TOPICAL CLINDAMYCIN PRODUCTS:
ACANYA® (clindamycin phosphate-benzoyl peroxide) gel
BENZAACLIN® (clindamycin phosphate-benzoyl peroxide) gel
CLEOCIN-T® (clindamycin phosphate) gel, lotion, solution, swab
CLINDAGEL® (clindamycin phosphate) gel
DUAC® (clindamycin phosphate-benzoyl peroxide) gel
EVOCLIN® (clindamycin phosphate 1%) foam
NEUAC™ (clindamycin phosphate-benzoyl peroxide) gel (kit is a plan exclusion)
ONEXTON™ (clindamycin phosphate-benzoyl peroxide) gel

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states’ Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.
TOPICAL CLINDAMYCIN PRODUCTS (cont.)

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. Incomplete forms or forms without the chart notes will be returned.

Criteria:
Cleocin-T (clindamycin phosphate) gel, lotion, solution, swab
Clindagel (clindamycin phosphate) gel
Evoclin (clindamycin phosphate 1%) foam

➢ **Criteria for initial therapy**: Cleocin-T, Clindagel, and Evoclin is considered *medically necessary* when **ALL** of the following criteria are met:

1. Individual is 12 years of age or older
2. Medical record documentation of a confirmed diagnosis of acne vulgaris
3. Individual is unable to use **ALL** of the following **topical acne products** due to either inadequate response, hypersensitivity or intolerance:
   - One topical over-the-counter acne product
   - All covered topical clindamycin products
   - All covered topical erythromycin or topical sulfacetamide products
   - All covered topical adapalene or topical tretinoin products
4. Absence of **ALL** of the following contraindications:
   - Hypersensitivity to clindamycin or lincomycin
   - History of antibiotic-associated colitis (including pseudomembranous colitis)
   - Colitis
   - History of regional enteritis or Crohn’s disease
   - Ulcerative colitis
5. Absence of **ALL** of the following exclusions:
   - Use in combination with erythromycin-containing products

➢ **Continuation of coverage (renewal request)**: Cleocin-T, Clindagel, and Evoclin is considered *medically necessary* with documentation of **ALL** of the following:

1. The individual has benefited from therapy but remains at high risk
2. The condition has not progressed or worsened while on therapy
3. Individual has not developed any contraindications or other exclusions to its continued use
Cleocin-T, Clindagel, and Evoclin for all other indications not previously listed is considered experimental or investigational based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

Criteria:

- Acanya (clindamycin phosphate-benzoyl peroxide) gel
- Benzaclin (clindamycin phosphate-benzoyl peroxide) gel
- Duac (clindamycin phosphate-benzoyl peroxide) gel
- Neuac (clindamycin phosphate-benzoyl peroxide) gel (kit is a plan exclusion)
- Onexton (clindamycin phosphate-benzoyl peroxide) gel

Criteria for initial therapy: Acanya, Benzaclin, Duac, Neuac and Onexton is considered medically necessary when ALL of the following criteria are met:

1. Individual is 12 years of age or older
2. Medical record documentation of a confirmed diagnosis of acne vulgaris
3. Individual is unable to use ALL of the following topical acne products due to either inadequate response, hypersensitivity or intolerance to:
   - One topical over-the-counter acne product
   - All covered topical clindamycin products
   - All covered topical erythromycin or topical sulfacetamide products
   - All covered topical adapalene or topical tretinoin products
   - All covered topical clindamycin products used simultaneously with topical benzoyl peroxide
4. Absence of ALL of the following contraindications:
   - Hypersensitivity to clindamycin or lincomycin
   - Hypersensitivity to benzoyl peroxide
   - History of antibiotic-associated colitis (including pseudomembranous colitis)
   - Colitis
   - History of regional enteritis or Crohn’s disease
   - Ulcerative colitis
5. Absence of ALL of the following exclusions:
   - Use in combination with erythromycin-containing products

Continuation of coverage (renewal request): Acanya, Benzaclin, Duac, Neuac and Onexton is considered medically necessary with documentation of ALL of the following:
TOPICAL CLINDAMYCIN PRODUCTS (cont.)

1. The individual has benefited from therapy but remains at high risk
2. The condition has not progressed or worsened while on therapy
3. Individual has not developed any contraindications or other exclusions to its continued use

- Acanya, Benzaclin, Duac, Neuac and Onexton for all other indications not previously listed is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Description:

Clindamycin phosphate alone or in combination with benzoyl peroxide is indicated for the topical treatment of acne vulgaris.

The pathogenesis of acne in multifactorial and includes hyperkeratinization of follicles, bacterial infectious process, production of sebum, androgens, and inflammation. Acne vulgaris is a chronic inflammatory dermatologic condition notable for open and/or closed comedones (blackheads – dark or blackish bumps; and whiteheads – tiny white bumps) and inflammatory lesions including papules (small, firm, may be painful pink bumps), pustules (small, may be painful bumps with pus), or nodules/cysts (large, hard, inflamed and painful bumps). Acne pimples occur on the face, neck, chest, shoulders, back, and upper arms caused by clogged pores due to excessive sebum (oil) production.

The prevalent bacterium implicated in acne is Propionibacterium acnes (P acnes), a gram-positive anaerobe that is normally found on the skin and is implicated in the inflammatory phase of acne. P acnes promotes lesions by secreting chemotactic factors that attract leukocytes to the follicle resulting in inflammation.

All anti-acne agents are effective in reducing inflammatory and non-inflammatory lesions when compared to placebo based on many years of clinical experience, multiple systematic reviews, and clinical practice guidelines. There is no evidence that confirms superiority of any one branded option over available brand or generic alternatives, including available over-the-counter (OTC) products. All anti-acne products have adequate track records of safety; most are generally well tolerated, but all cause skin irritation.

Published guidelines on the treatment of acne consistently recommend the use of topical antimicrobial, topical retinoid, azelaic acid, benzoyl peroxide, dapsone, and combination topical products, oral antibiotics or oral isotretinoin. The guidelines do not differentiate between branded options over other brand or generic options.

The American Academy of Dermatology has published guidelines for the care of acne vulgaris. The guidelines indicate that topical therapy is a standard of care in treatment and that topical retinoids and topical antibiotics are
effective treatments. The effectiveness of topical retinoids in the treatment of acne is well documented. These agents act to reduce obstruction within the follicle and are useful in the management of both comedonal and inflammatory acne. The value of topical antibiotics in the treatment of acne has been investigated in many clinical trials. Topical erythromycin and clindamycin have been demonstrated to be effective and well tolerated. A combination of topical retinoids and topical erythromycin or clindamycin is more effective than either agent used alone.

Both Veltin® and Ziana® are topical acne products with 1.2% clindamycin phosphate and 0.025% tretinoin in an aqueous based gel. Each gram contains, as dispensed, 10mg (1%) clindamycin and 0.25mg (0.025%) tretinoin. Clindamycin phosphate and tretinoin are also available separately as topical preparations for the treatment of acne. (For coverage criteria for Veltin and Ziana see Topical Retinoid and Combination Products Pharmacy Coverage Guidelines.)

There are many acne medications that are available as generic products in a variety of different formulations (gels, lotions, creams, ointments, solutions, and foams). The choice of delivery system (formulation) can be dependent on skin type (dry versus oily), site of application, and preference. Creams and lotions are useful for dry skin, gels and solutions are generally better for oily skin.

Resources:


Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

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<tr>
<th>Member Information</th>
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<td>Member Name (first &amp; last):</td>
<td>Date of Birth:</td>
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<td>Address:</td>
<td>City:</td>
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<th>Prescribing Provider Information</th>
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<td>Provider Name (first &amp; last):</td>
<td>Specialty:</td>
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<td>Office Address:</td>
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<td>Office Contact:</td>
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<th>Dispensing Pharmacy Information</th>
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<td>Pharmacy Name:</td>
<td>Pharmacy Phone:</td>
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<th>Requested Medication Information</th>
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<tbody>
<tr>
<td>Medication Name:</td>
<td>Strength:</td>
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<td>Directions for Use:</td>
<td>Quantity:</td>
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☐ Check if requesting brand only ☐ Check if requesting generic

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

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<th>Turn-Around Time For Review</th>
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<tr>
<td>Standard</td>
<td>Urgent. Sign here: ________________</td>
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<th>Clinical Information</th>
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<td>1. What is the diagnosis? Please specify below.</td>
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<tr>
<td>ICD-10 Code:</td>
<td>Diagnosis Description:</td>
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<td>2. Yes ☐ No ☐ Was this medication started on a recent hospital discharge or emergency room visit?</td>
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<td>3. ☐ Yes ☐ No ☐ There is absence of ALL contraindications.</td>
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<td>4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below. Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.</td>
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<td>Medication Name, Strength, Frequency</td>
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5. Are there any supporting labs or test results? Please specify below.

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Blue Cross Blue Shield of Arizona, Mail Stop A115, P.O. Box 13466, Phoenix, AZ 85002-3466
6. Is there any additional information the prescribing provider feels is important to this review? Please specify below. For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider’s Signature: ____________________________ Date: ____________

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.