Clinical Policy: Minocycline (Solodyn)
Reference Number: CP.PMN.##
Effective Date: XX/XX
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Minocycline (Solodyn®) is a tetracycline-class drug.

FDA approved indication
Solodyn is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitation of use: Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Solodyn should be used only as indicated.~~.~~

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

It is the policy of health plans affiliated with Centene Corporation® that Solodyn is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of acne vulgaris with inflammatory lesions;
2. Failure of two PDL topical antibiotics for acne, each trialed for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of ~~≥~~ ≥4 week trial of one PDL topical tretinoin unless contraindicated or clinically significant adverse effects are experienced *(Note: prior authorization may be required)*~~;~~;
4. ~~Failure of~~ Member experienced clinically significant adverse effects to immediate-release minocycline or has contraindication(s) to the excipients in immediate-release minocycline~~two PDL oral tetracycline antibiotics, each trialed for ≥ 46 weeks, unless clinically significant adverse effects are experienced~~;
5. ~~4.~~Failure of ≥ 4 week trial of one additional PDL oral tetracycline antibiotic, unless clinically significant adverse effects are experienced;
6. ~~5.~~No documentation of hypersensitivity to tetracyclines.

Approval duration: 12 weeks

B. Other diagnoses/indications

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1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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. Documentation of positive response to therapy;
3. Member has not received Solodyn daily for ≥ 12 weeks of therapy.

Approval duration: up to 12 weeks of total treatment

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 weeks

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 – CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	The recommended dosage is approximately 1 mg/kg once daily for 12 weeks.	Based on weight

VI. Product Availability

Extended-release tablets: 45†, 55, 65, 80, 90†, 105, 115, and 135† mg
†available as generic only

VII. Workflow Document


CP.PMN.XX
minocycline (Solodyn

Field Code Changed

VIII. References

1. Solodyn Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016. Available at: www.solodyn.com. Accessed January 11, 2017.
2. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74; 74(5):945-973.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PMN.51 Tetracycline Antibiotics (Solodyn, Doryx, Oracea) ~~Clinical changes made to criteria:~~ -Modified criteria related to trial and failure of PDL oral antibiotics to specifically require tetracycline class of antibiotics, one of which must be immediate-release minocycline, as they are considered first-line for systemic antibiotic therapy for acne for ≥ 4 weeks ~~Non-clinical changes to criteria:~~ -Converted to new template -Added no documentation of hypersensitivity to tetracyclines per PI -Added duration of trial to requirements related to trial and failure of topical therapies for clarity -Removed age requirement since tetracycline antibiotics on the PDL are not subjected to age restrictions -Updated references	03~~1~~/17	05/17

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

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.