Clinical Policy Title:	sarecycline
Policy Number:	RxA.280
Drug(s) Applied:	Seysara®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Seysara® is a tetracycline-class drug. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sarecycline (Seysara®)	Non-nodular moderate to severe 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 once daily without regard to food intake.	150 mg/day

Dosage Forms

- Tablets: 60 mg, 100 mg, 150 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	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 once daily 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 once daily	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 more frequent oral doses are	200 mg/day

	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 once 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 once daily or every other day	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

References

1. Seysara® Prescribing Information. Madison, NJ: Allergan, Inc. June 2020. Available at: www.seysara.com. Accessed February 24, 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.
4. Sarecycline Drug Monograph. Clinical Pharmacology. Available at: http://www.clinicalpharmacology-ip.com. Accessed February 24, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Background was updated to include limitation of use. 3. Dosing information was updated to clarify indication. 4. Continued therapy criteria II.A.1 was rephrased to	07/23/2020	09/14/2020

"Currently receiving medication that has been authorized by RxAdvance…". 5. Approval duration was updated for Initial and Continued therapy criteria to specify Commercial and Medicaid plans. 6. Therapeutic alternatives were updated to include registration of drugs. 7. Dosing frequency was updated to spell out in document. 8. References were updated.		
Policy was reviewed: 1. Last review date was updated. 2. Clinical policy verbiage added " The provision of provider samples does not guarantee…". 3. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 4. References were reviewed and updated.	02/24/2021	06/10/2021