



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Minocycline Extended-Release

Policy Number: 5.01.533

Last Review: 09/2018

Origination: 09/2010

Next Review: 09/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for minocycline extended-release (Solodyn, Ximino) when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered

Minocycline extended-release will be considered medically necessary for the treatment of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older when the patient has:

- Experienced a failure or intolerance of at least one topical retinoid, as well as a
- Failure or intolerance to doxycycline, tetracycline, or generic immediate-release minocycline

The initial approval will be for 12 weeks. If a patient has a flare of inflammatory lesions after the initial 12 week course, retreatment with minocycline extended-release tablets will be allowed if the patient is using topical maintenance therapy. Recertification will be approved for one year.

Minocycline extended-release tablets will be limited to one per day.

When Policy Topic is not covered

Minocycline extended-release is considered not medically necessary if the criteria above are not met.

Considerations

Minocycline extended-release for all other indications is considered investigational.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Minocycline extended-release is a tetracycline-class drug indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in individuals 12 years of age and older.

Rationale

Available guidelines for the management of acne recommend oral antibiotics for the management of moderate to severe acne (generally not as monotherapy) and do not differentiate between brand name and generic products. Oral antibiotics reduce the number of Propionibacterium acnes (*P. acnes*), which are thought to trigger the inflammatory response in acne, thus playing an important role in the pathogenesis of inflamed acne lesions. Tetracycline agents are considered the oral antibiotics of choice due to increasing antimicrobial resistance to other agents such as erythromycin and the other macrolides. To limit antibiotic resistance, patients should not use oral antibiotics chronically.

Minocycline extended-release is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. Acne is considered to be moderate to severe as follows:

Moderate: 6-20 inflammatory lesions but no more than 1 small nodule

Severe: > 21 inflammatory lesions but less than 5 nodules

Minocycline extended-release did not demonstrate effectiveness on non-inflammatory lesions. Safety of minocycline extended-release 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, minocycline extended-release should only be used as indicated. This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

The recommended dosage of minocycline extended-release is approximately 1mg/kg daily for 12 week. Higher doses have not shown to be of additional benefit in the treatment of inflammatory lesions of acne, and may be associated with more acute vestibular side effects.

References

1. Garner SE, Eady EA, Popescu C, Newton J, Li WA. Minocycline for acne vulgaris: efficacy and safety. *Cochrane Database Syst Rev.* 2003.
2. Jerry KL Tan. Current Measures for the Evaluation of Acne Severity: Methods for Grading Acne Severity. 2008.
3. National Guideline Clearinghouse. Guidelines of care for acne vulgaris management. 2008.
4. Simonart T, Dramaix M, De Maertelaer V. Efficacy of tetracyclines in the treatment of acne vulgaris: a review. *Br J Dermatol.* 2008; 158:208-16.
5. Strauss JS, Krowchuk DP, Leyden JJ, et al. Guidelines of care for acne vulgaris management. *J Am Acad Dermatol.* 2007; 56:651-63.

Billing Coding/Physician Documentation Information

Minocycline extended-release is considered a pharmacy benefit

Additional Policy Key Words

5.01.533; Solodyn, Ximino

Policy Implementation/Update Information

09/2010	New policy titled Minocycline Extended-Release
09/2011	Reviewed -- no changes made
09/2012	Reviewed – no changes made
09/2013	Reviewed – no changes made
09/2014	Reviewed – no changes made
09/2015	Reviewed – No changes made
09/2016	Reviewed – No changes made
09/2017	Reviewed – no changes made
09/2018	Added Ximino to policy

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The

medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.