

## PRIOR AUTHORIZATION POLICY

- POLICY:** Topical Retinoids – Tretinoin Products Prior Authorization Policy
- Single-entity topical tretinoin products
- Altreno™ (tretinoin lotion – Bausch Health)
  - Atralin™ (tretinoin gel – Valeant, generic)
  - Avita® (tretinoin cream, gel – Mylan, generic [Avita gel 0.025% is brand only])
  - Retin-A® (tretinoin cream, gel – Bausch Health, generic)
  - Retin-A Micro® (tretinoin gel microsphere – Valeant, generic)
  - Retin-A Micro® Pump (tretinoin gel microsphere – Valeant, generic [Retin-A Micro 0.06% gel and 0.08% gel are branded products only])
  - Tretin•X® (tretinoin cream – Onset Dermatologicals) [obsolete as of 08/19/2021]
- Combination topical tretinoin products
- Twyneo® (tretinoin 0.1% and benzoyl peroxide 3% cream – Sol-Gel Technologies)
  - Veltin™ (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Almirall)
  - Ziana® (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Valeant, generic)

**REVIEW DATE:** 08/04/2021; selected revision 12/22/2021, 03/09/2022

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### OVERVIEW

All of the single-entity and combination topical tretinoin products in this policy are indicated for the topical treatment of **acne vulgaris**.<sup>1-10</sup>

Topical tretinoin products have been used to treat numerous other medical skin conditions in addition to acne vulgaris.<sup>1,2</sup> Some indications have minimal published clinical data and thus appear experimental. Topical tretinoin products have also been used to treat a variety of cosmetic skin conditions, such as wrinkles, stretch marks, liver spots, premature aging, and photo-aged or photo-damaged skin.<sup>2</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of single-entity and combination topical tretinoin products. All approvals are provided for the duration noted below.

**Automation:** An age edit targeting patients > 30 years of age is recommended to monitor for appropriate use and to screen for cosmetic use. For patients > 30 years of age, coverage will be determined by the Prior Authorization criteria. For patients ≤ 30 years of age, coverage will be approved at the point of service.

### RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of single-entity topical tretinoin products is recommended in those who meet one of the following criteria:

#### FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 1 year.

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## Other Uses with Supportive Evidence

### 2. Treatment of Other Non-Cosmetic Conditions. Approve for 1 year.

Note: Examples of other non-cosmetic conditions include acne rosacea, actinic keratosis/treatment of precancerous lesions, ichthyosis, diabetic foot ulcers, mucositis, warts, lichen planus, lichen sclerosis, pseudofolliculitis, oral leukoplakia, molluscum contagiosum, Darier’s disease (keratosis follicularis), dermatitis/eczema, folliculitis, keratosis pilaris, basal cell carcinoma (skin cancer), confluent and reticulated papillomatosis, and cutis laxa.

## II. Coverage of combination topical tretinoin products (Twynéo; Veltin; Ziana, generic) is recommended in those who meet the following criteria:

### FDA-Approved Indication

#### 1. Acne Vulgaris. Approve for 1 year.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of single-entity and combination topical tretinoin products is not recommended in the following situations:

#### 1. Cosmetic Conditions. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.

Note: Examples of cosmetic conditions include liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photo-aged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation (caused by folliculitis, acne, or eczema), melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis, milia, nevus, poikiloderma (of Civatte), purpura (actinic/solar), keloids, and sebaceous hyperplasia.

#### 2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2020. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=>. Accessed on July 27, 2021. Search term: tretinoin.
  2. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: <http://www.micromedexsolutions.com/micromedex2/librarian/>. Accessed on July 27, 2021. Search term: tretinoin.
  3. Altreno™ lotion [prescribing information]. Bridgewater, NJ: Bausch Health; March 2020.
  4. Atralin™ gel [prescribing information]. Bridgewater, NJ: Valeant; July 2016.
  5. Avita® cream and gel [prescribing information]. Morgantown WV: Mylan; June 2018.
  6. Retin-A® gel and cream. [prescribing information]. Bridgewater, NJ: Bausch Health; September 2019.
  7. Retin-A Micro® gel. [prescribing information]. Bridgewater, NJ: Valeant; July 2017.
  8. Twynéo® cream [prescribing information]. Whippany, NJ; Sol-Gel Technologies; July 2021.
  9. Veltin™ gel [prescribing information]. Malvern PA: Almirall; June 2019.
  10. Ziana® gel [prescribing information]. Bridgewater, NJ: Valeant; March 2017.
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