Effective Date: 07/28/2021
Last Approval/Version: 07/2024
Next Review Due By: 01/2025
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.

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.

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.

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:
Topical Acne Products
Topical Rosacea Products

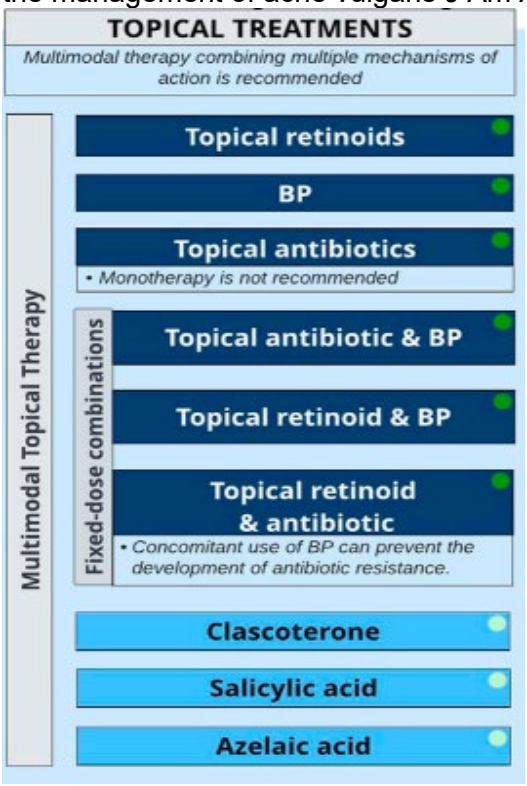
FDA-APPROVED USES:
Topical treatment of acne vulgaris

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:

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%
Acioxiay 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%
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%

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%
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%
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%
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%
Drixece 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%
Salicylic Acid-Sulfacetamide SUSP 5-10%
Spot Acne Treatment CREA 2.5%
Sulfacetamide Sodium (Acne) LOTN 10%
Vanoxide-HC LOTN 5-0.5%

Riax FOAM 9.5%
Riax PADS 9.5%
Salicylic Acid-Sulfacetamide SUSP 2-8%
Winlevi CREA 1%
Zacare KIT 4 & 0.2%
Zacare KIT 8 & 0.2%
Zaclir Cleansing LOTN 8%

REFERENCES

1. Illinois Medicaid Preferred Drug List, effective January 1, 2024.
2. 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. Accessed Feb 2020.
3. 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
Off-cycle Updates: **Products Affected – removed isotretinoin** **Required Medical Information** **Appendix** **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