

Prior Authorization DRUG Guidelines

RETIN-A®; RETIN-A® MICRO Tretinoin

Effective Date: 7/28/05

Date Developed: 7/28/05 by C. Wilhelmy MD Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

Archived 1/22/19

Tretinoin makes the keratinocytes in the sebaceous follicle become less adherent which allows for easy removal, inhibits microcomedone formation, and eliminates lesions already present.

Pre-Authorization Criteria:

Retin-A, Retin-A Micro, and tretinoin are subject to Prior Authorization for members greater than 35 years of age.

Below are the criteria used to determine if a member is eligible for these medications.

• A documented diagnosis of acne vulgaris

OR

A documented diagnosis of actinic keratoses

AND

Lesions are on the face

OR

• Lesions are not on the face and therapy includes the use of 5-fluorouracil in conjunction with tretinoin

OR

 A documented diagnosis of hypertrophic scars or keloids AND intralesional injection of corticosteroids is ineffective or not tolerated

OR

• A documented diagnosis ofkeratosis follicularis (Darier's disease, Darier-White disease)

OR

• A documented diagnosis of facial flat warts

OR

• A documented diagnosis of multiple flat warts

Note: Topical tretinoin is not covered for treatment of basal cell carcinoma, lichen planus, or dysplastic nevi because its use in these conditions is not supported by the peer reviewed medical literature.

WARNINGS *I* PRECAUTIONS-Use with caution in patients with eczema; avoid excessive exposure to sunlight and sunlamps; avoid contact with abraded skin, mucous membranes, eyes, mouth, angles of the nose. Palliation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin: Do not use the 0.05% cream for longer than 48 weeks or the 0.02% cream for longer than 52 weeks. Not for use on moderate- to heavily-pigmented skin. Gel is flammable; do not expose to high temperatures or flame.

PREGNANCY RISK FACTOR-C

PREGNANCY IMPLICATIONS-Oral tretinoin is teratogenic and fetotoxic in rats at doses 1000 and 500 times the topical human dose, respectively. Tretinoin does not appear to be teratogenic when used topically since it is rapidly metabolized by the skin; however, there are rare reports of fetal defects. Use for acne only ifbenefit to mother outweighs potential risk to fetus. During pregnancy, do not use for palliation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin.

LACTATION-Enters breast milk/compatible

PATIENT EDUCATION-For once-daily use, do not overuse. Avoid increased intake of vitamin A. Thoroughly wash hands before applying. Wash area to be treated at least 30 minutes before applying. Do not wash face more frequently than 2-3 times a day. Avoid using topical preparations that contain alcohol or harsh chemicals during treatment. You may experience increased sensitivity to sunlight; protect skin with sunblock (minimum SPF 15), wear protective clothing, or avoid direct sunlight. Stop treatment and inform prescriber if rash, skin irritation, redness, scaling, or excessive dryness occurs. When used for hyperpigmentation and tactile redness of facial skin, wrinkles will not be eliminated. Must be used in combination with a comprehensive skin care program.

REFERENCES

- 1. Winston, MH, Shalita, AR. Acne Vulgaris, Pathogenesis and Treatment. Pediatr Clin North Am 1991; 38:889.
- 2. Olin BR, editor. Drugs Facts and Comparisons (electronic online version). St. Louis: J.B. Lippincott Company, 2004.
- 3. USPDI Drug Information for the HealthCare Professional (online through Stat!Ref). Thomson MICROMEDEX, Greenwood Village, Colorado; 2004.
- 4. McEvoy GK, editor. AHFS Drug Information (online through Stat!Ref). American Society ofHealth-Systems Pharmacists, Bethesda, Maryland; 2004.
- 5. Retin-A Micro Package Insert. Ortho Dermatological, Skillman, NJ, May 2002

- 6. Leyden JJ, Berger RS, Dunlap FE, et al. Comparison of the efficacy and safety of a combination topical gel formulation ofbenzoyl peroxide and clindamycin with benzoyl peroxide, clindamycin and vehicle gel in the treatments of acne vulgaris. Am J Clin Dermatol 2001;2:33-9
- 7. Lesher JL, Jr. et al. An evaluation of a 2% erythromycin ointment in the topical therapyofacnevulgaris. J AmAcadDermatol1985; 12(3): 526-531
- 8. Shrager D, Webster G. Azelaic acid 20% cream combined with benzoyl peroxide 4% gel compared to Benzamycin gel in the treatment of acne vulgaris. Poster presented at the 57th Annual Meeting of the American Academy of Dermatology, March 19-24, 1999. New Orleans, LA
- 9. Leyden JJ, Tanghetti EA, Miller B, et al. Once-daily tazarotene 0.1% gel versus once daily tretinoin 0.1% microsponge gel for the treatment of facial acne vulgaris: a double blind randomized trial. Cutis 2002;69(S2):12-9

10. Thiboutot D. Acne: 1991-2001.1Am Acad Dermatol. 2002;47:109-17

Select Drug Information from <u>Lexi-Comp OnlineTM</u> Copyright (1978 to present) Lexi-Comp, Inc.

©2013 UpToDate® • www.uptodate.com

Epocrates 2013 – www.epocrates.com

Revision History:

Date Reviewed/Updated: 10/17/11 by A. Reeves MD

Date Reviewed/No Updates: 4/2/12; 1/16/13 by A. Reeves MD

Date Approved by P&T Committee: 7/28/05; 10/25/11; 4/24/12; 1/29/13

Date Reviewed/No Updates: 1/28/14 by C. Sanders MD

Date Approved by P&T Committee: 1/28/14

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review