Aczone 5% topical gel (dapsone)	<p>Aczone 5% topical gel is considered medically necessary when there is documentation of BOTH of the following:</p> <ol style="list-style-type: none"> 1. Trial of dapsone topical 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 2. Failure, contraindication, or intolerance to FOUR of the following generic topical products containing: <ol style="list-style-type: none"> A. Adapalene (may require prior authorization) B. benzoyl peroxide C. clindamycin D. erythromycin E. sodium sulfacetamide F. tretinoin (may require prior authorization)
Minocycline Products	
Amzeeq 4% topical foam (minocycline)	<p>Amzeeq 4% topical foam is considered medically necessary when there is documentation of failure, contraindication, or intolerance to BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE topical clindamycin-containing product (for example, clindamycin topical antibiotic [various formulations], clindamycin/benzoyl peroxide 1%/5% gel, clindamycin/tretinoin 1.2%/0.025% gel (may require prior authorization) 2. ONE topical erythromycin-containing product (for example, erythromycin topical antibiotics [various formulations], erythromycin/benzoyl peroxide 3%/5% gel)
Other Combination Products	
Acanya 1.2%/2.5% Gel (clindamycin phosphate/benzoyl peroxide)	<p>Acanya 1.2%/2.5% topical gel is considered medically necessary when there is documentation of BOTH of the following:</p> <ol style="list-style-type: none"> 1. Trial of clindamycin 1.2%/benzoyl peroxide 2.5% topical 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 2. Failure, contraindication, or intolerance to BOTH of the following: <ol style="list-style-type: none"> A. topical benzoyl peroxide (4% or 8% gel) with topical clindamycin (1% gel) concurrently

Product	Criteria
	B. benzoyl peroxide 5%/erythromycin 3% topical gel
BenzaClin 1%/5% Gel (clindamycin phosphate/benzoyl peroxide)	BenzaClin 1%/5% topical gel is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> 1. Trial of clindamycin 1%/benzoyl peroxide 5% topical 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 2. Failure, contraindication, or intolerance to BOTH of the following: <ol style="list-style-type: none"> A. topical benzoyl peroxide (4% or 8% gel) with topical clindamycin (1% gel) concurrently B. benzoyl peroxide 5%/erythromycin 3% topical gel
clindamycin phosphate/benzoyl peroxide 1.2%/3.75% topical gel	EFFECTIVE 7/1/2024 Clindamycin phosphate / benzoyl peroxide 1.2% / 3.75% topical gel is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> 1. clindamycin 5%/ benzoyl peroxide 1.2% topical gel 2. clindamycin 1% / benzoyl peroxide 5% topical gel
Neuac Kit (clindamycin phosphate/benzoyl peroxide 1.2%/5% gel)	Neuac Kit is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> 1. Neuac gel 2. topical benzoyl peroxide (4% or 8% gel) with topical clindamycin (1% gel) concurrently 3. benzoyl peroxide/erythromycin 5%/3% topical gel
Onexton 1.2%/3.75% Gel (clindamycin phosphate/benzoyl peroxide)	Onexton 1.2%/3.75% topical gel is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> 1. clindamycin 5%/ benzoyl peroxide 1.2% topical gel 2. clindamycin 1% / benzoyl peroxide 5% topical gel

Individual and Family Plans:

Product	Criteria
clindamycin phosphate/benzoyl peroxide 1.2%/3.75% topical gel	Clindamycin phosphate / benzoyl peroxide 1.2% / 3.75% topical gel is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> 1. clindamycin 5%/ benzoyl peroxide 1.2% topical gel 2. clindamycin 1% / benzoyl peroxide 5% topical gel
Onexton 1.2%/3.75% Gel (clindamycin phosphate/benzoyl peroxide)	Onexton 1.2%/3.75% topical gel is considered medically necessary when there is documentation of failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> 1. clindamycin 5%/ benzoyl peroxide 1.2% topical gel 2. clindamycin 1% / benzoyl peroxide 5% topical gel

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 non-retinoid topical acne 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

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. Sulfacetamide sodium and sulfur are used together to treat acne vulgaris; sulfacetamide is an antimicrobial and sulfur is an antimicrobial and a keratolytic agent that causes a peeling and drying effect. In addition to being indicated for the treatment of acne, sulfacetamide/sulfur products are used for acne rosacea and seborrheic dermatitis. Please refer to the product labeling for specific details.

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.; 2022. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs>. Accessed on August 26, 2022. Search terms: benzoyl peroxide, clindamycin, minocycline, sulfacetamide/sulfur, Twyneo.
2. Clinical Pharmacology © 2022. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on August 26, 2022. 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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