



Horizon BCBSNJ
Medical Necessity Guideline

Section	Drugs
Policy Number	
Effective Date	6/25/04
Review Date	2/25/05, 11/05, 4/13/06, 9/25/06, 10/19/07, 3/24/08, 9/26/08

Subject:

TRETINOIN PRODUCTS:

- BRAND NAMES**
- Avita (all topical)
 - Retin-A (all topical)
 - Retin-A Micro (all topical)
 - Tretin-X (all topical)
 - Ziana (all topical)
 - Atralin (all topical)

IMPORTANT NOTE:

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

FDA-APPROVED INDICATIONS

Atralin is indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of this product in the treatment of other disorders have not been established.

Avita is indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of this product in the treatment of other disorders have not been established.

Retin-A is indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of the long-term use of this product in the treatment of other disorders have not been established.

Retin-A Micro is indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of the long-term use of this product in the treatment of other disorders have not been established.

Tretin-X gel and cream are indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of the long-term use of this product in the treatment of other disorders have not been established.

Ziana is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

Accepted Compendial Uses:

- Treatment of Keratosis Follicularis (Darier's/Darier-White disease)
- Treatment of Verruca Plana
- Treatment of Verrucae Plantaris
- Treatment of actinic keratosis

Medical Necessity Guideline:

1. The following questionnaire may be used to determine medical necessity of Tretinoin products: Retin-A and Avita prescriptions.

CRITERIA FOR APPROPRIATENESS		
INITIAL REVIEW		
1. Does the patient have diagnosis of acne vulgaris?	Yes	No
2. Is the medication being prescribed Ziana?	Yes	No
3. Does the patient have one of the following off-label diagnoses? - keratosis follicularis (i.e., Darier's/Darier-White disease) - verruca plana - verruca plantaris - actinic keratosis	Yes	No

Guidelines for Approval			
Duration of Approval		12 months	
Set 1		Set 2	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	3	1
			2

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

<u>BLACK BOX WARNINGS</u> None
--

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements established by Horizon BCBS New Jersey's medical policies.

Horizon BCBSNJ has chosen to consider coverage of these tretinoin, except for Ziana, for the following off-label uses:

- keratosis follicularis (Darier-White disease)
- verruca plana
- verruca plantaris
- actinic keratoses

Ziana will only be covered for acne since there are no studies for these off-label uses in Ziana.

ADDITIONAL INFORMATION

Acne:

Tretinoin should be applied once a day, before retiring, to the skin where acne lesions appear, using enough to cover the entire affected area lightly. The liquid may be applied with the fingertip, gauze pad, or cotton swab. If gauze or cotton swab is employed, care should be taken not to over saturate it to the extent that the liquid would run onto areas not intended for treatment. Excessive application of the gel product results in "pilling" of the gel, which minimized the likelihood of over application by the patient.

Application may cause a transitory feeling of warmth or slight stinging. In cases where it has been necessary to temporarily discontinue therapy or reduce the frequency of application, therapy may be resumed or frequency of application increased when the patient is able to tolerate the treatment.

Alterations of vehicle of the drug, drug concentration, or dose frequency should be closely monitored by careful observation of the clinical therapeutic response and skin tolerance.

During the early weeks of therapy, an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on deep, previously unseen lesions, and should not be considered a reason to discontinue therapy.

Therapeutic results should be noticed after two to three weeks, but more than six weeks of therapy may be required before beneficial effects are seen.

Once the acne lesions have responded satisfactorily, it may be possible to maintain the improvement with less frequent applications, or other dosage forms.

Patients treated with tretinoin may use cosmetics, but the area to be treated should be cleaned thoroughly before the medication is applied.

CONTRAINDICATIONS/WARNINGS/PRECAUTIONS

If a reaction suggesting sensitivity occurs, use of the medication should be discontinued.

Exposure to sunlight, including sunlamps, should be minimized.

Patients with sunburn should be advised not to use the product until fully recovered.

Patients who are required to have considerable sun exposure should exercise caution. Use of a sunscreen product and protective clothing over the treated areas is recommended.

Weather extremes, such as wind or cold, also may be irritating to patients under treatment with tretinoin.

Tretinoin products should be kept away from the eyes, mouth, angles of the nose, and mucous membranes.

If irritation warrants, patients should be directed to use the medication less frequently.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with utmost caution in patients with this condition.

GEL formulations are flammable.

REFERENCES

1. Tretinoin Cream and Gel product information. Spear Pharmaceuticals, Inc. 2002.
2. Retin-A Cream, Gel, and Liquid product information. Ortho Pharmaceutical Corporation, Dermatological Division. February 2001.
3. Retin-A Micro product information. Ortho Dermatological, division of Ortho-McNeil Pharmaceuticals, Inc. May 2002.
4. Renova product information. Ortho Pharmaceutical Corporation, Dermatological Division. February 1998.
5. Avita Cream product information. Bertek Pharmaceuticals. January 2002.
6. Bershad, S. The modern age of acne therapy: A review of current treatment options. The Mount Sinai Journal of Medicine. 2001; 68(4-5): 279-286.
7. Russell, JJ. Topical therapy for acne. American Family Physician. 2000; 61(2): 357-366.
8. Brown, SK, Shalita, AR. Acne vulgaris. The Lancet. 1998; 351:1871-1876.
9. Drake, LA, Ceilley, RI, Cornelison, RL, et al. Guidelines of care for acne vulgaris. American Academy of Dermatology. J AM Acad Dermatol. 1990; 22:673-680.
10. Dinehart, SM. Ther treatment of actinic keratoses. J Am Acad Dermatol. 2000;42:S25-S28.
11. USPDI. MICROMEDEX, Thomson Healthcare. Greenwood Village, CO. 2003.
12. Ziana Product Information. Medicis Pharmaceutical Coporation. November 2006.
13. Atralin Product Information. Coria Laboratories, Ltd. July 2007.
14. Avita Gel Product Information. Bertek Pharmaceuticals, Inc. revised November 2001.
15. Tretin-X Product Information. Triax Pharmaceuticals, LLC. August 2005.
16. AHFS Drug Information. 2007.
17. Mason C, Oftedahl G, Neely C, et al. Health Care Guideline: Acne Management. Institute for Clinical Systems Improvement. Second Edition; September 2003.
18. American Academy of Dermatology. Guidelines of Care for Acne Vulgaris. www.aad.org. Accessed 10/22/2004.
19. American Academy of Dermatology. <http://www.aad.org>. Accessed December, 2004.
20. American Osteopathic College of Dermatology. <http://www.aacd.org>. Accessed December, 2004.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

This Horizon BCBSNJ Pharmacy Guideline is proprietary. It is to be used only as authorized by Horizon BCBSNJ and its affiliates. The contents of this Pharmacy Guideline are not to be copied, reproduced or circulated to other parties without the express written consent of Horizon BCBSNJ. The contents of this Pharmacy Guideline may be updated or changed without notice, unless otherwise required by law and/or regulation. However, benefit determinations are made in the context of Pharmacy Guidelines existing at the time of the decision and are not subject to later revision as the result of a change in Pharmacy Guideline.