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 that is made from vitamin A in treating 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

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 the conditions listed below. Tretinoin products are indicated for the topical treatment of patients with acne vulgaris and acne conglobata. They are also used in the topical treatment of skin conditions in high risk patients (i.e. immunocompromised, post organ transplant) with actinic keratosis, basal and squamous cell carcinoma.

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. Comodones
   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:
**Section:** Prescription Drugs  
**Effective Date:** January 1, 2020  
**Subsection:** Topical Products  
**Original Policy Date:** December 7, 2011  
**Subject:** Tretinoin  
**Page:** 3 of 5


**Prior – Approval Renewal Requirements**  
Same as above

**Policy Guidelines**

**Pre – PA Allowance**

<table>
<thead>
<tr>
<th>Age</th>
<th>Requirements</th>
</tr>
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<tbody>
<tr>
<td>Age 9-34: no restriction</td>
<td></td>
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<tr>
<td>Age 0-8 and 35 years or older: no Pre-PA allowance</td>
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</tr>
</tbody>
</table>

**Prior - Approval Limits**

| Duration | 12 months |

**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**  
Tretinoin products are indicated for the topical treatment of patients with acne vulgaris and acne conglobata. They are also used in the topical treatment of skin conditions in high risk patients (i.e. immunocompromised, post organ transplant) with actinic keratosis, basal and squamous cell carcinoma. Tretinoin is a retinoid metabolite of vitamin A. These products work by increasing the rate of cell turnover (5-21).

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

**References**

Section: Prescription Drugs

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Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2009</td>
<td>Added Epiduo to Retinoid criteria and corrected “milium” spelling.</td>
</tr>
<tr>
<td>July 2009</td>
<td>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.)</td>
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</table>
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.