Original Effective Date: 09/2012
Current Effective Date: 06/21/2023
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2024
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, Aklief cream (trifarotene), Altreno® (tretinoin), Arazlo (tazarotene lotion), Atralin (tretinoin gel), Avita (tretinoin), 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), Niacinamide-Tazarotene, Niacinamide-Tretinoin, Onzdeaxiademtar (BP-clindamycin-niacinamide-spironolactone-tretinoin), Onzdeaxiademvar (BP-clindamycin-niacinamide-spironolactone-tretinoin), Onzdeaxiazar (BP-clindamycin-niacinamide-tretinoin), Oxiatar (niacinamide-tretinoin), Retin-A (tretinoin), Retin-A Micro (tretinoin micronized), Saroxia (niacinamide-tretinoin), tazarotene, Taroxia (niacinamide-tretinoin), Tazorac (tazarotene), tretinoin, tretinoin microsphere, Tretin-X (tretinoin), Varoxia (niacinamide-tretinoin), Twyneo (tretinoin-benzoyl peroxide), 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.

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 PRODUCTS 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
   (ii) 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. 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

AGE RESTRICTIONS:

Aklief is indicated for 9 years and older
Altreno is indicated for 9 years and older
Atralin is indicated for 10 years and older
Arazlo is indicated for 9 years and older
All other products indicated for 12 years and older

QUANTITY:
Per specific formulary

Maximum Quantity Limits – << based on FDA label>>

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:
Dermatological Topical acne products

FDA-APPROVED USES:
Acne Vulgaris

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

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.

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	

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 LOTN 0.1%
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%
Aklief CREA 0.005%
Altreno LOTN 0.05%
Arazlo LOTN 0.045%
Atralin GEL 0.05%
Avita CREA 0.025%
Avita GEL 0.025%
Clindamycin-Tretinoin GEL 1.2-0.025%
Deoxiatar SOLN 1-4-0.025%
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%
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%
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 0.1%
Tretinoin Microsphere Pump GEL 0.04%
Tretinoin Microsphere Pump GEL 0.1%
Twyneo CREA 0.1-3%
Varoxia CREA 4-0.05%
Varoxia GEL 4-0.05%
Veltin GEL 1.2-0.025%
Ziana GEL 1.2-0.025%

REFERENCES

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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

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4. Atralin gel (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
5. Avita cream (tretinoin) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; June 2018.
6. Avita gel prescribing information. Mylan Pharmaceuticals Inc. Morgantown, WV June 2018.

SUMMARY OF REVIEW/REVISIONS	DATE
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