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: 07/27/2022

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.[1,2,11-22] 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.[1,2]

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.

Prior authorization and prescription benefit coverage are not recommended for cosmetic uses.

Automation: An age edit targeting patients > 30 years of age is in place 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.

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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.

Other Uses with Supportive Evidence

2. Treatment of Other Non-Cosmetic Conditions. Approve for 1 year.
Note: Examples of other non-cosmetic conditions include acanthosis nigricans, acne rosacea, actinic keratosis/precancerous lesions, alopecia areata, basal cell carcinoma (skin cancer), diabetic foot ulcers, dysplasia of cervix, folliculitis (e.g., pseudofolliculitis barbae), ichthyosis (e.g., congenital, lamellar, vulgaris, X-linked), keloid scars, keratosis (e.g., keratosis follicularis [Darier's disease], keratosis pilaris), lichen planus, lichen sclerosis, military osteoma cutis, molluscum contagiosum, mucositis, oral leukoplakia, papillomatosis, systemic sclerosis, and warts.

II. Coverage of combination topical tretinoin products (Twyneo; 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 (this is not an all-inclusive list): Examples of cosmetic conditions include actinic purpura, age spots (also called liver spots, solar lentigines, sun spots), melasma/cholasma, milia, mottled hyperpigmentation, mottled hypopigmentation, photo-aged or photo-damaged skin, pokiloderma (of Civatte), premature aging, scarring, sebaceous hyperplasia, seborrheic keratosis, skin laxity, skin roughness, solar elastosis, solar purpura, stretch marks, and wrinkles.

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

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