Tetracyclines

**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. Solodyn and Ximino** 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 regular-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 regular-release doxycycline; AND
- The patient must have tried and failed generic regular release minocycline HCl or the patient has an allergy, intolerance, or contraindication to the excipients in generic regular-release minocycline HCl;

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

**B. Acticlate, Adoxa, Doryx, and Targadox** 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 regular-release doxycycline or the patient has an allergy, intolerance, or contraindication to the excipients in generic regular-release doxycycline; AND
- The patient must have tried and failed generic regular-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 regular-release minocycline HCl;

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

C. **Oracea** 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 regular-release doxycycline OR The patient has an allergy, intolerance, or contraindication to the excipients in low dose generic regular-release doxycycline

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

D. **Acticlate, Adoxa, and Doryx, Solodyn, and Targadox** may be considered **medically necessary** when being used to treat other medical conditions for which they are medically indicated.

**Approval** will be for **12 months**

E. **Acticlate, Adoxa, Doryx, Oracea, Solodyn, and Targadox** considered **not medically necessary** for patients who do not meet the criteria set forth above.

**Continuation of Therapy**

A. The continuation of therapy with **Solodyn and Ximino** 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 **Acticlate, Adoxa, Doryx, and Targadox** 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**

**REFERENCES**

- Oracea capsules [prescribing information]. Fort Worth, TX: Galderma Laboratories, LP; July 2013.
- Solodyn film coated, extended release tablet [prescribing information]. Scottsdale, AZ. Medicis; February 2012.

**POLICY HISTORY**

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