BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

SEYSARA™ (sarecycline) oral tablet
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Seysara (sarecycline) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual is 9 years of age or older
3. Individual has a confirmed diagnosis of inflammatory lesions of non-nodular moderate to severe acne vulgaris

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4. Individual has a documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ALL** the following:
    a. Topical retinoid + benzoyl peroxide + topical antibiotic
    b. Generic doxycycline + benzoyl peroxide + topical retinoid
    c. Generic minocycline immediate release + benzoyl peroxide + topical retinoid
    d. Generic tetracycline + benzoyl peroxide + topical retinoid

5. Individual does **NOT** have the FDA-label contraindication of hypersensitivity to any of the tetracycline antimicrobials

6. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Intended use is for acne vulgaris only, treatment of other types of infections will not be approved

8. There are no significant interacting drugs such as concurrent use with oral isotretinoin and concurrent use with penicillin

9. Individual does not have end stage renal disease

10. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Initial approval duration: 12 weeks or (3 months)

- **Criteria for continuation of coverage (renewal request):** Seysara (sarecycline) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual's condition has responded while on therapy with response defined as **BOTH** of the following:
    a. Achieved and maintains at least a 20% decrease in number of inflammatory lesions from baseline
    b. Provider's assessment of success is an IGA of clear (0) or almost clear (1) and a decrease of 2-points from baseline IGA score

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:

i. *Clostridioides (*formerly *Clostridium) difficile* associate diarrhea and pseudomembranous colitis
ii. Photosensitivity reactions, skin erythema or other serious skin reactions
iii. Intracranial hypertension
iv. Papilledema

6. Intended use is for acne vulgaris only, treatment of other types of infections will not be approved

7. There are no significant interacting drugs such as concurrent use with oral isotretinoin and concurrent use with penicillin

8. Individual does not have end stage renal disease

9. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Renewal duration: 3 months at a time with a total of 12 months of lifetime use (initial + continuation)

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Seysara (sarecycline) is a tetracycline-class drug indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age or older. Efficacy beyond 12 weeks and safety beyond 12 months have not been established. Sarecycline has not been evaluated in the treatment of infections other than acne vulgaris. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, it should be used only as indicated.

Acne vulgaris is a chronic inflammatory dermatologic condition notable for open and/or closed comedones (blackheads – dark or blackish bumps; and whiteheads – tiny white bumps) and inflammatory lesions including papules (small, firm, that may be painful pink bumps), pustules (small, may be painful bumps with pus), or nodules/cysts (large, hard, inflamed, and painful bumps). Acne pimples occur on the face, neck, chest, shoulders, back, and upper arms that result from clogged pores due to excessive sebum (oil) production.

Rating disease severity is useful for the initial evaluation and management of acne, to aid in the selection of appropriate therapeutic agents, and to evaluate response to treatment. Several systems for grading acne exist; most employ lesion counting combined with some type of global assessment of severity (assessing the condition as mild, moderate, or severe) that represents a synthesis of the number, size, and extent of lesions. However, there is no consensus on a single or best grading or classification system.

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Mild acne consists of non-inflammatory lesions (comedones) and few inflammatory (papulopustular) lesions. Moderate acne will have more inflammatory lesions and occasional nodules; there may be mild scarring. With severe acne there may be widespread inflammatory lesions, nodules, or both, and scarring.

The prevalent bacterium implicated in the clinical course of acne is *Cutibacterium* (formerly *Propionibacterium*) *acnes* (*C acnes*), a gram-positive anaerobe that is normally found on the skin and is implicated in the inflammatory phase of acne. *C acnes* promotes lesions by secreting chemotactic factors that attract leukocytes to the follicle resulting in inflammation.

Systemic antibiotics are a standard of care in moderate and severe acne and treatment-resistant forms of inflammatory acne. Oral tetracycline antibiotics, such as minocycline and doxycycline, are routinely used for the management of inflammatory acne. The mechanism of action of the tetracycline class of antibiotics is thought to be due to inhibition of protein synthesis, resulting in a bacteriostatic action against susceptible micro-organisms. All the tetracyclines have a similar antimicrobial spectrum of activity and safety profiles and are used for the treatment of a wide range of gram-positive and gram-negative microorganisms.

Many years of clinical experience, multiple systematic reviews, and clinical practice guidelines have shown that all anti-acne agents are effective in treating acne lesions when compared to placebo. There is no evidence that confirms superiority of any one branded option over available brand or generic alternatives, including available over the counter (OTC) products. All anti-acne products have adequate records of safety, and most are generally well tolerated.

The American Academy of Dermatology has published guidelines for the care of acne vulgaris. The guidelines indicate that topical therapy is a standard of care in treatment and that topical retinoids and topical antibiotics are effective treatments. The effectiveness of topical retinoids in the treatment of acne is well documented. These agents act to reduce obstruction within the follicle and are useful in the management of both comedonal and inflammatory acne. The value of topical antibiotics in the treatment of acne has been investigated in many clinical trials. Topical erythromycin and clindamycin have been demonstrated to be effective and well tolerated. A combination of topical retinoids and topical erythromycin or clindamycin is more effective than either agent used alone. Systemic antibiotics are a standard of care in moderate and severe acne and treatment-resistant forms of inflammatory acne. Doxycycline and minocycline are more effective than tetracycline. There is no evidence that an extended-release formulation is more effective and better tolerated than immediate release formulation.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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Treatment of acne vulgaris (J Am Acad Dermatol 2016):

	Mild	Moderate	Severe
First-line treatment	BP or topical retinoid **– OR –** Topical combination therapy:* BP + antibiotic or BP + Retinoid or BP + Retinoid + antibiotic	Topical combination therapy:* BP + antibiotic or BP + Retinoid or BP + Retinoid + antibiotic **– OR –** Oral antibiotic **+** topical retinoid **+** BP **– OR –** Oral antibiotic **+** topical retinoid **+** BP **+** topical antibiotic	Oral antibiotic **+** Topical combination therapy:* BP + antibiotic or BP + Retinoid or BP + Retinoid + antibiotic **– OR –** Oral isotretinoin
Alternative treatment	Add topical retinoid or BP (if not on already) **– OR –** Consider alternate retinoid **– OR –** Consider topical dapsone	Consider alternate combination therapy **– OR –** Consider change in oral antibiotic **– OR –** Add combined oral contraceptive or oral spironolactone (females) **– OR –** Consider oral isotretinoin	Consider change in oral antibiotic **– OR –** Add combined oral contraceptive or oral spironolactone (females) **– OR –** Consider oral isotretinoin

BP: benzoyl peroxide.
* The drugs may be prescribed as a fixed combination product or as separate components.

Investigator Global Assessment Scale (IGA):
The IGA score uses morphologic descriptors that best describe the overall appearance of lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score – Grade	Morphological Description
0 – Clear	No evidence of papules or pustules
1 – Almost clear	Rare inflammatory papules (papules must be resolving, may be hyperpigmented, though not pink-red)
2 – Mild	Few inflammatory lesions (papules/pustules only; no nodulocytic lesions)
3 – Moderate	Multiple inflammatory lesions present; many papules/pustules; there may or may not be a few nodulocytic lesions
4 – Severe	Severe Inflammatory lesions are more apparent, many papules/pustules; there may or may not be a few nodulocytic lesions

Resources:

Seysara (sarecycline) product information, revised by Almirall, LLC. 03-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 26, 2024.

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ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT02320149: Study SC1401: A randomized, multicenter, double-blind, placebo-controlled study to evaluate safety & efficacy of 1.5 mg/kg per day of sarecycline compared to placebo in the treatment of acne. Protocol date December 16, 2015. Available from: http://clinicaltrials.gov. Last update posted February 15, 2019. Last verified January 2019. Accessed December 18, 2022. Re-evaluated January 02, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT02322866: Randomized, double-blind, placebo-controlled study to evaluate safety & efficacy of sarecycline in treatment of acne. Available from: http://clinicaltrials.gov. Last update posted February 01, 2019. Last verified January 2019. Accessed December 18, 2022. Re-evaluated January 02, 2025.