Original Effective Date: 09/2012
Current Effective Date: 06/20/2025
Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C4729-A

Topical Retinoids and Combinations

PRODUCTS AFFECTED

Adainzde (adapalene-BP-clindamyin), Adainzoxia (adapalene-BP-niacinamide), adapalene, adapalene-benzoyl peroxide-clindamycin, adapalene-benzoyl peroxide-niacinamide, adapalene-benzoyl peroxide, Adermica HP (BP-clindamycin- niacinamide-tretinoin) gel, Aklief cream (trifarotene), Alomira HP (BP-clindamycin-niacinamide-tretinoin) gel, Altreno (tretinoin), Aluris (niacinamide-tretinoin), Aluxof (BP-spironolactone-clindamycin-niacin-tretinoin), Alvox (niacinamide-tazarotene), Aphoria (adapalene-BP-niacinamide), Arazlo (tazarotene lotion), Atralin (tretinoin gel), Avidora (clindamycin-niacinamide-tretinoin), Avita (tretinoin), Awanis (dapsone-niacinamide-tretinoin), Cabtreo (adapalene-BP-clindamycin), clindamycin-tretinoin gel, Deoxiatar (clindamycin-niacinamide- tretinoin), Diasaxiatar (dapsone-niacinamide-tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Ethoxia (niacinamide-tazarotene), Fabior (tazarotene), Inzdeaxiavar (BP-clindamycin-niacinamide-tretinoin), Ithoxia (niacinamide-tazarotene), Lounzdomdioxatar (BP-spironolactone-clindamycin-niacin-tretinoin), niacinamide-tazarotene, niacinamide-tretinoin, Onzdeaxiademtar (BP-clindamycin-niacinamide-spironolactone-tretinoin), Onzdeaxiademvar (BP-clindamycin-niacinamide-spironolactone-tretinoin), Onzdeaxiazar (BP-clindamycin-niacinamide-tretinoin), Oxiatar (niacinamide-tretinoin), Oxiavar (niacinamide-tretinoin), Oxiavarry (niacinamide-tretinoin), Retin-A (tretinoin), Retin-A Micro (tretinoin micronized), Saroxia (niacinamide-tretinoin), Sorixia (niacinamide-tretinoin), Taroxia (niacinamide- tretinoin), tazarotene, tretinoin, tretinoin microsphere, Twyneo (tretinoin-benzoyl peroxide), Unzdomdioxiazar (BP-spironolactone-clindamycin-niacin-tretinoin), Varoxia (niacinamide-tretinoin), Veltin (clindamycin phosphate-tretinoin), Ziana (clindamycin phosphate-tretinoin)

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

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 inadequate response to a 4-week trial, serious side effects, or labeled contraindication to TWO formulary topical anti-acne agents (i.e., erythromycin solution, clindamycin solution, Differin OTC)
   AND
3. FOR TRETINOIN (GENERIC PRODUCT) REQUESTS: Documentation of a history of an inadequate response to a 4- week trial of Differin OTC
   AND
4. FOR NON-FORMULARY COMBINATION PRODUCT OR DOSAGE FORM (FOAM, SOLN) 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. 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: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

Aklief: 9 years of age and older

Altreno: 9 years of age and older
Atralin: 10 years of age and older
Arazlo: 9 years of age and older
Epiduo: 9 years of age and older
Twyneo: 9 years of age and older
All other products: 12 years of age and older

QUANTITY:
Per specific formulary

Maximum Quantity Limits – Based on individual product labeling

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

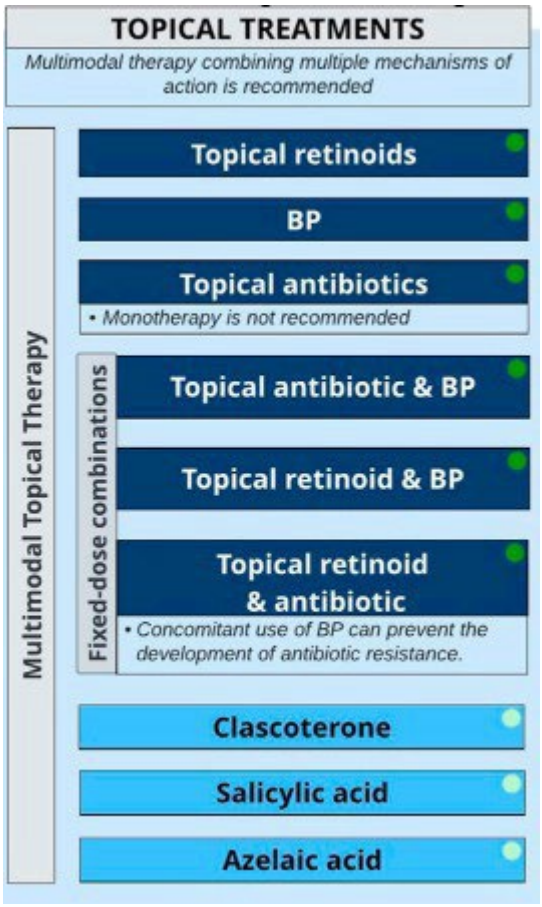
DRUG CLASS:
Acne Products

FDA-APPROVED USES:
Topical treatment of acne vulgaris

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Treatment algorith for the topical treatment of acne vularis 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:
Topical retinoid products are indicated for cosmetic and medical conditions (e.g., acne vulgaris, psoriasis, precancerous skin lesions). Cosmetic use is not a covered benefit. Therefore, Prior Authorization is in place to verify the use is for the diagnosis of a medical condition.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of topical retinoids 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:

Adainzde GEL 0.3-2.5-1%
Adainzoxia GEL 0.3-2.5-4%
Adapalene CREA 0.1%
Adapalene GEL 0.1%
Adapalene GEL 0.3%
Adapalene PADS 0.1%
Adapalene SOLN 0.1%
Adapalene Treatment GEL 0.1%
Adapalene-Benzoyl Per-Clindamy GEL 0.3-2.5-1%
Adapalene-Benzoyl Per-Niacinam GEL 0.3-2.5-4%
Adapalene-Benzoyl Peroxide GEL 0.1-2.5%
Adapalene-Benzoyl Peroxide GEL 0.3-2.5%
Adapalene-Benzoyl Peroxide PADS 0.1-2.5%
Adermica HP GEL 2.5-1-2-0.05%
Aklief CREA 0.005%
Alomira HP GEL 5-1-2-0.1%
Altreno LOTN 0.05%
Aluris CREA 4-0.05%
Aluris GEL 4-0.05%
Aluris LP CREA 4-0.025%
Aluris LP Plus CREA 4-0.025%
Aluris Plus CREA 4-0.05%
Aluxof HP THPK 10-4 & 2-4-0.1%
Aluxof THPK 10-4 & 2-4-0.05%
Alvox CREA 4-0.05%
Alvox HP CREA 4-0.1%
Aphoria GEL 0.3-2.5-4%
Arazlo LOTN 0.045%
Atralin GEL 0.05%
Avidora SOLN 1-4-0.025%
Avita CREA 0.025%
Avita GEL 0.025%
Awanis CREA 8.5-2-0.025%
Cabtreo GEL 0.15-3.1-1.2%
Clindamycin-Tretinoin GEL 1.2-0.025%
CVS Adapalene GEL 0.1%
Deoxiatar SOLN 1-4-0.025%
Diasaxiatar CREA 8.5-2-0.025%
Diasaxiatar GEL 8.5-2-0.025%
Differin CREA 0.1%
Differin GEL 0.1%
Differin GEL 0.3%
Differin LOTN 0.1%
Epiduo Forte GEL 0.3-2.5%
Epiduo GEL 0.1-2.5%
Ethoxia CREA 4-0.05%
Fabior FOAM 0.1%
Inzdeaxiavar GEL 2.5-1-2-0.05%
Ithoxia CREA 4-0.1%
Lounzdomdioxatar THPK 10-4 & 2-4-0.05%
Niacinamide-Tazarotene CREA 4-0.05%
Niacinamide-Tazarotene CREA 4-0.1%
Niacinamide-Tretinoin CREA 4-0.025%
Niacinamide-Tretinoin CREA 4-0.05%
Niacinamide-Tretinoin GEL 4-0.025%
Niacinamide-Tretinoin GEL 4-0.05%
Onzdeaxiademtar GEL 5-1-2-2-0.025%
Onzdeaxiademvar GEL 5-1-2-2-0.05%
Onzdeaxiazar GEL 5-1-2-0.1%
Oxiatar CREA 4-0.025%
Oxiavar CREA 4-0.05%
Oxiavarry CREA 4-0.05%
Retin-A CREA 0.025%
Retin-A CREA 0.05%
Retin-A CREA 0.1%
Retin-A GEL 0.01%
Retin-A GEL 0.025%
Retin-A Micro GEL 0.04%
Retin-A Micro GEL 0.1%
Retin-A Micro Pump GEL 0.04%
Retin-A Micro Pump GEL 0.06%
Retin-A Micro Pump GEL 0.08%
Retin-A Micro Pump GEL 0.1%
Saroxia CREA 4-0.05%
Sorixia CREA 4-0.05%
Taroxia CREA 4-0.025%
Taroxia GEL 4-0.025%
Tazarotene FOAM 0.1%
Tretinoin CREA 0.025%
Tretinoin CREA 0.05%
Tretinoin CREA 0.1%
Tretinoin GEL 0.01%
Tretinoin GEL 0.025%
Tretinoin GEL 0.05%
Tretinoin Microsphere GEL 0.04%
Tretinoin Microsphere GEL 0.08%
Tretinoin Microsphere GEL 0.1%
Tretinoin Microsphere Pump GEL 0.04%
Tretinoin Microsphere Pump GEL 0.08%
Tretinoin Microsphere Pump GEL 0.1%
Twyneo CREA 0.1-3%
Unzdomdioxiazar THPK 10-4 & 2-4-0.1%
Varoxia CREA 4-0.05%
Varoxia GEL 4-0.05%
Veltin GEL 1.2-0.025%
Ziana GEL 1.2-0.025%

REFERENCES

1. Tan J, Tanghetti E, Baldwin H, et al. The Role of Topical Retinoids in Prevention and Treatment of Atrophic Acne Scarring: Understanding the Importance of Early Effective Treatment. J Drugs Dermatol 2019; 18:255.
2. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. EichenfieldLF, Krakowski AC, Piggott C, Del Rosso J, Baldwin H, Friedlander SF, Levy M, Lucky A, MancciniAJ, Orlow SJ, Yan AC, Vaux KK, Webster G, Zaenglein AL, Thiboutot DM, American Acne and Rosacea Society. Pediatrics. 2013 May;131 Suppl 3:S163-86.
3. Zaenglein, A., Pathy, A., Schlosser, B., Alikhan, A., Baldwin, H., & Berson, D. et al. (2016). Guidelines of care for the management of acne vulgaris. Journal Of The American Academy Of Dermatology, 74(5), 945-973.e33. doi: 10.1016/j.jaad.2015.12.037
4. 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 Required Medical Information Duration of Approval Available Dosage Forms	Q2 2025
REVISION- Notable revisions: Required Medical Information Age Restrictions Drug Class Appendix Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q2 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Available Dosage Forms	Q2 2023
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file