BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**2/21/2019**
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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 the patient's diagnosis 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. Documented failure, contraindication per FDA label, intolerance to **ALL** the following:
     a. Topical retinoid + benzoyl peroxide + topical antibiotic
     b. Generic minocycline immediate release or extended release + benzoyl peroxide + topical retinoid
     c. Generic doxycycline + benzoyl peroxide + topical retinoid
     d. Generic tetracycline + benzoyl peroxide + topical retinoid
  5. There are **NO** FDA-label contraindications, such as:
     a. Hypersensitivity to any of the tetracycline antimicrobials
  6. Use is not for the treatment of other infections besides acne vulgaris
  7. There are no significant interacting drugs

  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 the patient's diagnosis or is in consultation with a Dermatologist
  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. 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 adverse drug effects that may exclude continued use
     a. Contraindications as listed in the criteria for initial therapy section

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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

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

6. There are no significant interacting drugs

Renewal duration: 3 months at a time with a total of 12 months of 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 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 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.

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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:

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 retinoid + BP or retinoid + BP + antibiotic	Topical combination therapy* BP + antibiotic or retinoid + BP or retinoid + BP + antibiotic **– OR –** Oral antibiotic **+** topical retinoid **+** BP **– OR –** Oral antibiotic **+** topical retinoid **+** BP **+** topical antibiotic	Oral antibiotic **+** Topical combination therapy* BP + antibiotic or retinoid + BP or retinoid + BP + antibiotic **– OR –** Oral isotretinoin

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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 component.

Resources:

Seysara (sarecycline) product information, revised by Almirall, LLC. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 14, 2021.

Graber E. Acne vulgaris: Overview and management. In: UpToDate, Dellavalle RP, Levy ML, Owen C, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated October 26, 2021. Accessed December 14, 2021.

Graber E. Acne vulgaris: Management of moderate to severe acne. In: UpToDate, Dellavalle RP, Moise ML, Owen C, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated February 17, 2021. Accessed December 14, 2021.