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5.90.03

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	December 7, 2011
Subject:	Tretinoin	**Page:**	1 of 5

Last Review Date: March 12, 2021

Tretinoin

Description

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

*This medication is currently pending tier determination and may not be available at this time

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 (5-21).

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 (5-21).

Related policies
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** for the treatment of acne vulgaris, acne conglobata or patients who are at high risk (i.e. immunocompromised, post organ transplant) with one of the following skin conditions: actinic keratosis, basal and squamous cell carcinoma; and if the conditions indicated below are met.

Tretinoin may be considered **investigational** for the treatment of all other indications.

Prior-Approval Requirements

Age 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 and squamous cell carcinoma (5-21).

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. Veltin [package insert]. Exton, PA: Almirall, LLC; June 2019.
21. Ziana [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.

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 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 Removed non-supported diagnoses: Grover's disease, Kyrle's disease, Keratosis Follicularis and Molluscum contagiosum Addition of high risk requirement for actinic keratosis, basal and squamous cell carcinoma per SME 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 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.