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Next Review Due By: 01/2025
Policy Number: C15974-A

Seysara (sarecycline)

PRODUCTS AFFECTED

Seysara (sarecycline)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Non-nodular moderate to severe acne vulgaris

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS:

1. Documentation of inflammatory lesions of non-nodular moderate to severe acne
AND
2. Prescriber attests to counseling female members of childbearing age regarding the risk of

Drug and Biologic Coverage Criteria

fetal harm

AND

3. Prescriber attests that Seysara is medically necessary and not provided only for convenience
AND
4. Documented failure, serious side effects, or contraindications to TWO formulary topical acne product classes (benzoyl peroxide, topical retinoid, topical antibiotic). Trial and failure demonstrated by continuous use of 30 days without improvement or stabilization of symptoms.
AND
5. Documentation of failure, serious side effects, or contraindication to generic minocycline AND doxycycline. Trial and failure demonstrated by continuous use of 30 days of EACH without improvement or stabilization of symptoms.

CONTINUATION OF THERAPY:

A. NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS: N/A Maximum duration of therapy is 12 weeks, continuation of therapy past 12 weeks will not be approved.

DURATION OF APPROVAL:

Initial authorization: 12 weeks, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

9 years of age and older

QUANTITY:

Dosing based on weight:

33-54 kg: 60 mg once daily

55-84 kg: 100 mg once daily

85-136 kg: 150 mg once daily

Maximum Quantity Limits – 30 tabs per 30 days of any one strength

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Tetracyclines

FDA-APPROVED USES:

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

Limitations 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

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COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Acne vulgaris is a multifactorial inflammatory disease affecting the pilosebaceous follicles of the skin. Pathogenic factors include follicular hyper keratinization, microbial colonization with *Propionibacterium acnes*, sebum production, and complex inflammatory mechanisms involving the immune system.

Patients with acne can experience significant psychological morbidity (i.e. anxiety, embarrassment, depression) and scarring due to acne can be disfiguring and lifelong. Prompt and appropriate treatment of acne can mitigate the negative psychological and physical outcomes that can accompany acne.

Role of Oral Antibiotics in Treatment of Acne

Systemic antibiotics are recommended after failure of topical therapies, and tetracyclines are the preferred antibiotic class. Guidelines of care for the management of acne vulgaris published by the American Academy of Dermatology make the following recommendations regarding systemic antibiotics: Systemic antibiotics are recommended in the management of moderate and severe acne and forms of inflammatory acne that are resistant to topical treatments. Doxycycline and minocycline are more effective than tetracycline, but neither is superior to each other. Although oral erythromycin and azithromycin can be effective in treating acne, its use should be limited to those who cannot use tetracyclines (i.e., pregnant women or children < 8 years of age). Erythromycin use should be restricted because of its increased risk of bacterial resistance. Systemic antibiotic use should be limited to the shortest possible duration, typically 3 months, to minimize the development of bacterial resistance. Monotherapy with systemic antibiotics is not recommended. Concomitant topical therapy with benzoyl peroxide or a retinoid should be used with systemic antibiotics and for maintenance after completion of systemic antibiotic therapy.

Seysara is a tetracycline-derived antibiotic with a narrow spectrum of activity targeting acne-specific pathogens with limited activity against gram-negative gastrointestinal organisms compared with other tetracyclines commonly used to treat acne.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Seysara (sarecycline) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Seysara (sarecycline) include: persons who have shown hypersensitivity to any of the tetracyclines.

OTHER SPECIAL CONSIDERATIONS:

Use of Seysara during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth. If *Clostridium difficile* Associated Diarrhea occurs, discontinue Seysara.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Seysara TABS 60MG
 Seysara TABS 100MG
 Seysara TABS 150MG

REFERENCES

1. Griffin M, Fricovsky E, Ceballos G, et al. Tetracyclines: a pleiotropic family of compounds with promising therapeutic properties. Review of the literature. Am J Physiol Cell Physiol. 2010;299(3):539-548.
2. Seysara (sarecycline) [prescribing information]. Malvern, PA: Almirall LLC; March 2023.
3. 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 Feb15.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Quantity References	Q1 2024
REVISION- Notable revisions: Required Medical Information Quantity Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file