

# Drug and Biologic Coverage Policy



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## Sarecycline

### Table of Contents

Overview.....	1
Initial Approval Criteria.....	1
Continuation of Therapy .....	2
Authorization Duration .....	2
Conditions Not Covered.....	2
Background.....	2
References .....	3

### Related Coverage Resources

#### **INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Overview

This policy supports medical necessity review for sarecycline (Seysara™).

Coverage for sarecycline (Seysara) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

### Initial Approval Criteria

Coverage criteria are listed for product in below table:

Non-Covered Product	Criteria
Seysara (sarecycline) tablet	<p><b>Sarecycline (Seysara) is considered medically necessary for the treatment of moderate to severe acne vulgaris when the individual meets BOTH of the following criteria:</b></p> <ol style="list-style-type: none"> <li>1. 9 years of age or older</li> <li>2. Documented failure, contraindication, or intolerance to <b>BOTH</b> of the following: <ol style="list-style-type: none"> <li>a. doxycycline capsule or tablet (monohydrate, hyclate or hyclate ER)</li> <li>b. minocycline capsule or tablet (immediate-release or extended-release)</li> </ol> </li> </ol>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Continuation of Therapy

Continuation of sarecycline (Seysara) is considered medically necessary for the treatment of moderate to severe acne vulgaris when initial criteria are met AND beneficial response is demonstrated.

## Authorization Duration

Initial and reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

### OVERVIEW

Seysara, a tetracycline, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.<sup>1</sup> Limitations of use. The efficacy of Seysara beyond 12 weeks and safety of Seysara beyond 12 months have not been established. The use of Seysara for the treatment of infections has not been evaluated.

### Guidelines

The American Academy of Dermatology (AAD) published guidelines for the management of acne in 2016.<sup>2</sup> Topical therapies, either as monotherapy or in combination with other topical agents or oral agents, are recommended for both initial control and maintenance of acne. Topical retinoids (tretinoin, adapalene, and tazarotene) are the cornerstone of acne management due to their comedolytic and anti-inflammatory properties. Topical benzoyl peroxide is also commonly used; the addition of benzoyl peroxide to antibiotic regimens enhance results and may reduce resistance development. Topical antibiotics (erythromycin and clindamycin) are effective but are not recommended for use as monotherapy due to risk of bacterial resistance.

Systemic antibiotics are recommended for the management of moderate and severe acne and for inflammatory acne resistant to topical treatments but like topical antibiotics, systemic antibiotics should not be used as monotherapy. Systemic antibiotics should be used in combination with a topical retinoid or topical benzoyl peroxide and should be used for the shortest possible duration; patients should be re-evaluated at 3 to 4 months. Of the systemic antibiotics, the tetracycline class of drugs is considered first-line, unless there are contraindications (e.g., pregnancy, patient age  $\leq$  8 years). Other systemic antibiotics that can be used are trimethoprim-sulfamethoxazole, trimethoprim, erythromycin, azithromycin, amoxicillin, and cephalexin. Oral contraceptives that contain an estrogen and a progestin are also effective for females with acne. Oral isotretinoin

is effective for most patients with severe acne, resulting in decreased sebum production, acne lesions, and acne scarring.

The Global Alliance to Improve Outcomes in Acne, an international group of dermatologists with an interest in acne research and education, published consensus guidelines in 2017.<sup>6</sup> The panel issued several consensus statements regarding the management of acne, and in general, the panel reiterated the recommendations issued by the AAD. Early and effective treatment is important to minimize the potential risk for acne scarring. Topical retinoids have an essential role in acne, and in general, the topical retinoids are similar in efficacy. Efficacy usually improves with higher concentrations but an increase in AEs must be considered. The panel also recommend the combination of topical retinoid and topical benzoyl peroxide as first-line for most patients with inflammatory acne, comedonal acne, or both. Neither topical nor systemic antibiotics should be used as monotherapy for acne treatment due to the risk of bacterial resistance. Furthermore, use of systemic antibiotics should be limited to 3 to 4 months. Oral contraceptives are also effective and are typically used in combination with topical agents (in females). Oral isotretinoin should be used first-line in patients with very severe (cystic and conglobate) acne. There are some data supporting the benefit of devices, such as laser intense pulsed light and photodynamic therapy, in the treatment of acne, but there are no well-designed studies comparing their effectiveness versus standard medical therapies.

## References

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7. Dréno B, Pécastaings S, Corvec S, et al. Cutibacterium acnes (Propionibacterium acnes) and acne vulgaris: a brief look at the latest updates. *J Eur Acad Dermatol Venereol*. 2018;32 Suppl 2:S5-S14.
8. Williams HC, Dellavalle RP, Garner S. Acne vulgaris. *Lancet*. 2012;379:361-72.
9. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2018. Available at: <http://fco.factsandcomparisons.com/lco/action/home>. Accessed on October 11, 2018. Search terms: doxycycline and minocycline.

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