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

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on July 19, 2022. Search term: tretinoin.
2. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: http://www.micromedexsolutions.com/micromedex2/librarian/. Accessed on July 19, 2022. Search term: tretinoin.
3. Altreno™ lotion [prescribing information]. Bridgewater, NJ: Bausch Health; March 2020.
4. Atralin™ gel [prescribing information]. Bridgewater, NJ: Valeant; July 2016.
5. Avita® cream and gel [prescribing information]. Morgantown WV: Mylan; June 2018.
6. Retin-A® gel and cream. [prescribing information]. Bridgewater, NJ: Bausch Health; September 2019.
7. Retin-A Micro® gel. [prescribing information]. Bridgewater, NJ: Valeant; July 2017.
8. Twyneo® cream [prescribing information]. Whippany, NJ; Sol-Gel Technologies; July 2021.
9. Veltin™ gel [prescribing information]. Malvern PA: Almirall; June 2019.
10. Ziana® gel [prescribing information]. Bridgewater, NJ: Valeant; March 2017.
11. Tom WL, Peng DH, Allaei A, et al. The effect of short-contact topical tretinoin therapy for foot ulcers in patients with diabetes. *Arch Dermatol*. 2005;141(11):1373-1377.
12. Ebell M. Topical tretinoin may hasten healing of diabetic ulcers. *Am Fam Physician*. 2006;73(6):1084.
13. Daly A. Follicular eruptions due to drugs. Available at: https://dermnetnz.org/topics/follicular-eruptions-due-to-drugs#:~:text=Mild%20folliculitis%20may%20respond%20to,Retinoids%2C%20such%20as%20tretinoin. Accessed on June 27, 2022.
14. Norwood DA, Michel D, Eraikhuemen NE, Carrion AJ. Pseudofolliculitis barbae: prevention and treatment. Available at: https://www.uspharmacist.com/article/pseudofolliculitis-barbae-prevention-and-treatment. Accessed on June 27, 2022.
15. National Organization for Rare Disorders – Lichen Schlerosus. Available at: https://rarediseases.org/rare-diseases/lichen-sclerosus/. Accessed on June 28, 2022.
16. Borghi A, Corazza M, Minghetti S, Virgili A. Topical tretinoin in the treatment of vulvar lichen sclerosus: an advisable option? Eur J Dermatol: EJD. 25.10.1684/ejd.2015.2595.
17. American Academy of Dermatology – Molluscum Contagiosum. Available at: https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-overview. Accessed on June 28, 2022.
18. Al-Taie A, Al-Shohani AD, Albasry Z, Altaee A. Current topical trends and novel therapeutic approaches and delivery systems for oral mucositis management. *J Pharm Bioallied Sci*. 2020;12(2):94-101.
19. American Academy of Dermatology – Keratosis pilaris. Available at: https://www.aad.org/public/diseases/a-z/keratosis-pilaris-overview. Accessed on June 28, 2022
20. Grandinetti LM, Tomecki KJ. Dermatologic signs of systemic disease. Available at: https://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/dermatology/dermatologic-signs-of-systemic-disease/. Accessed June 28, 2022.
21. Gaston A, Garry RF. Topical vitamin A treatment of recalcitrant common warts. *Virol J*. 2012;9:21.
22. Singh R, Pandey SS. Efficacy of topical 5% 5-fluorouracil and 0.05% tretinoin and electrosurgery in the treatment plane warts: a randomized controlled comparative trial. *Nepal J Dermatol, Venereol, & Leprology*. 2021;19(1):55-59.

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