Prior Authorization
Topical Retinoid – Tretinoin Products

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Product Identifier(s)

Effective 1/1/23 to 2/27/23: 108977

Effective 2/28/23: 00006

National Formulary Medical Necessity

Drugs Affected
Single-entity topical tretinoin products

- Altreno™ (tretinoin lotion)
- Atralin™ (tretinoin gel – generic)
- Avita® (tretinoin cream, gel – generic [Avita gel 0.025% is brand only])
- Retin-A® (tretinoin cream, gel – generic)
- Retin-A Micro® (tretinoin gel microsphere – generic)
- Retin-A Micro® Pump (tretinoin gel microsphere – generic [Retin-A Micro 0.06% gel and 0.08% gel are branded products only])
- Tretin•X® (tretinoin cream) [obsolete as of 08/19/2021]

Combination topical tretinoin products

- Twyneo® (tretinoin 0.1% and benzoyl peroxide 3% cream)
- Veltin™ (clindamycin phosphate 1.2% and tretinoin 0.025% gel)
- Ziana® (clindamycin phosphate 1.2% and tretinoin 0.025% gel – generic)

Cigna covers topical tretinoin products as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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.

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

FDA Indication(s)

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 Indication(s)

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

Conditions Not Covered

Single-entity and combination topical tretinoin products are considered not medically necessary for ANY other use including the following (this list may not be all inclusive):

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.

Background

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]

References

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Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Treatment of Other Non-Cosmetic Conditions:** The Note was revised. The following conditions were added: acanthosis nigricans; alopecia areata; dysplasia of cervix; an example of folliculitis (pseudofolliculitis barbae); keloid scars; military osteoma cutis; and systemic sclerosis. Ichthyosis was clarified as ichthyosis (e.g., congenital, lamellar, vulgaris, X-linked). "Confluent and reticulated papillomatosis" was renamed to "Papillomatosis". Cutix laxa and dermatitis/eczema were removed. **Conditions Not Recommended for Approval:** Under **Cosmetic Conditions**, it was clarified in the Note that the list of conditions is not all-inclusive. The following were added: sun spots as an example of age spots; milia; mottled hypopigmentation; and skin laxity. The following were deleted: geographic tongue; hyperpigmentation (caused by folliculitis, acne, or eczema); alopecia androgenetic; alopecia areata; milia; nervus; and keloids.	07/27/2022