STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets **ALL** of the following criteria?
   - The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
   - No history of minocycline or tetracycline sensitivity or allergy
   - No history of candidiasis or active oral candidiasis
   - Not being used for acutely abscessed periodontal pocket
   - Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
     - Uncontrolled diabetes mellitus
     - Chemotherapy
     - Radiation therapy
     - HIV infection
   - Not being 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
   - Age 18 years or older
   - Prescribed and administered by an oral health care professional

   If yes, **approve for 3 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MINOCYCLINE HCL MICROSPHERES (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

- The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
- No history of minocycline or tetracycline sensitivity or allergy
- No history of candidiasis or active oral candidiasis
- Not being used for acutely abscessed periodontal pocket
- Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
    - Uncontrolled diabetes mellitus
    - Chemotherapy
    - Radiation therapy
    - HIV infection
- Not being 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
- Age 18 years or older
- Prescribed and administered by an oral health care professional

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

    If yes, guideline does not apply.
    If no, continue to #2.

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MINOCYCLINE HCL MICROSPHERES (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets the following criteria?
   - The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   If yes, **approve for 6 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** renewal requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.
   - The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

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RATIONALE
Ensure appropriate use of ARESTIN consistent with its FDA approved indication, dosing, contraindications, and precautions. In clinical trials, an average of 29.5 (5-114), 31.7 (4-137), and 31 (5-108) sites were treated at baseline in the scaling and root planning (SRP) alone, SRP + vehicle, and SRP + ARESTIN groups, respectively.

FDA APPROVED INDICATIONS
ARESTIN is indicated as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis. ARESTIN may be used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing.

DOSAGE
ARESTIN is provided as a dry powder, packaged in a unit dose cartridge with a deformable tip, which is inserted into a spring-loaded cartridge handle mechanism to administer the product.

The oral health care professional removes the disposable cartridge from its pouch and connects the cartridge to the handle mechanism. ARESTIN is a variable dose product, dependent on the size, shape, and number of pockets being treated. In US clinical trials, up to 122 unit dose cartridges were used in a single visit and up to 3 treatments, at 3-month intervals, were administered in pockets with pocket depth of 5 mm or greater.

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MINOCYCLINE HCL MICROSPHERES (NSA)

REFERENCES

- Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma. August 2015.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A Created: 08/16
Commercial Effective: 08/01/18 Client Approval: 07/18 P&T Approval: 08/16

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