

Clinical Policy: Minocycline ER (Solodyn) and Microspheres (Arestin)

Reference Number: ERX.NPA.51

Effective Date: 01.11.17

Last Review Date: 11.17

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Minocycline ER [extended-release] (Solodyn[®]) and microspheres (Arestin[®]) are tetracycline derivative antibiotics.

FDA Approved Indication(s)

Solodyn is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitation(s) of use: Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Solodyn should be used only as indicated.

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.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Solodyn and Arestin are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Request is for Solodyn;
2. Diagnosis of acne vulgaris;
3. Member experienced clinically significant adverse effects to immediate-release minocycline or has contraindication(s) to the excipients in immediate-release minocycline;
4. Failure of ≥ 4 week trial of one additional formulary oral tetracycline antibiotic (e.g., immediate-release doxycycline, tetracycline) unless clinically significant adverse effects are experienced;
5. Dose does not exceed 1 mg/kg/day.

Approval duration: 12 weeks

B. Periodontitis (must meet all):

1. Request is for Arestin;
2. Diagnosis of chronic periodontitis (also known as adult periodontitis);
3. Prescribed by or in consultation with a periodontist;
4. Age ≥ 18 years;
5. Intolerance or contraindication to oral doxycycline hyclate at a sub-antimicrobial dose (20 mg PO twice a day) (e.g., unable to swallow capsules, allergic to a doxycycline product excipient, history of gastrointestinal disease);
6. Prescribed as an adjunct to a scaling and root planing procedure to reduce pocket depth (applied during procedure);
7. Dose is individualized depending on the size, shape, and number of pockets being treated.

Approval duration: 1 procedure

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acne Vulgaris (must meet all):

1. Request is for Solodyn;
2. Previously received medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
3. One of the following (a or b):
 - a. Member has not completed current 12-week course of treatment with Solodyn and is responding positively to therapy;
 - b. At least 12 months have elapsed since the last treatment course;
4. If request is for a dose increase, new dose does not exceed 1 mg/kg/day.

Approval duration: Up to 12 weeks of total treatment/365 days

B. Periodontitis (must meet all):

1. Request is for Arestin;
2. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
3. Member has not received 4 scaling and root planing procedures in the last 365 days;
4. Dose is individualized depending on the size, shape, and number of pockets being treated.

Approval duration: 1 procedure

C. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 weeks (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: General Information

- 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.
- The 2015 American Dental Association guidelines rank the following drug therapies as adjuncts to scaling and root planing for chronic periodontitis (rankings in order of strength are 1) strong, 2) in favor, 3) weak, 4) expert opinion for, 5) expert opinion against, 6) against):
 - “In favor”:
 - Systemic subantimicrobial-dose doxycycline
 - “Weak”:
 - Systemic antimicrobials at standard doses (similar benefit to subantimicrobial doses but increased risk of adverse effects)
 - Chlorhexidine chips (locally applied)

- Photodynamic therapy with diode laser
- “Expert opinion for”
 - Doxycycline hyclate gel (locally applied)
 - Minocycline microspheres (locally applied)

Appendix C: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxycycline (Vibramycin®)	Acne Vulgaris Adults, adolescents, and children 8 years and older weighing 45 kg or more: 100 mg PO every 12 hours on day 1, then 100 mg PO once daily Children 8 years and older and adolescents weighing less than 45 kg: 2.2 mg/kg/dose PO every 12 hours on day 1, then 2.2 mg/kg/dose PO once daily	Varies
minocycline (Minocin®)	Acne Vulgaris Adults: 200 mg PO initially, then 100 mg PO every 12 hours as adjunctive therapy. Alternatively, if more frequent oral doses are preferred, 100 to 200 mg PO initially, then 50 mg PO every 6 hours Children ≥ 8 years and adolescents: 4 mg/kg PO (max: 200 mg) initially, then 2 mg/kg/dose PO every 12 hours (max: 100 mg/dose) as adjunctive therapy	200 mg/day
tetracycline	Acne Vulgaris Adults: 1 g/day PO in divided doses, then decrease slowly to 125 to 500 mg PO daily or every other day Children ≥ 9 years and adolescents: 1 g/day PO in divided doses, then decrease slowly to 125 to 500 mg PO daily or every other day	Varies
doxycycline (Periostat®)	Periodontitis 20 mg BID (subantimicrobial-dose) for 3 to 9 months	40 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	1 mg/kg PO once daily for 12 weeks	1 mg/kg/day up to 135 mg/day
Periodontitis	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. <i>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.</i>	Dose is variable depending on size, shape, and number of pockets being treated.

VI. Product Availability

Drug Name	Availability
Solodyn	45 mg [†] , 55 mg, 65 mg, 80 mg, 90 mg [†] , 105 mg, 115 mg, and 135 mg [†]
Arestin	Unit-dose cartridge: minocycline hydrochloride microspheres equivalent to 1 mg of minocycline free base (1 or 12 unit-dose cartridges per box)

[†]Available as generic only

VII. References

1. Solodyn Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016. Available at: <http://www.solodyn.com>. Accessed September 11, 2017.
2. Minocycline Extended Release Tablets Prescribing Information. Baltimore, MD: Lupin Pharmaceuticals, Inc.; June 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed September 20, 2017.
3. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016; 74(5):945-973.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.
5. Arestin Prescribing Information. Bridgewater, NJ: OraPharma, a division of Valeant Pharmaceuticals North America LLC. May 2017. Available at <http://www.valeant.com/Portals/25/Pdf/PI/arestin-pi.pdf>. Accessed September 2017.
6. Smiley CJ, Tracy SL, Abt E, et al. Systematic review and meta-analysis on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts. July 2015. JADA 146(7): 508-524.e5.
7. Smiley CJ, Tracy SL, Abt E, et al. Evidence-based clinical practice guideline on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts. July 2015. JADA 146(7): 525-535.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.16	01.17
4Q17 Annual Review Converted to new template. Initial: Modified “Member has failed both generic immediate-release minocycline and doxycycline, unless intolerant or contraindicated” to the following: “Member experienced clinically significant adverse effects to immediate-release minocycline or has contraindication(s) to the excipients in immediate-release minocycline” and “Failure of ≥ 4 week trial of one additional formulary oral tetracycline antibiotic (e.g., immediate-release doxycycline, tetracycline) unless clinically significant adverse effects are experienced” as tetracycline class of antibiotics are considered first-line for systemic antibiotic therapy for acne. Added weight based max dose (and on re-auth). Updated approval duration from 3 months to 12 weeks per PI. Age edit not applied since formulary tetracycline antibiotics are not subjected to age restrictions. Re-auth: Added a requirement that member has not received Solodyn daily for ≥ 12 weeks of therapy per PI. Modified to include retreatment as an option if 12 months have elapsed since the last treatment course. Changed approval duration from 6 months to “up to 12 weeks of total treatment/365 days” as safety of minocycline ER tablets has not been established beyond 12 weeks of use.	09.11.17	11.17
Arestin added for periodontitis.	09.26.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2017 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.