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5.90.003

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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2026 |
| **Subsection:** | Topical Products | **Original Policy Date:** | December 7, 2011 |
| **Subject:** | Tretinoin | **Page:** | 1 of 6 |

***Last Review Date:*** December 12, 2025

# Tretinoin

## Description

Aklief (trifarotene), Altreno (tretinoin), Atralin (tretinoin), Avita (tretinoin), Cabtreo* (adapalene + benzoyl peroxide + clindamycin phosphate), Differin (adapalene), Epiduo (adapalene + benzoyl peroxide), Refissa (tretinoin), Plixda** (adapalene), Renova (tretinoin), Retin-A (tretinoin), Tretin-X (tretinoin), Twyneo (tretinoin + benzoyl peroxide), Ziana (tretinoin + clindamycin phosphate)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

**This medication is included in this policy but is not available on the market as of yet

**Background**
Tretinoin is a retinoid medication derived from vitamin A used to treat both non-inflammatory and inflammatory types of acne, including blackheads, whiteheads, papules, pustules, and nodules (1-4).

Tretinoin products may also be used for cosmetic purposes such as treatment for wrinkles, fine lines and solar or photo aging. These indications are excluded from plan coverage.

**Regulatory Status**
FDA approved indication: Tretinoin products are indicated for the topical treatment of acne vulgaris (5-22).

Off-Label Use:
Tretinoin products are also indicated topically to treat malignant and pre-malignant skin conditions in high risk patients with actinic keratosis, basal and squamous cell carcinoma. Current FDA approved options for the treatment of high-risk patients with basal and squamous cell cancers include hedgehog pathway inhibitors, intralesional chemotherapy, and other established treatment options (3).

Some products have cosmetic indications which are excluded from coverage (5-22).

**Related policies**
Aczone, Tazarotene, Winlevi

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Tretinoin may be considered **medically necessary** if the conditions indicated below are met.

Tretinoin may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age**
**Cabtreo:** 9 years of age or older
**All other medications:** 35 years of age or older

**Diagnoses**

Patient must have **ONE** of the following**:**

1. Acne vulgaris
    a. Comedones
    b. Cysts (eruptive vellus hair cyst, cystic acne)
    c. Papules
    d. Pustules

2. Acne conglobata

3. Patient is at high risk (i.e., immunocompromised, post organ transplant) with one of the following diagnoses:
    a. Actinic keratosis
    b. Basal cell carcinoma
    c. Squamous cell carcinoma

## Prior – Approval *Renewal* Requirements

Same as above

## Policy Guidelines

### Pre – PA Allowance

**Age** Age 9-34: no restriction
Age 0-8 and 35 years or older: no Pre-PA allowance

### Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Tretinoin is a retinoid derived from vitamin A used for the topical treatment of patients with acne vulgaris and acne conglobata. Tretinoin is also used in the topical treatment of skin conditions in high risk patients (i.e., immunocompromised, post organ transplant) such as actinic keratosis, basal cell carcinoma, and squamous cell carcinoma (5-22).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of tretinoin while maintaining optimal therapeutic outcomes.

**References**

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20. Twyneo [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; July 2021.
21. Ziana [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
22. Cabtreo [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2023.

## Policy History

| Date | Action |
|---|---|
| March 2009 | Added Epiduo to Retinoid criteria and corrected “milium” spelling |
| July 2009 | Add Refissa (tretinoin 0.05% cream) to PA as a line extension. (NOTE: Refissa is only FDA-approved for cosmetic purposes; however, other |

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| | tretinoin 0.05% products that are approved for acne are assigned the same GCN used in claim adjudication.) |
| August 2009 | Addition of Ziana (tretinoin 0.025% + clindamycin 1.2% gel) for treatment of acne |
| April 2010 | Addition of Differin 0.1% lotion, which is FDA approved for the same indications as the Differin gel and Differin cream |
| October 2010 | Addition of Veltin (tretinoin 0.025% + clindamycin 1.2% gel) for treatment of acne |
| December 2012 | Annual review and update |
| June 2014 | Annual editorial review and reference update<br>Removed non-supported diagnoses: Grover's disease, Kyrle's disease, Keratosis Follicularis and Molluscum contagiosum<br>Addition of high-risk requirement for actinic keratosis, basal and squamous cell carcinoma per SME<br>Addition of Retin-A Micro Pump 0.8% gel |
| September 2015 | Annual editorial review and reference update |
| December 2016 | Annual editorial review and reference update<br>Policy number change from 5.14.03 to 5.90.03 |
| September 2017 | Annual editorial review and reference update |
| September 2018 | Annual editorial review and reference update |
| October 2018 | Addition of Altreno lotion |
| November 2018 | Annual review and reference update |
| March 2019 | Annual review. Addition of Plixda topical solution. Revised off-label use statement and changed Pre-PA allowance to age 9-34 only per SME |
| November 2019 | Addition of Aklief |
| December 2019 | Annual review |
| March 2020 | Annual review |
| March 2021 | Annual editorial review and reference update |
| December 2021 | Annual review |
| June 2022 | Annual review. Addition of Twyneo cream to policy per FEP |
| September 2023 | Annual review. Changed policy number to 5.90.003 |
| February 2023 | Added Cabtreo gel to the policy as product requiring formulary exception and PA |
| September 2024 | Annual review |
| September 2025 | Annual review |
| December 2025 | Annual review. Removed Veltin from PA due to discontinuation |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.**