Tetracyclines

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the prior authorization (PA) criteria for Tetracyclines is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines, and to encourage use of more cost-effective generic immediate release agents prior to the use of a generic or brand name delayed release agent, a brand name immediate release agent, or a more costly generic when using for the treatment of acne or rosacea.

POLICY

Criteria for Initial Approval

A. Minolira, Solodyn, Ximino, extended-release 24 hour Minocycline, and their generic equivalents may be considered **medically necessary** for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years and older when the following criteria are met:

- The patient must have tried and failed prescription topical acne treatment unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs); AND
- The patient must have tried and failed generic immediate-release doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release doxycycline; AND
- The patient must have tried and failed generic immediate-release minocycline HCl or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release minocycline HCl;

Initial approval will be for **12 weeks** per 12 month period

B. Doryx, Doryx MPC, doxycycline delayed release tablets and their generic equivalents may be considered **medically necessary** for the treatment of acne when the following criteria are met:
- The patient must have tried and failed prescription topical acne treatment unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs); AND
- The patient must have tried and failed generic immediate-release doxycycline or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release doxycycline; AND
- The patient must have tried and failed generic immediate-release minocycline HCl unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release minocycline HCl;

Initial approval will be for **16 weeks** per 12 month period

C. Oracea and generic equivalents may be considered **medically necessary** for the treatment of inflammatory lesions of rosacea when the following criteria is met:
- The patient must have tried and failed topical metronidazole unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)**;** AND
- The patient must have tried and failed low dose generic immediate-release doxycycline **OR** The patient has an allergy, intolerance, or contraindication to the excipients in low dose generic immediate-release doxycycline

Initial **approval** will be for **16 weeks** per 12 month period

D. Seysara (sarecycline) may be considered **medically necessary** for the treatment of non-nodular moderate to severe acne vulgaris in patients 9 years and older when the following criteria are met:
- The patient must have tried and failed prescription topical acne treatment unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs); AND
- The patient must have tried and failed generic immediate-release doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release doxycycline; AND
- The patient must have tried and failed generic immediate-release minocycline HCl unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) or the patient has an allergy, intolerance, or contraindication to the excipients in generic immediate-release minocycline HCl;

Initial approval will be for **12 weeks** per 12 month period

E. Doryx, and Doryx MPC may be considered **medically necessary** when being used to treat other medical conditions for which it is indicated.

Approval will be for **12 months**

F. Oracea, Seysara, Solodyn, Ximino, extended-release 24 hour Minocycline are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Continuation of Therapy

A. The continuation of therapy with Minolira, Solodyn, Ximino, and extended-release 24 hour Minocycline may be considered **medically necessary** when the following criteria are met:
- The patient must meet initial criteria for approval; AND
- The patient must complete a full course of initial therapy (12 weeks) with significant improvement; AND
- Continuing therapy beyond the initial approval period is considered medically necessary

Approval will be for **12 months**

B. The continuation of therapy with Doryx and Doryx MPC doxycycline delayed release tablets and their generic equivalents may be considered **medically necessary** when the following criteria are met:
- The patient must meet initial criteria for approval; AND
- The patient must complete a full course of initial therapy (16 weeks) with significant improvement; AND
- Continuing therapy beyond the initial approval period is considered medically necessary

Approval will be for **12 months**

C. The continuation of therapy with Oracea may be considered **medically necessary** when the following criteria are met:
- The patient must meet initial criteria for approval; AND
- The patient must complete a full course of initial therapy (16 weeks) with significant improvement; AND
- Continuing therapy beyond the initial approval period is considered medically necessary

Approval will be for **12 months**

D. The continuation of therapy with Seysara may be considered **medically necessary** when the following criteria are met:
- The patient must meet initial criteria for approval; AND
- The patient must complete a full course of initial therapy (12 weeks) with significant improvement; AND
- Continuing therapy beyond the initial approval period is considered medically necessary

Approval will be for **12 months**

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

- Doryx MPC (doxycycline hyclate) [prescribing information]. Greenville, NC: Mayne Pharma USA; July 2018.
- Del Rosso JQ, Baldwin H, Webster G. American Acne and Rosacea Society rosacea medical management guidelines. J Drugs Dermatol. 2008;7(6):531-533.
- Doryx delayed-release tablets (doxycycline hyclate) [prescribing information]. Greenville, NC: Mayne Pharma; July 2018.
- Minolira extended-release tablets [prescribing information]. Princeton, NJ: Promius Pharma LLC; May 2017.
- Oracea capsules [prescribing information]. Fort Worth, TX: Galderma Laboratories, LP; December 2014.
- Sapadin AN, F. R. (2006). Tetracyclines: nonantibiotic properties and their clinical implications. *J Am Acad Dermatol* , 54:258-65.
- Simonart T, D. M. (2007). Efficacy of tetracyclines in the treatment of acne vulgaris: a review. *Br J Dermatol.*, 158:208-16.
- Seysara [prescribing information]. Irvine, CA: Allergan USA, Inc.; 2018.
- Solodyn [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2017.
- Strauss JS, K. D. (2007). Guidelines of care for acne vulgaris management. *J Am Acad Dermatol* , 56(4):651-63.
- Ximino extended-release capsules [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; April 2017.

POLICY HISTORY

Policy #: 05.01.60
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