Clinical Policy: Minocycline ER (Emrosi, Solodyn, Ximino, Minolira), Microspheres (Arestin), Foam (Zilxi)

Reference Number: CP.PMN.80
Effective Date: 06.01.17
Last Review Date: 05.25
Line of Business: Commercial*, HIM*, Medicaid Revision Log

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

Description

Minocycline ER [extended release] (Emrosi™, Solodyn®, Ximino®, Minolira™), microspheres (Arestin®), and foam (Zilxi®) are tetracycline-class drugs.

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***For Commercial and Health Insurance Marketplace (HIM) in all states except Florida,** if request is through pharmacy benefit, Arestin is excluded and should not be approved using these criteria.*

FDA Approved Indication(s)

Solodyn, Ximino, and Minolira are 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, Ximino, and Minolira did not demonstrate any effect on non-inflammatory acne lesions. Safety of these drugs have not been established beyond 12 weeks of use. These formulations of minocycline have 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, Ximino, and Minolira 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.

Emrosi and Zilxi are indicated for the treatment of inflammatory lesions of rosacea in adults.

Limitation(s) of use: Emrosi and Zilxi have not been evaluated in the prevention (Emrosi only) or treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Emrosi and Zilxi should be used only as indicated.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Solodyn, Ximino, minocycline ER, Minolira, Arestin, Emrosi, and Zilxi 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 minocycline ER (Solodyn, Ximino) or Minolira;
3. Age ≥ 12 years;
4. Member must use immediate-release minocycline, unless contraindicated or clinically significant adverse effects are experienced;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
5. Failure of a ≥ 4 week trial of one additional preferred oral tetracycline antibiotic (e.g., immediate-release doxycycline), unless clinically significant adverse effects are experienced or all are contraindicated;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Dose does not exceed 135 mg per day.

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);*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
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:
Medicaid/Commercial – 1 procedure
HIM – Arestin is excluded in all states except Florida; in Florida, approval is for 1 procedure

C. Rosacea (must meet all)**:**

1. Diagnosis of rosacea with inflammatory lesions (papules and pustules);
2. Request is for Zilxi or Emrosi;
3. Age ≥ 18 years;
4. Failure of ≥ 6 consecutive weeks of two of the following (*see Appendix B*) at maximally tolerated doses, unless clinically significant adverse effects are experienced or all are contraindicated: oral doxycycline, topical metronidazole, topical ivermectin, topical azelaic acid;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
5. Dose does not exceed the following (a or b):
   a. Zilxi: 1 can per month;

b. Emrosi: 40 mg (1 capsule) per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acne Vulgaris (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for minocycline ER (Solodyn, Ximino) or Minolira;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 135 mg per day.

Approval duration: 12 weeks

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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:
Medicaid/Commercial – 1 procedure
HIM – Arestin is excluded in all states except Florida; in Florida, approval is for 1 procedure

C. Rosacea (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for Zilxi or Emrosi;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. Zilxi: 1 can per month;
   b. Emrosi: 40 mg (1 capsule) per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

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
metronidazole (Metrocream® 0.75%, Metrogel® 1%, Metrolotion® 0.75%)	Rosacea Apply thin film topically to affected area QD for 1% and BID for 0.75%	Not applicable
azelaic acid (Finacea® 15% gel)	Rosacea Apply in a thin film topically to the affected area BID Reassess if no improvement in 12 weeks	Not applicable
doxycycline (Oracea®)	Rosacea 40 mg PO once daily in the morning (1 hour before or 2 hours after a meal)	300 mg/day PO; 40 mg PO/day for Oracea

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Soolantra® (ivermectin cream)	Rosacea Apply pea size amount to the affected areas of the face QD	1 g/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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to minocycline or any tetracyclines
- Boxed warning(s): none reported

Appendix D: 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)

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>
</table></td><td>1 mg/kg/day PO up to 135 mg/day PO</td></tr>
</table>

<table>
<tr><th>Drug Name</th><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Wt. (lbs)</th><th>Wt. (kg)</th><th>Tablet Strength (mg)</th><th>Actual mg/kg dose</th></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></td></tr>
<tr><td>Minocycline extended release capsule (Emrosi)</td><td>Rosacea</td><td>The recommended dosage is 40 mg PO once daily.</td><td>40 mg/day</td></tr>
<tr><td>Minocycline extended release capsules (Ximino)</td><td>Acne vulgaris</td><td>The recommended dosage is approximately 1 mg/kg PO once daily for 12 weeks. The following table shows capsule strength and body weight to achieve approximately 1 mg/kg:
<table>
<tr><th>Wt. (lbs)</th><th>Wt. (kg)</th><th>Capsule Strength (mg)</th><th>Actual mg/kg dose</th></tr>
<tr><td>99-131</td><td>45-59</td><td>45</td><td>1-0.76</td></tr>
<tr><td>132-199</td><td>60-90</td><td>90</td><td>1.5-1</td></tr>
<tr><td>200-300</td><td>91-136</td><td>135</td><td>1.48-0.99</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 intervals, were administered in pockets with pocket depth of 5 mm or greater.</td><td>Dose is variable depending on size, shape, and number of pockets being treated.</td></tr>
</table>

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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.*	
Minocycline extended release tablets (Minolira)	Acne vulgaris	The recommended dosage is approximately 1 mg/kg PO once daily for 12 weeks. The following list shows tablet strength and body weight to achieve approximately 1 mg/kg: Weight (kg): tablet strength (mg) 45-59 kg: half of the 105 mg tablet 60-89 kg: half of the 135 mg tablet 90-125 kg: 105 mg 126-136 kg: 135 mg	1 mg/kg/day PO up to 135 mg/day PO
Minocycline foam (Zilxi)	Rosacea	Apply as a thin layer to affected areas of the face once daily. Gently rub into skin.	One application/ day

VI. Product Availability

Drug Name	Availability
Minocycline extended release tablets (Solodyn)	Extended-release tablets: 45 mg†, 55 mg, 65 mg, 80 mg, 90 mg†, 105 mg, 115 mg, and 135 mg†
Minocycline extended release capsules (Emrosi, Ximino)	• Extended-release capsules (Ximino): 45 mg, 90 mg, and 135 mg • Extended-release capsule (Emrosi): 40 mg
Minocycline extended release tablets (Minolira)	Extended-release tablets: 105 mg 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)
Minocycline foam (Zilxi)	Foam: 1.5% (30 g can)

†*Available as generic only*

VII. References

1. Arestin Prescribing Information. Bridgewater, NJ: OraPharma, a division of Valeant Pharmaceuticals North America LLC. May 2024. Available at: https://www.arestin.com/. Accessed January 22, 2025.
2. Emrosi Prescribing Information. Scottsdale, AZ: Journey Medical Corporation; November 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219015s000lbl.pdf. Accessed January 22, 2025.

3. Minolira Prescribing Information. Princeton, NJ: Promius Pharma, LLC.; June 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=523856a4-530b-4a23-a80a-d72ab08e2c08 /. Accessed January 22, 2025.
4. Solodyn Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; September 2017. Available at: http://www.solodyn.com/. Accessed January 22, 2025.
5. Ximino Prescribing Information. Princeton, NJ: Sun Pharmaceuticals; November 2020. Available at: http://www.ximinorx.com/. Accessed January 22, 2025.
6. Zilxi Prescribing Information. Scottsdale, AZ: Journey Medical Corporation; March 2022. Available at: https://zilxi.com/. Accessed January 22, 2025.
7. 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.
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9. 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. JADA 2015; 146(7): 508-524.e5.
10. 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. JADA 2015; 146(7): 525-535.
11. Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: The 2019 update by the National Rosacea Society Expert Committee. J Am Acad Dermatol 2020; 82: 1501-10.
12. Del Rosso JQ, Tanghetti E, Webster G, et al. Update on the Management of Rosacea from the American Acne & Rosacea Society (AARS). J Clin Aesthet Dermatol. 2019;12(6): 17-24.
13. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024 May; 90(5): 1006.e1-1006.e30.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: no significant changes; revised requirement for IR minocycline for acne vulgaris to "must use" language; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	03.01.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.14.22	05.22
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less.	04.27.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
2Q 2023 annual review: no significant changes; clarified that Arestin is excluded for all HIM plans except Florida where it is NF and can follow this policy for coverage criteria and duration as stated; references reviewed and updated.	02.14.23	05.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2024 annual review: no significant changes; clarified that Arestin is excluded for Commercial line of business on the pharmacy benefit; references reviewed and updated.	01.11.24	05.24
RT4: added Emrosi to criteria with corresponding criteria set for rosacea indication.	12.04.24	
2Q 2025 annual review: no significant changes; added reference to minocycline ER (generic Solodyn and Ximino); references reviewed and updated.	01.22.25	05.25
Added step therapy bypass for IL HIM per IL HB 5395.	07.14.25	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.