

Pharmacy Policy Bulletin: J-0191 Topical Tretinoin Therapy – Commercial and Healthcare Reform	
Number: J-0191	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial (1.): 1. Retin A = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-0191-014	Original Date: 05/14/2014
Effective Date: 07/18/2025	Review Date: 06/25/2025

Drugs Product(s):	• Altreno (tretinoin) lotion • Atralin (tretinoin) gel • Avita (tretinoin) cream and gel • Retin-A (tretinoin) cream and gel • Retin-A Micro (tretinoin) gel • Retin-A Micro Pump (tretinoin) gel
FDA-Approved Indication(s):	• Acne vulgaris

Background:	• Topical retinoid therapies (for example tretinoin) are vitamin A derivatives which can be indicated for the treatment of acne vulgaris. Certain formulations of tretinoin, such as Renova 0.02% cream or Refissa (tretinoin/emollient) 0.05% cream are indicated for fine wrinkles on face, hyperpigmentation of skin, and roughness of skin. • Retinoids can play a role in bone growth, cell proliferation and differentiation. They are intracrine and paracrine mediators of cell differentiation and proliferation. Tretinoins regulate the formation of isomers based on cellular action. Tretinoin appears to prevent horny cell cohesion and to increase epidermal cell turnover and mitotic activity. Subsequently, in patients with acne, expulsion of existing comedones occurs, and formation of new comedones is prevented through sloughing and expulsion of horny cells from the follicle. • Prescribing Considerations: ○ Topical tretinoin is minimally absorbed; however, cases of malformation have been reported in animal and human studies and risk cannot be completely eliminated. Therefore, topical tretinoin should not be used during pregnancy.
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Approval Criteria

I. Approval Criteria

When a benefit, coverage of topical tretinoin therapies may be approved when the following criterion is met **(A.)**:

A. The member has a diagnosis of acne vulgaris (ICD-10: L70.0).

- II.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I.** Use of retinoid therapies in the following conditions **(A. through D.)** is considered cosmetic and will not be approved:
- A.** Facial Wrinkles
 - B.** Facial Mottled hyperpigmentation (liver spots)
 - C.** Hypopigmentation associated with photoaging
 - D.** Facial skin roughness
- II.** If there is an age indicator, the group will only cover tretinoin up to that age. A request for a patient older than the group indicated age will not be covered (see Policy J-0026 – Coverage Outside Contract Parameters).
- III.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- IV.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. DRUGDEX System. New York: Thomson Reuters; 2025.
2. Atralin [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2024.
3. Altreno [package insert]. Bridgewater, NJ: Bausch Health Americas, Inc.; March 2020.
4. Avita [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; July 2018.
5. Retin-A [package insert]. Bridgewater, NJ: Bausch Health Americas, Inc.; May 2024.
6. Retin-A Micro [package insert]. Bridgewater, NJ: Bausch Health Americas, Inc.; April 2025.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.