Clinical Policy: Age Limit for Topical Tretinoin

Reference Number: PA.CP.PMN.191
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

Description
This policy applies to topical tretinoin agents with health plan-approved age limits. Examples of such agent include: tretinoin cream and gel (e.g., Retin-A®, Retin-A Micro®).

FDA Approved Indication(s)
Topical tretinoin is indicated for the treatment of acne vulgaris.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that topical tretinoin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all)**:**

1. Member's age exceeds the health plan-approved age limit;
2. Diagnosis of acne vulgaris;
3. Requested dose does not exceed health plan-approved quantity limit.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acne Vulgaris (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Requested dose does not exceed health plan-approved quantity limit.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Retin-A cream/gel is contraindicated in patients with hypersensitivity to any of the ingredients.
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	Apply a thin layer to the affected area(s) QHS	Once daily

VI. Product Availability

- Cream (20 g, 45 g tubes): 0.025%, 0.05%, 0.1%
- Gel (20 g, 45 g tubes): 0.025%, 0.05%, 0.1%
- Microsphere gel (20 g tube, 45 g tube, 50 g bottle with pump): 0.04%, 0.08%, 0.1%

VII. References

1. Retin-A Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLCl June 2002. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/16921s21s22s25lbl.pdf. Accessed December 14, 2018.
2. Retin-A Micro Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2014. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020475s021lbl.pdf. Accessed December 14, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed December 14, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	

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