Topical Tretinoin Products
Prior Approval Criteria
October 2015

Medications

- Atralin™ (tretinoin gel)
- Avita® (tretinoin cream, gel)
- Generic topical tretinoin products
- Retin-A® (tretinoin cream, gel, liquid)
- Retin-A® Micro® (tretinoin gel microsphere)
- Retin-A Micro® Pump (tretinoin gel microsphere)
- Tretin•X™ (tretinoin cream)
- Veltin™ (clindamycin phosphate 1.2% and tretinoin 0.025% gel)
- Ziana® (clindamycin phosphate 1.2% and tretinoin 0.025% gel)

Overview

The following topical tretinoin products are indicated for the topical treatment of acne vulgaris: Atralin, Avita, Retin-A, Retin-A Micro, Tretin•X, and generics. Renova® and Refissa® (tretinoin emollient creams) are indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs alone. Ziana and Veltin are combination products containing clindamycin phosphate 1.2% and tretinoin 0.025% gel that are indicated for the topical treatment of acne vulgaris in patients aged ≥ 12 years.

Topical tretinoin has been used to treat numerous other medical skin conditions in addition to acne vulgaris. 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.

Policy Statement

Prior authorization is recommended for prescription benefit coverage of topical tretinoin products. Use should be limited to the treatment of medical conditions, and prescription benefit coverage is not recommended for cosmetic conditions. Approval is for 1 year in duration.

Automation: An age edit targeting patients aged > 30 years is recommended to monitor for appropriate use and to screen for cosmetic use. Therefore, patient’s ≤ 30 years of age will be approved at the point-of-service. For patients > 30 years of age, coverage will be determined by the prior authorization criteria.

Prior authorization and prescription benefit coverage is not recommended for Renova or Refissa.

Recommended Authorization Criteria

A. Coverage of topical tretinoin products is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indication
1. **Acne Vulgaris.** Approve for 1 year.

Topical tretinoins are indicated for this use.¹

**Other Uses with Supportive Evidence**

**Treatment of Other Non-Cosmetic Conditions Not Listed Above** (e.g., Acanthosis nigricans, Acne, Acne keloidalis nuchae, Acne rosacea, Actinic cheilitis, Actinic dermatitis, Actinic keratosis, Basal cell carcinoma, Bowen’s disease, Cystic acne, Darier’s disease, Darier-White disease, Dermal mucinosis, Discoid lupus erythematosus, Epidermoid cysts, Epidermolytic hyperkeratosis, Erythrokeratoderma variabilis, Favre Raucochet Disease with comedones, Folliculitis in the presence of previous failure to topical antibiotics, Fox Fordyce disease, Grover’s disease, Hiradenitis suppurativa, Hyperkeratosis, Hyperkeratosis follicularis, Hyperkeratotic eczema, Ichthyoses, Ichthyosis vulgaris, Keratoacanthoma, Keratosis follicularis, Keratoderma, Keratoderma palmaris et plantaris, Keratosis rubra figurate, Kyrle’s disease, Lamellar ichthyosis, Leukoplakia, Lichen planus, Mal de Meleda, Malignancy, Mendes da Costa syndrome, Mendes da Costa syndrome, Molluscum contagiosum, Non-bullous congenital ichthyosis, Papillon-Lefevre syndrome, Porokeratosis, Pseudo follicular barbae, Pseudoacanthosis nigricans, Psoriasis, Psoriasis, erythrokeratotic or palmoplantar, Psoriasis, pustular, Psoriatic arthritis, Rosacea, Sebaceous cysts, Senile keratosis, Solar keratosis, Squamous cell carcinoma, Transient acantholytic dermatosis, Tylotic eczema, Verucca planae (e.g., flat warts) located on the face, X-linked ichthyosis, Von Zumbusch pustular.) Approve for 1 year.

B. Coverage of the combination of clindamycin plus tretinoin (Ziana, Veltin) is recommended in those who meet the following criteria:

**FDA-Approved Indication**

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

Ziana and Veltin are indicated for this use.³⁻⁴

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Topical tretinoin products, Veltin, and Ziana have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Cosmetic Conditions** (e.g., 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, sebaceous hyperplasia). Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.

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**


