### Topical Tretinoin Products

- Altreno (tretinoin lotion)
- Atralin™ (tretinoin gel)
- Avita® (tretinoin cream, gel)
- Retin-A® (tretinoin cream, gel)
- Retin-A® Micro® (tretinoin gel microsphere)
- Retin-A Micro® Pump (tretinoin gel microsphere)
- Tretin-X™ (tretinoin cream)
- Generic topical tretinoin products

### Overview

The following topical tretinoin products are indicated for the topical treatment of acne vulgaris: Altreno, Atralin, Avita, Retin-A, Retin-A Micro, Tretin•X, and generics.1-2 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.1

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.2

### Policy Statement

This policy involves the use of topical tretinoin products. Prior authorization is recommended for pharmacy benefit coverage of topical tretinoin products. Approval is recommended for those who meet the conditions of coverage in the Criteria and Initial/Extended Approval for the diagnosis provided. Conditions Not Recommended for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.
**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**

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 if:

   Topical tretinoin are indicated for this use.¹

**Other Uses with Supportive Evidence**

2. **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, Epidermolysis hyperkeratosis, Erythrodermatoderma variabilis, Favre Raucocyt Disease with comedones, Folliculitis in the presence of previous failure to topical antibiotics, Fox Fordyce disease, Grover’s disease, Hiradenitis suppurative, 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, Psuedoacanthosis nigricans, Psoriasis, Psoriasis, erythrodermic 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.

**Initial Approval/ Extended Approval.**

A) **Initial Approval:** 365 days (1 year)

B) **Extended Approval:** 365 days (1 year)

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Topical tretinoin products 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. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).
1. **Cosmetic Conditions** (e.g., alopecia, hyperpigmentation, liver spots, melasma/cholasma, seborrheic keratosis, stretch marks, scarring, wrinkles, premature aging, photo-aged or photo-damaged skin, mottled hyper- and hypopigmentation, benign facial lentigines, roughness, telangiectasia, skin laxity, keratinocytic atypia, melanocytic atypia, dermal elastosis). 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.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**REFERENCES**