



Medication Policy Manual

Policy No: dru507

Topic: Once daily tetracycline products

Date of Origin: January 1, 2018

- generic doxycycline hyclate delayed-release
- generic minocycline HCl extended release

Committee Approval Date: July 14, 2017

Next Review Date: July 2018

Effective Date: January 1, 2018

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Doxycycline hyclate delayed-release and minocycline HCl extended-release are oral tetracycline antibiotics used to treat susceptible bacterial infections including moderate to severe acne vulgaris.

This policy applies to the generic products.

Policy/Criteria

- I. Most contracts require prior authorization approval of doxycycline hyclate delayed-release and minocycline HCl extended-release prior to coverage. These products may be considered medically necessary when at least two oral antibiotic medications (listed in Appendix 1) have been ineffective, or not tolerated, unless all are contraindicated.

- II. Administration, Quantity Limitations, and Authorization Period
 - A. OmedaRx considers doxycycline hyclate delayed-release and minocycline HCl extended-release to be a self-administered medications.
 - B. When prior authorization is approved, doxycycline hyclate delayed-release and minocycline HCl extended-release may be authorized in quantities of up to thirty tablets per month.
 - C. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

- Generically available oral antibiotics for acne vulgaris include: tetracycline, doxycycline, and minocycline. They have established effectiveness and provide the best treatment value.
- There is no evidence that delayed-release doxycycline hyclate or extended-release minocycline is more effective or better tolerated than generically available immediate-release products and they are more expensive.
- Clinical guidelines consider systemic antibiotics (e.g. doxycycline and minocycline) the standard of care in moderate to severe inflammatory acne vulgaris; however, no preferences are given to any specific dosing regimen. ^[1,2] In addition, oral erythromycin, azithromycin, and sulfamethoxazole-trimethoprim provide additional treatment options in patients who cannot use tetracyclines. ^[2]
- Clinical guidelines for the treatment of chlamydial infections recommend azithromycin or immediate-release doxycycline as the standard of care. ^[3]

Appendix 1: Examples of immediate release (IR) oral antibiotics for acne vulgaris ^[1,2,4]		
Name	Dose	Select adverse effects
Tetracycline	Up to 500 mg daily or 25 to 50 mg/kg/day	Photosensitivity, gastrointestinal distress; contraindicated in pregnancy and young children
Doxycycline IR	Up to 200 mg daily	Photosensitivity, gastrointestinal distress; contraindicated in pregnancy and young children
Minocycline IR	Up to 200 mg daily	Dizziness, drug-induced lupus, skin discoloration; contraindicated in pregnancy and young children
Erythromycin	Off-label	Gastrointestinal distress
Azithromycin	Off-label	Gastrointestinal distress
Sulfamethoxazole-Trimethoprim	Off-label	Gastrointestinal distress

Cross References
None

Codes	Number	Description
N/A		

References

1. Graber, E. Treatment of acne vulgaris. In: UpToDate, Ofori, AO (Ed) Waltham, MA, 2014.
2. Strauss, JS, Krowchuk, DP, Leyden, JJ, et al. Guidelines of care for acne vulgaris management. *J Am Acad Dermatol.* 2007;56:651-63. PMID: 17276540
3. Sexually Transmitted Disease Treatment Guidelines, 2010. Department of Health and Human Services Centers for Disease Control and Prevention. [cited 2/23/15]; Available from: <http://www.cdc.gov/std/treatment/2010/std-treatment-2010-rr5912.pdf>.
4. Eichenfield, LF, Krakowski, AC, Piggott, C, et al. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. *Pediatrics.* 2013;131 Suppl 3:S163-86. PMID: 23637225