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

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/19/15**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE: 3/15/18
	ARCHIVE DATE:

ARESTIN® (minocycline hcl) subgingival powder

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.**

ARESTIN® (minocycline hcl) subgingival powder (cont.)

Description:

Arestin® (minocycline microspheres) is indicated as an adjunct to scaling and root planing (SRP) procedures for reduction of pocket depth in patients with adult periodontitis. It may be used as part of a periodontal maintenance program which includes good oral hygiene and SRP.

Arestin® (minocycline microspheres) is a subgingival sustained-release product containing the antibiotic minocycline hydrochloride incorporated into a bioresorbable polymer, Poly (glycolide-co-dl-lactide) or PGLA, for professional subgingival administration into periodontal pockets. Each unit-dose cartridge delivers minocycline hydrochloride equivalent to 1 mg of minocycline free base.

The mechanism of action of Arestin® (minocycline microspheres) as an adjunct to SRP procedures for reduction of pocket depth in patients with adult periodontitis is unknown. Minocycline is a member of the tetracycline class of antibiotics and has a broad spectrum of activity. It is bacteriostatic and exerts its antimicrobial activity by inhibiting protein synthesis. *In vitro* susceptibility testing has shown that the organisms *Porphyromonas gingivalis, Prevotella intermedia, Fusobacterium nucleatum, Eikenella corrodens, and Actinobacillus actinomycetemcomitans,* which are associated with periodontal disease, are susceptible to minocycline.

Qualitative and quantitative changes in plaque microorganisms have not been demonstrated in individuals with periodontitis, using this product. The emergence of minocycline-resistant bacteria in single-site plaque samples was studied in subjects before and after treatment with Arestin® (minocycline microspheres) at 2 centers. There was a slight increase in the numbers of minocycline-resistant bacteria at the end of the 9-month study period (package insert). Individuals treated with Arestin® (minocycline microspheres) were found to have statistically significant reduced probing pocket depth compared with those treated with SRP for reduction of pocket depth alone.

Periodontal disease refers to inflammatory conditions of gingivitis and periodontitis; both involve a variety of pathogenic bacterial organisms and host response to these bacteria. Gingivitis is the more common form of inflammatory periodontal disease. It is limited to inflammation that involves only the gingival soft tissues, gingival epithelium and subjacent fibrous connective tissues. Gingivitis is characterized by red, swollen tissues that bleed on brushing or probing. Edema and hyperplasia may be present that can result in a false pocket.

Inflammation that extends into deeper tissues to involve bone, with resultant resorption of the bone that supports the tooth, is known as periodontitis. Along with bone loss there is the formation of a deepened space between the root of the tooth and the gingiva giving rise to a periodontal pocket.

Periodontitis can present as a chronic and slowly progressive disease (the most common form) or as an aggressive disease. Severe periodontitis can result in tooth mobility, pain and discomfort, abscess formation, impaired ability to chew food, and eventual tooth loss.

Oral bacteria in and around the teeth and mouth inhabit the periodontal pocket; there are over 700 species of aerobic and anaerobic bacteria identified in the human oral cavity. The bacteria within the periodontal pocket can further periodontal disease through induction of inflammation and stimulation of the immune response in the host. It is the host inflammatory-immune response that ultimately leads to the clinical signs of gingivitis and chronic periodontitis leading to their characteristic features of fibrous connective tissue degradation, resorption of alveolar bone that supports the tooth, and periodontal pocket formation.

ARESTIN® (minocycline hcl) subgingival powder (cont.)

Treatment options for periodontitis includes individual education on proper oral hygiene; controlling any risk factors (such as smoking cessation, controlling diabetes mellitus, and others); removal of bacterial plaque, biofilm, and calculus by periodontal SRP; use of chemotherapeutic agents to reduce, eliminate, or change the quality of microbial pathogens; and surgery. SRP remain the gold standard for non-surgical management of periodontitis. The goal of periodontitis treatment is to thoroughly clean the pockets around teeth and prevent damage to surrounding bone. Treatment may be performed by a periodontist, a dentist or a dental hygienist.

Arestin (minocycline microspheres)

Medication class:
Antibiotic, Tetracycline Derivative

FDA-approved indication(s):
- An adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis. May be used as part of a periodontal maintenance program that includes good oral hygiene, scaling, and root planing

Recommended Dose:
- The dose depends on the size, shape, and number of pockets being treated
- One cartridge is used per pocket with $\geq$ 5 mm of pocket depth
- There are 6 periodontal pockets for each tooth

Maximum dosage
- Not stated

Available Dosage Forms:
- 1 mg microsphere cartridge, 12 cartridges per tray in a resealable foul pouch, 2 pouches per box

Warnings and Precautions:
- Arestin is not used for treatment of gingivitis that can be managed by oral hygiene alone
- Use of Arestin in an acutely abscessed periodontal pocket is not recommended
- The safety and effectiveness of Arestin has not been established for the treatment of periodontitis in an individual with coexistent oral candidiasis
- Arestin has not been clinically tested in immunocompromised individuals, such as those immunocompromised by Uncontrolled diabetes mellitus, Chemotherapy Radiation therapy Infection with HIV
- Arestin has not been clinically tested for use in the regeneration of alveolar bone, **EITHER** in preparation for **OR** in conjunction with the placement of endosseous (dental) implants **OR** in the treatment of failing implants
- Arestin should not be used during the last half of pregnancy, infancy, and childhood to the age of 8 years
- Tetracyclines should not be used in a pregnant or nursing woman
- Arestin should not be used in an individual who develops or has had an autoimmune reaction such as lupus-like syndrome
- Photosensitivity manifested as an exaggerated sunburn reaction may occur when the individual is exposed to direct sunlight or ultraviolet light

ARESTIN® (minocycline hcl) subgingival powder (cont.)

Criteria:

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

  1. Requesting provider is an oral health care professional
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of periodontitis
  4. Prescription requests specify **ALL** of the following:
     - Use will be for periodontal pocket depth of 5 mm or more
     - Number of pockets of 5 mm or more that require treatment
     - Only one cartridge will be used per pocket
  5. Individual has failure, contraindication or intolerance to **EITHER** Doxycycline or Metronidazole
  6. Will be used as an adjunct to scaling and root planing procedures for reduction of pocket depth
  7. Will be used as part of a periodontal maintenance program that includes good oral hygiene
  8. There are **NO** contraindications:
     - Contraindications include:
       - Known sensitivity to minocycline or tetracyclines

  Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request):** Arestin (minocycline microspheres) is considered ***medically necessary*** and will be approved with documentation of **ALL** of the following:

  1. Continues to be seen by an oral health care professional
  2. Meets all of the same initial criteria as above

  Renewal duration: 1 month

Resources:

Arestin (minocycline microspheres). Package Insert. Revised by manufacturer 05/2017. Accessed 02-09-2018.

Arestin (minocycline microspheres). Package Insert. Revised by manufacturer 06/2016. Accessed 02-14-2017.

Arestin (minocycline microspheres). Package Insert. Revised by manufacturer 07/2012. Accessed 02-25-2015.

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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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Pharmacy Prior Authorization Request Form

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.