



Original Effective Date: 04/01/2012  
 Current Effective Date: 05/31/2024  
 Last P&T Approval/Version: 04/24/2024  
 Next Review Due By: 04/2025  
 Policy Number: C4190-A

## Topical Acne

### PRODUCTS AFFECTED

Acanya (clindamycin phosphate-benzoyl peroxide), Acioxaiy (azelaic acid-niacinamide) Cream, Aczone (dapsone), Adult Acnomel (resorcinol-sulfur) Cream, Amzeeq (minocycline) HCL micronized foam, azelaic acid-niacinamide, Azelex (azelaic acid), Benzaclin (clindamycin phosphate-benzoyl peroxide), Benzamycin (erythromycin-benzoyl peroxide), Benzefoam (benzoyl peroxide), Benzepro (benzoyl peroxide), benzoyl peroxide, benzoyl peroxide-hydrocortisone, benzoyl peroxide-erythromycin, BP Foam, BP Wash (benzoyl peroxide), BPO (benzoyl peroxide), Cleocin-T (clindamycin phosphate), Clindacin ETZ (clindamycin phosphate), Clindacin Foam (clindamycin phosphate), Clindacin Pac (clindamycin phosphate), Clindacin-P (clindamycin phosphate), Clindagel (clindamycin phosphate), clindamycin phosphate, clindamycin phosphate-benzoyl peroxide, clindamycin phos-niacinamide gel, dapsone, dapsone-niacinamide, Deoxia gel, Diaoxia Gel (dapsone-niacinamide), Diasoxia (dapsone-niacinamide), Dimoxia Gel (niacinamide-spiroinolactone), Draxace (salicylic acid-sulfacetamide sodium), Draxacey (salicylic acid-sulfacetamide sodium), Drixeece (salicylic acid-sulfacetamide sodium), Eceoxia (niacinamide-sulfacetamide), Erypad (erythromycin), Erygel (erythromycin), erythromycin, Evoclin (clindamycin phosphate), Inova (benzoyl peroxide-vitamin E), Klaron (sulfacetamide sodium), Neuac (clindamycin phosphate-benzoyl peroxide), niacinamide-spiroinolactone, niacinamide-sulfacetamide, NuCaraClin PAK (clindamycin phosphate gel), Onexton (clindamycin phosphate-benzoyl peroxide), resorcinol-sulfur, Rezamid (resorcinol-sulfur), Riax (benzoyl peroxide), salicylic acid-sulfacetamide, sulfacetamide sodium lotion, Vanoxide HC (benzoyl peroxide- hydrocortisone), Winlevi (clascoterone cream), Zacare (benzoyl peroxide-hyaluronate), Zaclir (benzoyl peroxide)

### COVERAGE POLICY

*Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

## Drug and Biologic Coverage Criteria

### **DIAGNOSIS:**

Acne Vulgaris

### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

#### **A. ACNE VULGARIS:**

1. Documented diagnosis of acne vulgaris  
AND
2. Documentation of an adequate trial (at least 4 weeks), serious side effects, or labeled contraindication to ALL of the following topical treatments: benzoyl peroxide, topical clindamycin, topical erythromycin, topical adapalene (Differin gel 0.1% OTC ONLY) used alone or in combination  
AND
3. Documentation member will be using requested product in combination with at least ONE other topical agent for the treatment of acne  
AND
4. FOR NON-FORMULARY COMBINATION PRODUCT REQUESTS: Documentation of ONE of the following:
  - (i) The member has tried and failed ALL formulary/preferred alternatives (single ingredient used in combination and combination products) AND generic NON-formulary drugs with matching member indication PRIOR to use of the requested therapy  
OR
  - (ii) The member has an FDA labeled contraindication or serious side effects to ALL formulary/preferred alternatives AND generic NON-formulary drugs or they are likely to be less effective, or cause harm for the member  
OR
  - (iii) The member is currently receiving the requested medication and is at medical risk if therapy changes

### **CONTINUATION OF THERAPY:**

#### **A. ACNE VULGARIS:**

1. Documentation of adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation  
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity  
AND
3. Documentation of positive clinical response as demonstrated by improvements in the condition's signs and symptoms

### **DURATION OF APPROVAL:**

Initial authorization: 6 months, Continuation of therapy: 12 months

### **PRESCRIBER REQUIREMENTS:**

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## Drug and Biologic Coverage Criteria

None

### **AGE RESTRICTIONS:**

Benzoyl peroxide 2.5%: 9 years of age and older

Dapsone 7.5%: 9 years of age and older

All Others: 12 years of age and older

### **QUANTITY:**

Benzoyl Peroxide Wash 240 grams/30 days

### **PLACE OF ADMINISTRATION:**

The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## **DRUG INFORMATION**

### **ROUTE OF ADMINISTRATION:**

Topical

### **DRUG CLASS:**

Topical Acne Products

### **FDA-APPROVED USES:**

Topical treatment of acne vulgaris

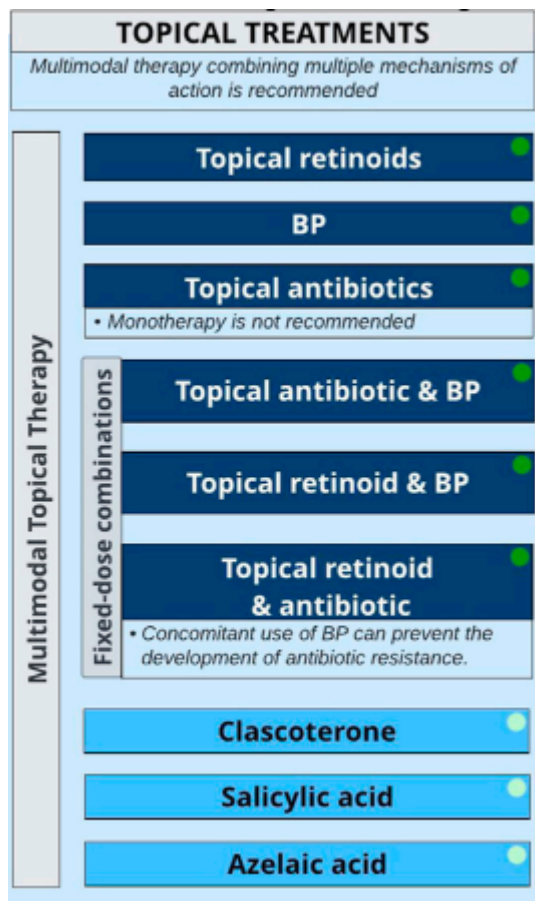
### **COMPENDIAL APPROVED OFF-LABELED USES:**

None

**APPENDIX**

**APPENDIX:**

Treatment algorithm for the topical treatment of acne vulgaris in adults, adolescents, and preadolescents (9 years of age and older). For both Mild and Moderate to Severe. Adopted from the Guidelines of care for the management of acne vulgaris J Am Acad Dermatol 2024.



**Key:**

- Strong recommendation in favor of the intervention
- Conditional recommendation in favor of the intervention

**BACKGROUND AND OTHER CONSIDERATIONS**

**BACKGROUND:**

Acne vulgaris is a chronic, inflammatory skin disease. Acne primarily presents with open or closed comedones, papules, pustules, or nodules on the face or trunk and may result in pain, erythema, hyperpigmentation, or scars. Acne vulgaris is a common skin condition affecting 9.4% of the global population (2010), representing the eighth most prevalent disease globally. Acne affects approximately 85% of teenagers but can occur in most age groups and can persist into adulthood. Over 50 million people in the United States have acne.

There is no universally accepted acne severity grading system in the clinical setting, however consistent use of a grading system may help support decision making and treatment response assessment. Grading typically assesses lesion type, lesion number, affected areas, dyspigmentation, and scarring. Acne quality of life measures should also be considered.

Treatment options for acne include topical therapies, systemic antibiotics, hormonal agents, oral isotretinoin, and dietary and environmental interventions. Topical therapies may be used for initial treatment of acne and as maintenance monotherapy (except topical antibiotics) or used in combination with other topical therapies. Per the American Academy of Dermatology “When managing acne with topical therapies, multimodal therapy combining multiple mechanisms of actions is recommended as a good practice statement to optimize efficacy and to reduce the risk of antibiotic resistance.”

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of topical acne products are considered experimental/investigational and therefore, will follow Molina’s Off-Label policy. Refer to individual product label for contraindications.

**OTHER SPECIAL CONSIDERATIONS:**

None

**CODING/BILLING INFORMATION**

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPCS CODE	DESCRIPTION
NA	

## Drug and Biologic Coverage Criteria

### AVAILABLE DOSAGE FORMS:

Acanya GEL 1.2-2.5%  
Acioxaiy CREA 15-4%  
Acne Maximum Strength CREA 10%  
Acne Treatment BAR 10%  
AcneFree Acne Clearing System KIT 2.5 & 3.7%  
AcneFree Severe Clearing Syst KIT 2.5 & 10%  
Aczone GEL 5%  
Aczone GEL 7.5%  
Adult Acnomel CREA 2-8%  
Amzeeq FOAM 4%  
Azelaic Acid-Niacinamide CREA 15-4%  
Azelex CREA 20%  
BenzaClin GEL 1-5%  
BenzaClin with Pump GEL 1-5%  
Benzamycin GEL 5-3%  
BenzEFoam FOAM 5.3%  
BenzePrO Creamy Wash LIQD 7%  
BenzePrO FOAM 5.2%  
BenzePrO FOAM 5.3%  
BenzePrO FOAM 9.7%  
BenzePrO Foaming Cloths MISC 6%  
BenzePrO LIQD 6.8%  
BenzePrO MISC 5.8%  
Benzoyl Perox-Hydrocortisone LOTN 5-0.5%  
Benzoyl Peroxide FOAM 5.3%  
Benzoyl Peroxide FOAM 9.8%  
Benzoyl Peroxide Forte- HC LOTN 7.5-1%  
Benzoyl Peroxide GEL 6.5%  
Benzoyl Peroxide GEL 8%  
Benzoyl Peroxide PADS 9.5%  
Benzoyl Peroxide-Erythromycin GEL 5-3%  
BP Wash LIQD 2.5%  
BP Wash LIQD 7%  
BPO Foaming Cloths MISC 6%  
BPO GEL 8%  
CeraVe Acne Foaming Cream LIQD 4%  
Clean & Clear Continuous CREA 10%  
Clearasil Daily Clear Acne CREA 10%  
Clearasil Rapid Rescue Spot CREA 10%  
Clearskin CREA 10%  
Cleocin-T GEL 1%  
Cleocin-T LOTN 1%  
Clindacin ETZ KIT 1%  
Clindacin ETZ SWAB 1%  
Clindacin FOAM 1%  
Clindacin Pac KIT 1%  
Clindacin-P SWAB 1%  
Clindagel GEL 1%  
Clindamycin Phos-Benzoyl Perox GEL 1.2-2.5%  
Clindamycin Phos-Benzoyl Perox GEL 1.2-3.75%  
Clindamycin Phos-Benzoyl Perox GEL 1.2-5%  
Clindamycin Phos-Benzoyl Perox GEL 1-5%  
Clindamycin Phos-Niacinamide GEL 1-4%  
Clindamycin Phos-Niacinamide LOTN 1-4%  
Clindamycin Phosphate FOAM 1%  
Clindamycin Phosphate GEL 1%  
Clindamycin Phosphate LOTN 1%  
Clindamycin Phosphate SOLN 1%  
Clindamycin Phosphate SWAB 1%  
CVS Acne Cleansing BAR 10%  
CVS Acne Control Cleanser CREA 10%  
CVS Acne CREA 10%  
CVS Creamy Acne Face Wash LIQD 4%  
CVS Targeted Acne Spot CREA 2.5%  
Dapsone GEL 5%  
Dapsone GEL 7.5%  
Dapsone-Niacinamide GEL 6-4%  
Dapsone-Niacinamide GEL 8.5-4%  
Deoxia GEL 1-4%  
Deoxia LOTN 1-4%  
Diaoxia GEL 6-4%  
Diasoxia CREA 6-4%  
Diasoxia CREA 8.5-4%  
Diasoxia GEL 8.5-4%  
Dimoxia GEL 4-5%  
Draxace Lotion Cleanser SUSP 2-8%  
Draxacey SUSP 2-8%  
Drixece SUSP 5-10%  
Eceoxia CREA 4-10%  
Effaclar Duo SOLN 5.5%  
Enzoclear FOAM 9.8%  
Epsolay CREA 5%  
Ery PADS 2%  
Erygel GEL 2%  
Erythromycin GEL 2%  
Erythromycin SOLN 2%  
Evoclin FOAM 1%  
GNP Acne Treatment CREA 10%  
Inova KIT 4 & 5%  
Inova KIT 8 & 5%  
Klaron LOTN 10%  
Neuac GEL 1.2-5%  
Neutrogena Clear Pore LIQD 3.5%  
Neutrogena On-The-Spot CREA 2.5%  
Niacinamide-Spironolactone GEL 4-5%  
Niacinamide-Sulfacetamide CREA 4-10%  
NuCaraClinPAK KIT 1%  
Onexton GEL 1.2-3.75%  
PanOxyl Creamy Wash LIQD 4%  
PanOxyl LIQD 2.5%  
PR Benzoyl Peroxide LIQD 6.9%  
PR Benzoyl Peroxide Wash LIQD 7%  
Resorcinol-Sulfur LOTN 2-5%  
Rezamid LOTN 2-5%  
Riax FOAM 5.5%  
Riax FOAM 9.5%  
Riax PADS 9.5%  
Salicylic Acid-Sulfacetamide SUSP 2-8%

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Drug and Biologic Coverage Criteria  
 Salicylic Acid-Sulfacetamide SUSP 5-10%  
 Spot Acne Treatment CREA 2.5%  
 Sulfacetamide Sodium (Acne) LOTN 10%  
 Vanoxide-HC LOTN 5-0.5%

Winlevi CREA 1%  
 Zacare KIT 4 & 0.2%  
 Zacare KIT 8 & 0.2%  
 Zaclir Cleansing LOTN 8%

**REFERENCES**

1. Zaenglein, Andrea L. et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2016 May;74(5):945-73.e33. doi: 10.1016/j.jaad.2015.12.037. Epub 2016 Feb 17. Available at: [https://www.jaad.org/article/S0190-9622\(15\)02614-6/fulltext](https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext). Accessed Feb 2020.
2. Reynolds, R. V., Yeung, H., Cheng, C. E., Cook-Bolden, F., Desai, S. R., Druby, K., ... Barbieri, J. S. (2024). Guidelines of care for the management of acne vulgaris. *Journal of the American Academy of Dermatology.* <https://doi.org/10.1016/j.jaad.2023.12.017>

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions Quantity Appendix Background Contraindications/Exclusions/Discontinuation Available dosage Forms References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Other Special Considerations Available Dosage Forms	Q2 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file