Clinical Policy: Sarecycline (Seysara)

Reference Number: ERX.NPA.109
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 weeks

B. Other diagnoses/indications
1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 weeks (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 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 QD	Varies
minocycline (Minocin®)	Adults: 200 mg PO initially, then 100 mg PO every 12 hours as adjunctive therapy. Alternatively, if 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	200 mg/day
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	150 mg/day

Indication	Dosing Regimen	Maximum Dose
	• 85-136 kg: 150 mg Each dose is taken PO QD without regard to food intake.	

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 19, 2021.
2. Zaenglein AL, Pathy AL, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74:945-73.
3. 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
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.31.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.03.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.19.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.