

Clinical Policy: Topical Tretinoin in Adult Acne Vulgaris

Reference Number: GA.PMN.09

Effective Date: 3/16

Last Review Date: 4/2021

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Tretinoin is a topical acne medication that induces differentiation and decreases proliferation of APL cells.

FDA Approved Indication(s)

Topical tretinoin is indicated for:

- Acne vulgaris
- Fine facial wrinkles
- Mottled facial hyperpigmentation
- Tactile facial roughness

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that topical tretinoin is **medically necessary** only for adult acne vulgaris when the following criteria are met:

I. Initial Approval Criteria

*** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria ***

A. Acne Vulgaris (must meet all):

1. Prescribed by a MD/DO, PA, or NP
2. Member is between the ages of 22 and 40
3. Member has one of the following indications:
 - a) Documented comedonal (noninflammatory) acne
 - b) Documented mild papulopustular and mixed (comedonal and papulopustular) acne when combination of a preferred drug list (PDL) topical Benzoyl Peroxide and a PDL topical antibiotic (clindamycin or erythromycin) has been tried and failed unless intolerant or contraindicated.
 - c) Documented moderate to severe papulopustular and mixed (comedonal and papulopustular) acne when used in combination with Doxycycline, Minocycline, Sarecycline, or Tetracycline plus PDL topical Benzoyl Peroxide unless intolerant/contraindicated (see Section IV: Dosage and Administration)
4. Request is for a PDL tretinoin product

Approval duration: 3 months

II. Continued Therapy

A. Acne Vulgaris (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has shown a positive response to therapy
3. If member is on a regimen with antibiotic (oral or topical) therapy, Benzoyl Peroxide is included
4. Member does not have any contraindications to Tretinoin therapy

Approval duration: 6 months

III.: General Information

Acne vulgaris is the most skin condition that is inflammatory and chronic in nature usually containing comedones (blackheads and whiteheads) and inflammatory lesions (papules, pustules, nodules). Although acne is not physically disabling, it has a psychological impact that can be devastating, leading to low self-esteem, depression, and anxiety. Therefore there is a great demand for effective acne therapies. Medical therapies for acne target one or more of four key factors that promote the development of acne lesions: follicular hyperproliferation and abnormal desquamation, increased sebum production, Propionibacterium acnes proliferation, and inflammation. Topical retinoids are beneficial for both comedonal (noninflammatory) and inflammatory acne making them recommended as initial therapy for most patients. When inflammation is involved antimicrobial therapies (eg, benzoyl peroxide or topical antibiotics) is beneficial. Topical and oral antibiotics are more effective when given in combination with topical retinoids. Moderate to severe inflammatory acne often warrant more aggressive treatment with oral antibiotics. The use of benzoyl peroxide with topical or oral antibiotics decreases the emergence of antibiotic resistant bacteria. Therefore, use of benzoyl peroxide is recommended in patients receiving antibiotic therapy.

IV. Dosage and Administration

Drug Name	Recommended Dosing Regimen	Notes
Doxycycline	<ul style="list-style-type: none"> • 100mg/day or modified doxycycline 40mg/day 	
Minocycline Minocycline (Solodyne®) Minocycline (Minolira®)	<ul style="list-style-type: none"> • 50 or 100mg twice daily or extended-release 1mg/kg/d up to 135mg/d 	<ul style="list-style-type: none"> •
Sarecycline (Seysara®)	33-54 kg: 60mg once daily 55-84 kg: 100mg once daily	

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Drug Name	Recommended Dosing Regimen	Notes
	85-136 kg: 150mg once daily	
Tetracycline	250-500mg twice daily	

V. Product Availability

Various creams, ointments, gels

VI. References

1. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15.
2. Graber E. Treatment of Acne Vulgaris. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on August 29, 2016.)
3. Titus S, Hodge J. Diagnosis and Treatment of Acne. Am Fam Physician. 2012;86(8):734-740
4. Graber E. Treatment of Acne Vulgaris. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on August 29, 2016.)
5. Graber E. Treatment of Acne Vulgaris. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 22, 2019.)

Reviews, Revisions, and Approvals	Date	Approval Date
New policy created	03/16	03/16
Updated tretinoin wording to say “topical tretinoin” including policy name. Updated criteria #2 to say ‘topical Benzoyl Peroxide’.	12/17	
Changed treatment for moderate to severe papulopustular and mixed acne to requiring trial and failure of combination benzoyl peroxide and topical antibiotic (erythromycin or clindamycin). Changed treatment of moderate to severe acne to requiring topical tretinoin to be combined with an oral antibiotic (doxycycline or tetracycline at specified doses) and topical benzoyl peroxide	4/18	
Annual review. No changes made.	12/18	
Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/19	
Annual review. Updated treatment recommendation to add minocycline as option for moderate to severe acne and references. Updated fonts	3/19	4/19
Annual review. No changes	4/2020	4/2020

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Reviews, Revisions, and Approvals	Date	Approval Date
Annual review. Added sarecycline as a treatment option. Added a Dosage and Administration table. Changed Centene logo to PSHP logo	4/2021	4/2021

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should

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consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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