



Effective Date: 07/28/2021  
 Last Approval/Version: 04/2024  
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 Policy Number: C21454-A

## Topical Acne and Topical Rosacea - IL Medicaid Only

### PRODUCTS AFFECTED

ADAPALENE CREAM-GEL-SOLUTION, WINLEVI CREAM (clascoterone), FABIOR FOAM (tazarotene), TAZAROTENE FOAM, ARAZLO LOTION (tazarotene), ATRALIN GEL (tretinoin, ATRA), RETIN-A GEL-CREAM-MICROGEL (tretinoin, ATRA), ALTRENO LOTION (tretinoin, ATRA), TRETINOIN MICROSPHERE GEL, CLINDACIN FOAM (clindamycin), CLINDAMYCIN PHOSPHATE FOAM, CLINDAGEL GEL (clindamycin), CLEOCIN-T LOTION (clindamycin), DAPSONE GEL, ERYGEL GEL (erythromycin), ERY PADS (erythromycin), KLARON LOTION (sulfacetamide), SULFACETAMIDE SODIUM LOTION, ADAPALENE/BENZOYL PEROXIDE GEL-PADS, BENZAMYCIN GEL (benzoyl peroxide; erythromycin), ACANYA GEL (benzoyl peroxide; clindamycin), CLINDAMYCIN PHOSPHATE/BENZOYL PEROXIDE GEL, ONEXTON GEL (benzoyl peroxide; clindamycin), NEUAC GEL-KIT (benzoyl peroxide; clindamycin), CLINDACIN ETZ KIT (clindamycin), CLINDACIN PAC KIT (clindamycin), CLINDAMYCIN PHOSPHATE/TRETINOIN GEL, ZIANA GEL (clindamycin; tretinoin), SODIUM SULFACETAMIDE/SULFUR 10%-5% CREAM, AVAR CLEANSER (sulfacetamide; sulfur), SODIUM SULFACETAMIDE/SULFUR CLEANSER-WASH-PADS, SUMADAN WASH-KIT (sulfacetamide; sulfur), SUMAXIN WASH-PADS (sulfacetamide; sulfur), ZMA CLEAR (sulfacetamide; sulfur), BP CLEANSING WASH (benzoyl peroxide), SODIUM SULFACETAMIDE/SULFUR CLEANSER IN UREA

### 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, Rosacea

### REQUIRED MEDICAL INFORMATION:

#### A. ACNE VULGARIS:

**Molina Reviewer Note:** Preferred topical acne products require prior authorization for members under the age of 10. Preferred topical tretinoin products require prior authorization for members over age 35. Trial and failure of other agents not required if the product is preferred.

1. Documentation of a diagnosis of acne vulgaris.  
AND
2. FOR NON-PREFERRED TOPICAL RETINOIDS (per Illinois Medicaid Preferred Drug List): Documentation of an adequate trial (of at least 4 weeks) of at least two preferred topical retinoid products.  
OR
3. FOR OTHER NON-PREFERRED TOPICAL PRODUCTS (per Illinois Medicaid Preferred Drug List): Documentation of an adequate trial (of at least 4 weeks) of two topical treatments for acne: topical antibiotic, topical retinoid or topical benzoyl peroxide.  
AND
4. Prescriber attests that (or the clinical reviewer has found) the member does not have any FDA labeled contraindications that have not been addressed by the prescriber within the documentation submitted for review.  
OR
5. FOR PREFERRED PRODUCTS: For members under age 10 or over age 35, documentation that the requested product is FDA labeled or compendia supported for the member's current age and diagnosis.  
AND
6. FOR NON-FORMULARY PRODUCTS (NOT LISTED on the Illinois Medicaid Preferred Drug List): Review using Medical Necessity policy.

#### B. ROSACEA

**Molina Reviewer Note:** Preferred topical acne products, which may also be FDA labeled for rosacea, require prior authorization for members under the age of 10. Trial and failure of other agents not required if the product is preferred.

1. Documentation of a diagnosis of rosacea.  
AND
2. FOR NON-PREFERRED PRODUCTS (per Illinois Medicaid Preferred Drug List): Documentation of a trial and failure of a formulary preferred topical metronidazole product.  
AND
3. Prescriber attests that (or the clinical reviewer has found) the member does not have any FDA labeled contraindications that have not been addressed by the prescriber within the documentation submitted for review.  
OR
4. FOR PREFERRED PRODUCTS: For members under age 10, documentation that the requested product is FDA labeled or compendia supported for the member's current age and diagnosis.  
AND
5. FOR NON-FORMULARY PRODUCTS (NOT LISTED on the Illinois Medicaid Preferred Drug List): Review using Medical Necessity policy.

## Drug and Biologic Coverage Criteria

### CONTINUATION OF THERAPY:

#### A. ALL INDICATIONS:

1. Prescriber attests to (or the clinical reviewer has found) adherence to therapy at least 85% of the time.  
AND
2. Prescriber attests that (or the clinical reviewer has found) the member has had no intolerable adverse effects or drug toxicity.  
AND
3. Prescriber attests to (or the clinical reviewer has found) positive clinical response as demonstrated by improvements in the condition's signs and symptoms.

### DURATION OF APPROVAL:

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

### PRESCRIBER REQUIREMENTS:

None

### AGE RESTRICTIONS (for Non-preferred products only):

ACNE:

*Note: Preferred topical acne products require prior authorization for members under the age of 10. Preferred topical tretinoin products require prior authorization for members over age 35.*

ROSACEA:

*Note: Preferred topical acne products, which may also be FDA labeled for rosacea, require prior authorization for members under the age of 10.*

### QUANTITY:

See Illinois PDL for quantity limitations.

### 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:

Acne Products  
Rosacea Agents  
Antiseborrheic Products

### FDA-APPROVED USES (for select products):

## Drug and Biologic Coverage Criteria

ACANYA Gel: indicated for the topical treatment of acne vulgaris in patients 12 years or older

Aczone Gel 7.5%: indicated for the topical treatment of acne vulgaris in patients 9 years of age and older

Amzeeq foam: indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Azelex: indicated for the topical treatment of mild-to-moderate inflammatory acne vulgaris

BP 10-1(sodium sulfacetamide 10% and sulfur 1 %): indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Clindacin P: indicated in the treatment of acne vulgaris

Cleocin T topical solution, Cleocin T Topical Gel, Cleocin T Topical Lotion: indication in the treatment of acne vulgaris

EPIDUO FORTE: indicated for the topical treatment of acne vulgaris.

ERYGEL Topical Gel: indicated for the topical treatment of acne vulgaris.

EVOCLIN Foam: indicated for acne vulgaris in patients 12 years and older.

FINACEA (azelaic acid) foam, gel: indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea

Klaron Lotion: indicated in the topical treatment of acne vulgaris.

Metrogel 1%, MetroCream 0.75%, Noritate 1% cream: indicated for the treatment of inflammatory papules, pustules, and erythema of rosacea

MIRVASO (brimonidine) topical gel: indicated for the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older

Neuac Gel, 1.2%/5%:indicated for the topical treatment of inflammatory acne

ONEXTON Gel: indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

RHOFADE (oxymetazoline hydrochloride) cream, 1%: indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Rosadan 0.75% Cream and Gel: indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.

SOOLANTRA (ivermectin) cream, 1%: s indicated for the treatment of inflammatory lesions of rosacea

Sumaxin (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads: indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis

## Drug and Biologic Coverage Criteria

Sumadan (sodium sulfacetamide 9% & sulfur 4.5%) Wash: indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis

Winlevi (clascoterone): indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

ZIANA (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel: indicated for the topical treatment of acne vulgaris in patients 12 years or older

ZILXI (minocycline) topical foam: indicated for the treatment of inflammatory lesions of rosacea in adults

### 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.

## 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

**AVAILABLE DOSAGE FORMS**

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

## Drug and Biologic Coverage Criteria

Clindacin ETZ KIT 1%	NuCaraClinPAK KIT 1%
Clindacin ETZ SWAB 1%	OC8 GEL 7%
Clindacin FOAM 1%	Onexton GEL 1.2-3.75%
Clindacin Pac KIT 1%	PanOxyl Creamy Wash LIQD 4%
PR Benzoyl Peroxide Wash LIQD 7%	PanOxyl LIQD 2.5%
RA Acne Treatment CREA 10%	PR Benzoyl Peroxide LIQD 6.9%
RA Vanishing Acne Treatment CREA 10%	Salicylic Acid-Sulfacetamide SUSP 5-10%
Resorcinol-Sulfur LOTN 2-5%	Spot Acne Treatment CREA 2.5%
Rezamid LOTN 2-5%	Sulfacetamide Sodium (Acne) LOTN 10%
Riax FOAM 5.5%	Vanoxide-HC LOTN 5-0.5%
Riax FOAM 9.5%	Winlevi CREA 1%
Riax PADS 9.5%	Zacare KIT 4 & 0.2%
Salicylic Acid-Sulfacetamide SUSP 2-8%	Zacare KIT 8 & 0.2%
	Zaclir Cleansing LOTN 8%

## REFERENCES

1. Illinois Medicaid Preferred Drug List, effective January 1, 2024
2. Cleocin T (clindamycin phosphate topical solution, gel, lotion) [prescribing information]. New York, NY: Pharmacia & Upjohn Co. Division of Pfizer; December 2019
3. 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
4. Clindagel (clindamycin phosphate) topical gel [prescribing information]. San Antonio, Texas: Valeant Pharmaceuticals North America LLC; November 2017
5. Evoclin (clindamycin phosphate) foam 1% [prescribing information]. Research Triangle Park, NC: Manufactured for: Stiefel Laboratories, Inc.; January 2012
6. Cleocin P (clindamycin phosphate topical solution) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; November 2016
7. ACZONE (dapson) Gel [prescribing information]. Irvine, Ca: Allergan; February 2016
8. Erygel Topical Gel [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018
9. KLARON (sodium sulfacetamide lotion) Lotion, 10% [prescribing information]; Bridgewater, NJ; Dermik Laboratories, a business of sanofi-aventis U.S. LLC
10. Epiduo Forte [prescribing information]; Fort Worth, TX: Galderma Laboratories, L.P.; July 2015
11. BenzaClin Topical Gel (clindamycin - benzoyl peroxide gel) [prescribing information]; Bridgewater, NJ; Dermik Laboratories, a business of sanofi-aventis U.S. LLC; June 2010
12. ONEXTON (clindamycin phosphate and benzoyl peroxide) gel [prescribing information]; Bridgewater, NJ: Bausch Health US, LLC. April 2020
13. Acanya (clindamycin phosphate and benzoyl peroxide) gel [prescribing information]; Bridgewater, NJ: Bausch Health US, LLC. September 2020
14. Sumaxin (sodium sulfacetamide 10% and sulfur 4%) [prescribing information]; Fairfield, NJ, Medimetriks Pharmaceuticals, Inc; October 2017
15. Sumadan(sodium sulfacetamide 10% and sulfur 4%) Wash [prescribing information]; Fairfield, NJ, Medimetriks Pharmaceuticals, Inc; March 2013
16. BP 10-1 (sodium sulfacetamide 10% and sulfur 15) [prescribing information]; Alpharetta, GA: Acella Pharmaceuticals, LLC: March 2019
17. Neuac (clindamycin phosphate and benzoyl peroxide gel) [prescribing information]; Fairfield,

## Drug and Biologic Coverage Criteria

NJ: Medimetriks Pharmaceuticals, Inc.; November 2015

18. ZIANA (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel [prescribing information]; Buffalo, NY: Medicis, The Dermatology Company; November 2006
19. Amzeeq (minocycline) topical foam [prescribing information]; Bridgewater, NJ: VYNE Pharmaceuticals Inc.; January 2021
20. FINACEA (azelaic acid) foam [prescribing information]; Madison, NJ: LEO Pharma Inc.; December 2020
21. FINACEA (azelaic acid) gel [prescribing information]; Pine Brook, NJ: Intendis Inc.; July 2020
22. MIRVASO (brimonidine) topical gel [prescribing information]; Fort Worth, TX, Galderma Laboratories; November 2011
23. SOOLANTRA (ivermectin) cream, 1% [prescribing information]; Fort Worth, TX, Galderma Laboratories; July 2018
24. Rosadan (Metronidazole Topical Cream, 0.75%) Cream [prescribing information]; Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; July 2017
25. ZILXI (minocycline) topical foam [prescribing information]; Bridgewater, NJ: VYNE Pharmaceuticals Inc.; January 2021
26. RHOFADE (oxymetazoline hydrochloride) cream, 1% [prescribing information]; Charleston, SC: EPI Health; November 2019
27. Winlevi (clascoterone) [prescribing information]; Cranbury, NJ: Sun Pharmaceuticals Industries, Inc., September 2021

SUMMARY OF REVIEW/REVISIONS	DATE
Off-cycle Updates: Products Affected – removed isotretinoin Required Medical Information References	07/2024
Off-cycle Updates: RMI – clarified age restrictions References	04/2024
ANNUAL REVIEW - Notable revisions: Products Affected Required Medical Information Age Restrictions Other Special Considerations Available Dosage Forms	01/2024
Annual updates	01/2023
New criteria creation	07/2021