

PRIOR AUTHORIZATION POLICY

POLICY: Topical Retinoids – Tretinoin Products Prior Authorization Policy Single-entity topical tretinoin products

- Altreno (tretinoin lotion Bausch Health)
- AtralinTM (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

OVERVIEW

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

Topical tretinoin products have been used to treat numerous other medical skin conditions in addition to acne vulgaris.^{1,2} 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.²

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 <u>single-entity topical tretinoin products</u> is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. Acne Vulgaris. Approve for 1 year.

Other Uses with Supportive Evidence

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

<u>Note</u>: 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 <u>combination topical tretinoin products (Twyneo; Veltin; Ziana, generic)</u> 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.

<u>Note</u>: 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.
- DRUGDEX[®] System. Thomson Reuters (Healthcare) Inc. Available a 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. Twyneo® 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.