



Original Effective Date: 04/01/2012
 Current Effective Date: 06/21/2023
 Last P&T Approval/Version: 04/26/2023
 Next Review Due By: 04/2024
 Policy Number: C4190-A

Topical Acne

PRODUCTS AFFECTED

Aczone (dapsone), Acanya (clindamycin phosphate-benzoyl peroxide), Acioxaiy (azelaic acid-niacinamide) Cream, Aktipak (erythromycin-benzoyl peroxide), Amzeeq (minocycline) HCL micronized foam, Azelaic Acid-Niacinamide, Adult Acnomel (resorcinol-sulfur) Cream, 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), Clearasil Daily Clear cream, Clindacin ETZ (clindamycin phosphate), Clindacid 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), Duac (clindamycin phosphate-benzoyl peroxide), 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-Sulfure, 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.

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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.

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: ONE of the following apply:
(i) The member has tried and failed ALL formulary 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 prescriber has provided documentation from the member's medical record stating that ALL formulary alternatives AND generic NON-formulary drugs are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the member
OR
(iii) The prescriber states that the member is currently receiving the requested medication and is at medical risk if s/he changes therapy

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:

None

Drug and Biologic Coverage Criteria

AGE RESTRICTIONS:

Benzoyl peroxide 2.5%, Dapsone 7.5% is ≥ 9 years of age, all others ≥ 12 years of age

QUANTITY:

Differin gel 0.1% 45 grams/30 days, 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:

External

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 management of acne vulgaris in adolescents and young adults. Adopted from the Guidelines of care for the management of acne vulgaris' J Am Acad Dermatol 2016

	Mild	Moderate	Severe
1st Line Treatment	Benzoyl Peroxide (BP) or Topical Retinoid -or- Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic	Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic -or- Oral Antibiotic + Topical Retinoid + BP -or- Oral Antibiotic + Topical Retinoid + BP + Topical Antibiotic	Oral Antibiotic + Topical Combination Therapy** BP + Antibiotic or Retinoid + BP or Retinoid + BP + Antibiotic -or- Oral Isotretinoin
Alternative Treatment	Add Topical Retinoid or BP (if not on already) -or- Consider Alternate Retinoid -or- Consider Topical Dapsone	Consider Alternate Combination Therapy -or- Consider Change in Oral Antibiotic -or- Add Combined Oral Contraceptive or Oral Spironolactone (Females) -or- Consider Oral Isotretinoin	Consider Change in Oral Antibiotic -or- Add Combined Oral Contraceptive or Oral Spironolactone (Females) -or- Consider Oral Isotretinoin

Fig 1. Treatment algorithm for the management of acne vulgaris in adolescents and young adults. The *double asterisks* (**) indicate that the drug may be prescribed as a fixed combination product or as separate component. *BP*, Benzoyl peroxide.

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BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of topical acne products are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

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 Acnomet 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%
BenzEFoamUltra FOAM 9.8%
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%
BenzePrO Short Contact FOAM 9.8%
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 Foam FOAM 5.3%
BP Foam FOAM 9.8%
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 Daily Clear CREA 2-8%
Clearasil Rapid Rescue Spot CREA 10%
Clearskin CREA 10%
Cleocin-T GEL 1%
Cleocin-T LOTN 1%
Cleocin-T SOLN 1%
Cleocin-T SWAB 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 1.2-5%
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 GEL 8.5-4%
Dimoxia GEL 4-5%
Draxace Lotion Cleanser SUSP 2-8%
Draxacey SUSP 2-8%
Drixice SUSP 5-10%
Duac GEL 1.2-5%
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 PADS 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%
OC8 GEL 7%
Onexton GEL 1.2-3.75%
PanOxyl Creamy Wash LIQD 4%
PanOxyl LIQD 2.5%
PR Benzoyl Peroxide LIQD 6.9%

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PR Benzoyl Peroxide Wash LIQD 7%
 RA Acne Treatment CREA 10%
 RA Vanishing Acne Treatment CREA 10%
 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%

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.

SUMMARY OF REVIEW/REVISIONS	DATE
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