



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/19/2015  
LAST REVIEW DATE: 2/17/2022  
LAST CRITERIA REVISION DATE: 2/17/2022  
ARCHIVE DATE:

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## ARESTIN® (minocycline hcl) subgingival powder

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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.

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**



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### 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. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an oral health care professional
2. Individual is 18 years of age or older
3. A confirmed diagnosis of periodontitis
4. Individual has failure, contraindication per FDA label or intolerance to **EITHER** doxycycline or metronidazole
5. Prescription request must specify **ALL** of the following:
  - a. Periodontal pocket depth are 5 mm or more
  - b. Number of pockets of 5 mm or more that require treatment
  - c. Only one cartridge will be used per pocket
6. Will not be used in an acutely abscessed periodontal pocket
7. Will not be used 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
8. Will be used as an adjunct to scaling and root planing procedures for reduction of pocket depth
9. Will be used as part of a periodontal maintenance program that includes good oral hygiene
10. There are **NO** FDA-label contraindications:
  - a. Contraindications include:
    - i. 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. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an oral health care professional
2. Meets all of the same initial criteria #2 through #10 as above

**Renewal duration:** 1 month



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- 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**
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### 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.



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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.

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.

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### **Resources:**

Arestin (minocycline microspheres) product information, revised by OraPharma, Inc. 06-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 13, 2021.

Wilder RS, Moretti AJ. Overview of gingivitis and periodontitis in adults. In: UpToDate, Deschler DG, Kinins L (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Topic last updated October 19, 2021. Accessed December 13, 2021.

Chow AW. Complications, diagnosis, and treatment of odontogenic infections. In: UpToDate, Durand ML, Bogorodskaya M (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Topic last updated August 28,2020. Accessed December 13, 2021.