

PRIOR AUTHORIZATION POLICY

POLICY: Tretinoin (Topical) Products

- Altreno™ (tretinoin lotion – Dow Pharmaceuticals, a division of Valeant Pharmaceuticals)
- Atralin™ (tretinoin gel – Valeant Pharmaceuticals, generics)
- Avita® (tretinoin cream, gel – Mylan, generics [Avita gel 0.025% is brand only])
- Retin-A® (tretinoin cream, gel – Valeant Pharmaceuticals, generics)
- Retin-A® Micro® (tretinoin gel microsphere – Valeant Pharmaceuticals, generic)
- Retin-A Micro® Pump (tretinoin gel microsphere – Valeant Pharmaceuticals, generics [Retin-A Micro gel 0.06% and 0.08% are branded products only])
- Tretin•X® (tretinoin cream – Onset Dermatologicals)
- Veltin™ (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Aqua Pharmaceuticals)
- Ziana® (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Valeant Pharmaceuticals, generics)

TAC APPROVAL DATE: 07/31/2019

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.¹⁻³ Renova® and Refissa® (tretinoin emollient creams) are not indicated for use in the treatment of acne vulgaris.¹ Renova is indicated as adjunctive treatment for mitigation (palliation) of fine wrinkles in persons who use comprehensive skin care and sun avoidance programs. Refissa is indicated as adjunctive treatment for 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 gel products containing clindamycin phosphate 1.2% and tretinoin 0.025%; these products are indicated for the topical treatment of acne vulgaris in patients aged ≥ 12 years.^{1,2}

Topical tretinoin products have 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

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. For the single-entity products, coverage for the treatment of acne vulgaris is approved for a duration of 3 years and coverage for other non-cosmetic conditions is approved for a duration of 1 year. Coverage for the treatment of acne vulgaris for the tretinoin plus clindamycin combination products (Ziana, generics; Veltin) is for a duration of 1 year.

Automation: An age edit targeting patients > 30 years of age is recommended to monitor for appropriate use and to screen for cosmetic use. Therefore, patients ≤ 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

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

FDA-Approved Indication

1. Acne Vulgaris. Approve for 3 years.

Other Uses with Supportive Evidence

2. Treatment of Other Non-Cosmetic Conditions Not Listed Above (e.g., 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, cutis laxa). Approve for 1 year.

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

FDA-Approved Indication

1. Acne Vulgaris. Approve for 1 year.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Topical tretinoin products and topical clindamycin/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. 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

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2019. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=->. Accessed on September July 24, 2019. Search term: tretinoin.
2. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: <http://www.micromedexsolutions.com/micromedex2/librarian/>. Accessed on July 24, 2019. Search term: tretinoin.
3. Altreno™ [prescribing information]. Bridgewater NJ: Dow Pharmaceutical Sciences, a division of Valeant Pharmaceuticals North America LLC; August 2018.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No criteria changes.	07/19/2017
DEU revision	12/22/2017: Added Retin-A Micro gel 0.06% (brand only) to the list of products; no criteria changes.	--
Annual revision	No criteria changes.	07/18/2018
Select revision	Addition of Atreno (tretinoin lotion)	09/19/2018
Annual revision	No criteria changes.	07/31/2019

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.