Clinical Policy: Sarecycline (Seysara)

Reference Number: CP.PMN.189
Effective Date: 03.01.19
Last Review Date: 02.21
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Sarecycline (Seysara™) is a tetracycline-class drug.

FDA Approved Indication(s)

Seysara is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitation(s) of use:

- Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. Seysara 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, Seysara should be used only as indicated.

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 Centene Corporation® that Seysara is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of acne vulgaris;
2. Age ≥ 9 years;
3. Failure of two preferred oral tetracycline antibiotics (e.g., immediate-release minocycline, doxycycline), each used for 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 weeks

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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 weeks (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): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and 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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and 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
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxycycline (Vibramycin®)	Adults, adolescents, and children ≥ 8 years old weighing ≥ 45 kg: 100 mg PO every 12 hours on day 1, then 100 mg PO QD Children ≥ 8 years old and adolescents weighing < 45 kg: 2.2 mg/kg/dose PO every 12 hours on day 1, then 2.2 mg/kg/dose PO QD	Varies
doxycycline, extended-release (Doryx®)	Adults, adolescents, and children ≥ 8 years old weighing ≥ 45 kg: 120 mg PO every 12 hours on day 1, then 120 mg PO daily Children ≥ 8 years old and adolescents weighing < 45 kg: 5.3 mg/kg PO in 2 divided doses on day 1, followed by 2.6 mg/kg PO once daily	Varies
minocycline (Minocin®)	Adults: 200 mg PO initially, then 100 mg PO every 12 hours as adjunctive therapy. Alternatively, if	200 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	more frequent oral doses are preferred, 100 to 200 mg PO initially, then 50 mg PO every 6 hours Children ≥ 8 years and adolescents: 4 mg/kg PO (max: 200 mg) initially, then 2 mg/kg/dose PO every 12 hours (max: 100 mg/dose) as adjunctive therapy	
tetracycline	Adults: 1 g/day PO in divided doses, then decrease slowly to 125 to 500 mg PO daily or every other day Children ≥ 9 years and adolescents: 1 g/day PO in divided doses, then decrease slowly to 125 to 500 mg PO QD or QOD	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to any of the tetracyclines
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	Weight-based dosing according to the following: • 33-54 kg: 60 mg • 55-84 kg: 100 mg • 85-136 kg: 150 mg Each dose is taken PO QD without regard to food intake.	150 mg/day

VI. Product Availability

Tablets: 60 mg, 100 mg, 150 mg

VII. References

1. Seysara Prescribing Information. Madison, NJ: Allergan, Inc. June 2020. Available at: www.seysara.com. Accessed November 3, 2020.
2. Sarecycline Drug Monograph. Clinical Pharmacology. Accessed October 2020. http://www.clinicalpharmacology-ip.com.
3. Zaenglein AL, Pathy AL, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74:945-73.
4. Moore A, et al. Once-daily oral sarecycline 1.5 mg/kg/day is effective for moderate to severe acne vulgaris: results from two identically designed, Phase 3, randomized, double-blind clinical trials. J Drugs Dermatol. 2018;17(9):987-96.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.13.18	02.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
No significant changes; removed TBD HIM from included lines of business.	04.23.19	
1Q 2020 annual review: no significant changes; references reviewed and updated; added HIM line of business.	10.31.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.03.20	02.21

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.