



Original Effective Date: 04/01/2012
 Current Effective Date: 06/20/2025
 Last P&T Approval/Version: 04/30/2025
 Next Review Due By: 04/2026
 Policy Number: C4190-A

Topical Acne

PRODUCTS AFFECTED

Abenor (niacinamide-sulfacetamide) Cream, Acanya (clindamycin phosphate-benzoyl peroxide), Acioxaiy (azelaic acid-niacinamide) Cream, Aczone (dapsone), Adalina (niacinamide- spironolactone) gel, Adult Acnomel (resorcinol-sulfur) Cream, Alixi (dapsone-niacinamide) Cream, Amzeeq (minocycline) HCL micronized foam, Apexol (salicylic acid-sulfacetamide), Cleanser, Aporix (clindamycin phos-niacinamide) gel and lotion, azelaic acid-niacinamide, Azelex (azelaic acid), Benzacilin (clindamycin phosphate-benzoyl peroxide), Benzamycin (erythromycin-benzoyl peroxide), benzoyl peroxide, benzoyl peroxide-hydrocortisone, benzoyl peroxide-erythromycin, BP Wash (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- spironolactone), Draxace (salicylic acid-sulfacetamide sodium), Draxacey (salicylic acid-sulfacetamide sodium), Drixace (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-spironolactone, niacinamide-sulfacetamide, NuCaraClin PAK (clindamycin phosphate gel), Onexton (clindamycin phosphate-benzoyl peroxide), resorcinol-sulfur, Rezamid (resorcinol-sulfur), Riox (benzoyl peroxide), salicylic acid-sulfacetamide, sulfacetamide sodium lotion, Vanoxide HC (benzoyl peroxide- hydrocortisone), Winlevi (clascoterone cream), Zicare (benzoyl peroxide-hyaluronate)

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 improvement in the condition's signs and symptoms

DURATION OF APPROVAL:

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

Drug and Biologic Coverage Criteria

PRESCRIBER REQUIREMENTS:

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

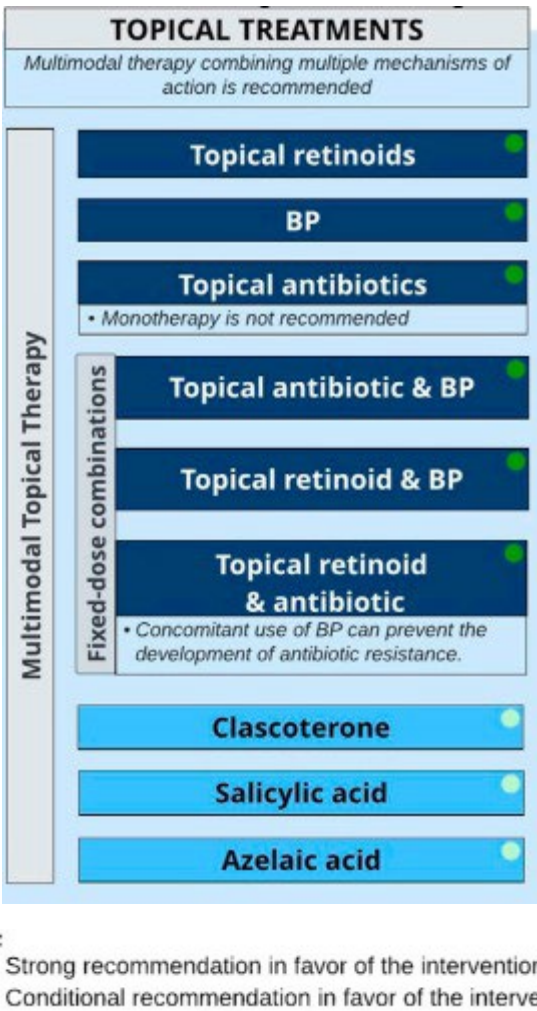
COMPENDIAL APPROVED OFF-LABELED USES:

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.



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.”

Drug and Biologic Coverage Criteria

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Abenor CREA 4-10%	Clearasil Rapid Rescue Spot CREA 10%
Acanya GEL 1.2-2.5%	Clearskin CREA 10%
Acioxaiy CREA 15-4%	Cleocin-T LOTN 1%
Acne Maximum Strength CREA 10%	Clindacin ETZ KIT 1%
Acne Treatment BAR 10%	Clindacin ETZ SWAB 1%
AcneFree Acne Clearing System KIT 2.5 & 3.7%	Clindacin FOAM 1%
AcneFree Severe Clearing Syst KIT 2.5 & 10%	Clindacin Pac KIT 1%
Aczone GEL 5%	Clindacin-P SWAB 1%
Aczone GEL 7.5%	Clindagel GEL 1%
Adalina GEL 4-5%	Clindamycin Phos (Once-Daily) GEL 1%
Adult Acnomet CREA 2-8%	Clindamycin Phos (Twice-Daily) GEL 1%
Alixi CREA 6-4%	Clindamycin Phos-Benzoyl Perox GEL 1.2-2.5%
Alixi HP CREA 8.5-4%	Clindamycin Phos-Benzoyl Perox GEL 1.2-3.75%
Amzeeq FOAM 4%	Clindamycin Phos-Benzoyl Perox GEL 1.2-5%
Apexol Cleanser SUSP 2-8%	Clindamycin Phos-Benzoyl Perox GEL 1-5%
Apexol HP Cleanser SUSP 5-10%	Clindamycin Phos-Niacinamide GEL 1-4%
Aporix GEL 1-4%	Clindamycin Phos-Niacinamide LOTN 1-4%
Aporix LOTN 1-4%	Clindamycin Phosphate FOAM 1%
Azelaic Acid-Niacinamide CREA 15-4%	Clindamycin Phosphate LOTN 1%
Azelex CREA 20%	Clindamycin Phosphate SOLN 1%
BenzaClin GEL 1-5%	Clindamycin Phosphate SWAB 1%
BenzaClin with Pump GEL 1-5%	CVS Acne Cleansing BAR 10%
Benzamycin GEL 5-3%	CVS Acne Control Cleanser CREA 10%
Benzoyl Perox-Hydrocortisone LOTN 5-0.5%	CVS Acne CREA 10%
Benzoyl Peroxide Forte- HC LOTN 7.5-1%	CVS Acne Treatment CREA 10%
Benzoyl Peroxide PADS 9.5%	CVS Creamy Acne Face Wash LIQD 4%
Benzoyl Peroxide-Erythromycin GEL 5-3%	CVS Targeted Acne Spot CREA 2.5%
BP Wash LIQD 2.5%	Dapsone GEL 5%
CeraVe Acne Foaming Cream LIQD 4%	Dapsone GEL 7.5%
Clean & Clear Continuous CREA 10%	Dapsone-Niacinamide GEL 6-4%
Clearasil Daily Clear Acne CREA 10%	Dapsone-Niacinamide GEL 8.5-4%

Drug and Biologic Coverage Criteria

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%
 Drixice SUSP 5-10%
 Eceoxia CREA 4-10%
 Effaclar Duo SOLN 5.5%
 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%
 Resorcinol-Sulfur LOTN 2-5%
 Rezamid LOTN 2-5%
 Riax PADS 9.5%
 Rumilo CREA 15-4%
 Salicylic Acid-Sulfacetamide SUSP 2-8%
 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%

REFERENCES

1. Zaenglein, Andrea L. et al. Guidelines of care for the management of acne vulgaris. [J Am Acad Dermatol](https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext). 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: Products Affected Duration of Approval Available Dosage Forms	Q2 2025
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

Drug and Biologic Coverage Criteria

Q2 2022 Established tracking in new format	Historical changes on file
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