BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 02/21/19
LAST REVIEW DATE: 02/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

SEYSARA™ (sarecycline) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy 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 BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Seysara (sarecycline) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Dermatologist
  2. Individual is 9 years of age or older
  3. A confirmed diagnosis of inflammatory lesions of non-nodular moderate to severe acne vulgaris
  4. Individual has failed, or is intolerant to, or has a contraindication such that the individual is unable to use **ALL** the following preferred step therapy agents:
     - Topical retinoid + benzoyl peroxide + topical antibiotic
     - Generic minocycline immediate release or extended release
     - Generic doxycycline
     - Generic tetracycline
  5. There are **NO** contraindications
     - Contraindications include:
       - Hypersensitivity to any of the tetracycline antimicrobials or any component of the product
  6. Use is not for the treatment of other infections besides acne vulgaris

  Initial approval duration: 12 weeks or (3 months)

- **Criteria for continuation of coverage (renewal request):** Seysara (sarecycline) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in or is in consultation with a Dermatologist
  2. Individual's condition responded or has worsened while on therapy [this can be modified or changed depending on drug or condition]
     - Response is defined as:
       - Achieved and maintains at least a 30% decrease in number of inflammatory lesions from baseline
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - *Clostridioides (*formerly *Clostridium) difficile* associate diarrhea and pseudomembranous colitis

SEYSARA™ (sarecycline) oral tablet (cont.)

- Photosensitivity reactions, skin erythema or other serious skin reactions
- Intracranial hypertension
- Papilledema

5. There are no significant interacting drugs

6. Use is not for the treatment of other infections besides acne vulgaris

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

Description:

Seysara (sarecycline) is a tetracycline-class drug indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 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.

Mild acne consist 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.

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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:

Treatment of acne vulgaris:

	Mild	Moderate	Severe
First-line treatment	BP or topical retinoid **– OR –** Topical combination therapy*¶	Topical combination therapy*¶ **– OR –** Oral antibiotic **+** Topical retinoid **+** BP **– OR –** Oral antibiotic **+** Topical retinoid **+** BP **+** Topical antibiotic	Oral antibiotic **+** Topical combination therapy*¶ **– 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 drug may be prescribed as a fixed combination product or as separate component.
¶ Topical combination therapy = one of the following combination regimens:
A. BP + topical antibiotic
B. Topical retinoid + BP
C. Topical retinoid + BP + topical antibiotic

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Resources:

Seysara product information accessed 02-13-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b200957c-3004-4988-be97-9fd619a83649

UpToDate: Title: Treatment of acne vulgaris. Current through Month, year. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-acne-vulgaris?search=acne&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

Garner SE, Eady EA, Popescu C, Newton J, Li WA. Minocycline for acne vulgaris: efficacy and safety. Cochrane Database Syst Rev. 2003.

Jerry KL Tan. Current Measures for the Evaluation of Acne Severity: Methods for Grading Acne Severity. 2008.

National Guideline Clearinghouse. Guidelines of care for acne vulgaris management. 2008.

Simonart T, Dramaix M, De Maertelaer V. Efficacy of tetracyclines in the treatment of acne vulgaris: a review. Br J Dermatol. 2008; 158:208-16.

Strauss JS, Krowchuk DP, Leyden JJ, et al. Guidelines of care for acne vulgaris management. J Am Acad Dermatol. 2007; 56:651-63.

Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol 2016: 74:945.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.