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

Reference Number: PA.CP.PMN.80
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Minocycline ER [extended release] (Solodyn®) and microspheres (Arestin®) are tetracycline-class drugs.

FDA approved indication
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 (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Solodyn and Arestin are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all)**:**
1. Diagnosis of acne vulgaris;
2. Request is for Solodyn;
3. Age ≥ 12 years;
4. Member experienced clinically significant adverse effects to immediate-release minocycline or has contraindication(s) to the excipients in immediate-release minocycline;
5. Failure of ≥ 4 week trial of one additional PDL oral tetracycline antibiotic, unless clinically significant adverse effects are experienced;

Approval duration: 12 weeks

B. Periodontitis (must meet all)**:**
1. Diagnosis of chronic periodontitis (also known as adult periodontitis);
2. Request is for Arestin;
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 PA.CP.PMN.53 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. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Request is for Solodyn;
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 135 mg/day.

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

B. Periodontitis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Request is for Arestin;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 weeks

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 – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list

V. Dosage and Administration

<table>
<tr><th>Drug Name</th><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Minocycline extended release tablets (Solodyn)</td><td>Acne vulgaris</td><td>The recommended dosage is approximately 1 mg/kg PO once daily for 12 weeks. The following table shows tablet strength and body weight to achieve approximately 1 mg/kg:
<table>
<tr><th>Wt (lbs)</th><th>Wt (kg)</th><th>Tablet Strength (mg)</th><th>Actual mg/kg dose</th></tr>
<tr><td>99-109</td><td>45-49</td><td>45</td><td>1-0.92</td></tr>
<tr><td>110-131</td><td>50-59</td><td>55</td><td>1.10-0.93</td></tr>
<tr><td>132-157</td><td>60-71</td><td>65</td><td>1.08-0.92</td></tr>
<tr><td>158-186</td><td>72-84</td><td>80</td><td>1.11-0.95</td></tr>
<tr><td>187-212</td><td>85-96</td><td>90</td><td>1.06-0.94</td></tr>
<tr><td>213-243</td><td>97-110</td><td>105</td><td>1.08-0.95</td></tr>
<tr><td>244-276</td><td>111-125</td><td>115</td><td>1.04-0.92</td></tr>
<tr><td>277-300</td><td>126-136</td><td>135</td><td>1.07-0.99</td></tr>
</table></td><td>1 mg/kg/day PO up to 135 mg/day PO</td></tr>
<tr><td>Minocycline microspheres (Arestin)</td><td>Periodontitis</td><td>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</td><td>Dose is variable depending on size, shape, and number of</td></tr>
</table>

		intervals, were administered in pockets with pocket depth of 5 mm or greater. _____ *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.*	pockets being treated.

VI. Product Availability

Drug Name	Availability
Minocycline extended release tablets (Solodyn)	Extended-release tablets: 45†, 55, 65, 80, 90†, 105, 115, and 135† mg
Minocycline microspheres (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; September 2017. Available at: http://www.solodyn.com/. Accessed January 29, 2018.
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.; 2018. 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 January 29, 2018.
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
2Q 2018 annual review: added Arestin and criteria for periodontitis; acne vulgaris: added age; removed criteria related to topical treatments and hypersensitivity to tetracyclines; added max dose; specified request is for Solodyn. Re-auth: modified approval duration from "up to 12 weeks of total treatment" to "up to 12 weeks of total treatment/365 days"; references reviewed and updated.	02.06.18	