



Effective Date..... 12/15/2023
Next Review Date..... 12/15/2024
Coverage Policy Number IP0167

Topical Tretinoin Products

Table of Contents

Overview 1
Medical Necessity Criteria 2
Reauthorization Criteria 4
Authorization Duration 4
Conditions Not Covered..... 4
Background..... 4
References 4

Related Coverage Resources

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.

Overview

This policy supports medical necessity review for the following topical tretinoin products:

- **Altreno™** (tretinoin 0.05% lotion)
- **Atralin™** (tretinoin 0.05% gel)
- **Avita®** (tretinoin 0.025% cream, gel)
- **Retin-A®** (tretinoin [0.025%, 0.05%, 0.1% cream] and [0.01%, 0.025% gel])
- **Retin-A® Micro/Micro Pump** (tretinoin microsphere 0.04%, 0.06%, 0.08%, 0.1% gel)
- **tretinoin** 0.025% cream
- **tretinoin** 0.05% cream
- **tretinoin** 0.05% gel
- **tretinoin** 0.1% cream
- **tretinoin microsphere** 0.04%, 0.08% and 0.1% gel and gel with pump
- **Veltin™** (clindamycin/tretinoin 1.2%-0.025% gel)
- **Ziana®** (clindamycin/tretinoin 1.2%-0.025% gel)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The product(s) in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

| Non-Covered Product | Criteria |
|---|---|
| Altreno (tretinoin 0.05% lotion) | <p>There is documentation the individual meets BOTH of the following (1 <u>and</u> 2):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic</u> Conditions (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). 2. Inadequate response, contraindication, or is intolerant to ALL of the following (A, B, <u>and</u> C): <ol style="list-style-type: none"> A. tretinoin cream, gel, or microgel [may require prior authorization] B. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] C. tazarotene cream or gel |
| Atralin (tretinoin 0.05% gel) | <p>There is documentation the individual meets ALL of the following (1, 2, <u>and</u> 3):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic</u> Conditions (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). 2. The individual has tried tretinoin 0.05% gel (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction [may require prior authorization] 3. Inadequate response, contraindication, or is intolerant to BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] B. tazarotene cream or gel |
| Avita (tretinoin 0.025% cream, gel) | <p>There is documentation the individual meets ALL of the following (1, 2, <u>and</u> 3):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic</u> Conditions (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). 2. The individual has tried tretinoin 0.025% cream/gel AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction [may require prior authorization] 3. Inadequate response, contraindication, or is intolerant to BOTH of the following (A <u>and</u> B): <ol style="list-style-type: none"> A. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] B. tazarotene cream or gel |
| Retin-A | <p>There is documentation the individual meets ALL of the following (1, 2, <u>and</u> 3):</p> |

| Non-Covered Product | Criteria |
|---|--|
| (tretinoin [0.025%, 0.05%, 0.1% cream] and [0.01%, 0.025% gel]) | <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic Conditions</u> (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). 2. The individual has tried <u>tretinoin cream/gel</u> (the bioequivalent generic product in the same strength) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction [may require prior authorization] 3. Inadequate response, contraindication, or is intolerant to BOTH of the following (A and B): <ol style="list-style-type: none"> A. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] B. tazarotene cream or gel |
| Retin-A Micro/Micro Pump (tretinoin microsphere 0.04%, 0.06%, 0.08%, 0.1% gel) | <p>There is documentation the individual meets ALL of the following (1, 2, and 3):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic Conditions</u> (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease). 2. The individual has tried <u>tretinoin microsphere gel</u> AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction [may require prior authorization] 3. Inadequate response, contraindication, or is intolerant to BOTH of the following (A and B): <ol style="list-style-type: none"> A. adapalene cream, 0.3% gel, lotion, or solution [may require prior authorization] B. tazarotene cream or gel |
| tretinoin 0.025% cream | <p>There is documentation the individual meets the following criteria:</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris or Other <u>Non-Cosmetic Conditions</u> (for example, ichthyosis, pseudofolliculitis barbae, molluscum contagiosum, Darier's disease) |
| tretinoin 0.05% gel | |
| tretinoin 0.05% cream | |
| tretinoin 0.1% cream | |
| tretinoin microsphere 0.04%, 0.08% and 0.1% gel/gel with pump | |
| Veltin (clindamycin/tretinoin 1.2%-0.025% gel) | <p>There is documentation the individual meets BOTH of the following (1 and 2):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris 2. The individual has tried <u>clindamycin/tretinoin 1.2%-0.025% gel</u> AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction |
| Ziana (clindamycin/tretinoin 1.2%-0.025% gel) | <p>There is documentation the individual meets BOTH of the following (1 and 2):</p> <ol style="list-style-type: none"> 1. Treatment of Acne Vulgaris 2. The individual has tried <u>clindamycin/tretinoin 1.2%-0.025% gel</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction |

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Topical tretinoin products are considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Topical tretinoin products are considered not medically necessary for **ANY** other use, including the following (this list is not all inclusive):

Cosmetic Conditions. Under many benefit plans, services are not covered when they are performed solely for the purpose of altering appearance or self-esteem, or to treat psychological symptomatology or psychosocial complaints related to one's appearance.

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 Renova[®] and Refissa[®] are also topical tretinoin products; these products are not indicated for use in the treatment of acne vulgaris.¹

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.^{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. *Viol 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.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.