UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Topical Retinoid Products

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| Program | Prior Authorization - Topical Retinoid Products |
| Medication | Topical Retinoid Products<br>BRAND OR GENERIC REQUESTS: Retin-A Micro® (tretinoin microspheres), Differin® (adapalene) RX ONLY, Fabior™ (tazarotene), Tazorac® (tazarotene), Retin-A Micro Pump® (tretinoin microspheres), Epiduo® (adapalene/benzoyl peroxide), Epiduo Forte Pump® (adapalene/benzoyl peroxide), Epiduo Pump® (adapalene/benzoyl peroxide), Atralin™ (tretinoin), Avita® (tretinoin), Retin-A® (tretinoin), Altreno® (tretinoin), Aklief (trifarotene) |
| Markets in Scope | California, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island |
| Issue Date | 9/2009 |
| Pharmacy and Therapeutics Approval Date | 6/2020 |
| Effective Date | 8/2020 |

*Note: Differin gel 0.1% OTC does not require prior authorization.

## 1. 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.

## 2. Coverage Criteria:

**A.** Non-preferred products will be approved based on **all** of the following:

1. The member has a non-cosmetic medical condition (e.g. acne vulgaris, psoriasis, precancerous skin lesions)

**-AND-**

2. Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma, vitiligo)

**-AND-**

3. **One** of the following**:**
   a. If the patient has a diagnosis of acne vulgaris, the patient has a history of failure, contraindication, or intolerance to a trial of **both** of the following:
      - Differin OTC

- Tretinoin cream

**-OR-**

b. If the patient does NOT have a diagnosis of acne vulgaris, the patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products (document drugs, duration, and date of trials).
**NOTE:** Step therapy is not limited to topical retinoids.
**NOTE:** In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products

**Authorization will be issued for 12 months.**

**B.** **Tretinoin cream** will be approved based on the following:

1. Patient has a history of failure, contraindication, or intolerance to a trial of Differin OTC.

**Authorization will be issued for 12 months.**

**Appendix:**

Examples of non-cosmetic medical conditions include, but are not limited to, the following:

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| Acanthosis nigricans | Keratoderma |
| Acne | Keratoderma palmaris et plantaris |
| Acne keloidalis nuchae | Keratosis rubra figurata |
| Acne rosacea | Kyrle's disease |
| Acne vulgaris | Lamellar ichthyosis |
| Actinic cheilitis | Leukoplakia |
| Actinic dermatitis | Lichen planus |
| Actinic keratosis | Mal de Meleda |
| Basal cell carcinoma | Malignancy |
| Bowen's disease | Mendes da Costa syndrome |
| Cystic acne | Molluscum contagiosum |
| Darier's disease | Non-bullous congenital ichthyosis |
| Darier-White Disease | Papillon-Lefevre syndrome |
| Dermal mucinosis | Porokeratosis |
| Discoid lupus erythematosus | Pseudofollicular barbae |
| Epidermoid cysts | Pseudoacanthosis nigricans |
| Epidermolytic hyperkeratosis | Psoriasis |
| Erythrokeratoderma variabilis | Psoriasis erythrodermic, palmoplantar |
| Favre Racouchot disease | Psoriasis pustular |

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| Flat warts | Psoriatic arthritis |
| Folliculitis | Rosacea |
| Fox Fordyce disease | Sebaceous cysts |
| Grover's disease | Senile keratosis |
| Hidradenitis suppurativa | Solar keratosis |
| Hyperkeratosis | Squamous cell carcinoma |
| Hyperkeratosis follicularis | Transient acantholytic dermatosis |
| Hyperkeratotic eczema | Tylotic eczema |
| Ichthyoses | X-linked ichthyosis |
| Ichthyosis vulgaris | Verruca planae |
| Keratoacanthoma | Von Zumbusch pustular |
| Keratosis follicularis | Warts |

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Atralin prescribing information. DPT Laboratories. San Antonio, TX. August 2014.
2. Avita cream prescribing information. Mylan Pharmaceuticals Inc. Morgantown, WV June 2018.
3. Avita gel prescribing information. Mylan Pharmaceuticals Inc. Morgantown, WV January 2018.
4. Differin gel prescribing information. Galderma Laboratories LP. Fort Worth, TX. February 2018.
5. Differin lotion prescribing information. Galderma Laboratories LP. Fort Worth, TX. February 2018.
6. Differin cream prescribing information. Galderma Laboratories LP. Fort Worth, TX. February 2018.
7. Retin-A prescribing information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. June 2018.
8. Retin-A Micro prescribing information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ October 2017.9. Tazorac cream prescribing information. Allergan. Irvine, CA. December 2013.
9. Tazorac cream prescribing information. Allergan. Irvine, CA. July 2017.
10. Tazorac gel prescribing information. Allergan. Irvine, CA. July 2018.
12. Fabior prescribing information. Stiefel Laboratories, Inc. Research Triangle Park, NC. June 2018.
13. Altreno prescribing information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. November 2019.
14. Aklief cream prescribing information. Galderma Laboratories, L.P. Fort Worth, Texas. October 2019.

| Program | Prior Authorization/Notification – Topical Retinoid Products |
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| Change Control | |
| Date | Change |
| 9/2009 | Criteria were taken from a previously approved AmeriChoic policy. Policy was reformatted. |
| 12/2010 | Annual Review |
| 12/2011 | Annual Review |
| 12/2012 | Annual Review |
| 6/2013 | •Converted policy to new UHC enterprise wide formatting.<br>•Created non-preferred criteria for non-preferred products (Retin-A micro, Tazorac, Tretin-X, Differin) for acne diagnosis<br>•Created "other medical use" criteria for preferred and for non-preferred agents<br>•Created Tazorac criteria specific for psoriasis |
| 9/2013 | •Revised list of approvable off-label uses of tretinoin products<br>•Removed QL criteria<br>•Revised Background Medical vs. Cosmetic indications table |
| 6/2016 | Clinical criteria and policy template updated to align with E&I. |
| 8/2016 | Removed preferred products from this policy and added in additional non-preferred drugs. Added non-preferred criteria. |
| 3/2017 | Updated policy to account for Atralin moving to non-preferred. |
| 4/2017 | Updated policy to require all prescription products to require a step through Differin OTC. |
| 8/2017 | Moved non-cosmetic medical conditions table from criteria to appendix. Added vitiligo as an example of a cosmetic condition. |
| 3/2018 | Clarified step therapy language- step does not need to be through three preferred retinoids, as long as one of the products is Differin OTC. |
| 5/2018 | Removed Refissa from the policy and updated non-preferred header. Separated step therapy language into acne and non-acne sections. |
| 1/2019 | Added Altreno as target medication. Updated references. |
| 1/2020 | Added Aklief and removed Tretin-X (discontinued). Updated references. |
| 6/2020 | Annual review, no changes to criteria. |