

STEP THERAPY CRITERIA

DRUG CLASS	MINOCYCLINE EXTENDED-RELEASE BRAND ONLY	
BRAND NAME (generic)	SOLODYN (BRAND ONLY) (minocycline HCl extended-release tablets)	
Status: CVS Caremark Criteria		
Type: Initial Step Therapy; Post Step Therapy Prior Authorization		Ref# 526-F

FDA-APPROVED INDICATION

Solodyn

Solodyn is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitations of Use

Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn 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, Solodyn should be used only as indicated.

INITIAL STEP THERAPY

If the patient is 12 years of age or older AND has filled a prescription for a 30 day supply of generic minocycline extended-release OR minocycline OR doxycycline extended-release OR doxycycline within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Solodyn brand will be covered with prior authorization when the following criteria are met:

- The patient is 12 years of age or older with a diagnosis of inflammatory, non-nodular moderate to severe acne vulgaris

AND

- The patient experienced an inadequate treatment response with generic minocycline extended-release or minocycline or doxycycline extended-release or doxycycline after a trial of at least 30 days

OR

- The patient experienced an intolerance, contraindication to or a potential drug interaction with generic minocycline extended-release or minocycline AND doxycycline extended-release or doxycycline that would prohibit a 30 day trial

AND

- The patient experienced an inadequate treatment response with tetracycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, or azithromycin after a trial of at least 30 days

RATIONALE

If the patient has filled a prescription for a for a 30 day supply of generic minocycline extended-release OR minocycline OR doxycycline extended-release OR doxycycline within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria, then prior authorization is required.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and practice guidelines in order to decrease the potential for inappropriate utilization. Solodyn is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Solodyn should be used only as indicated. Solodyn did not demonstrate any effect on non-inflammatory acne lesions. Safety of Solodyn has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections.

The American Academy of Pediatrics, The American Academy of Dermatology, and The Global Alliance to Improve Outcomes in Acne have established guidelines for the treatment of acne vulgaris. Patients with acne vulgaris may be treated with topical products, antibacterial, keratolytic, or retinoid, (e.g., salicylic acid, benzoyl peroxide, azelaic acid, adapalene, tretinoin, tazarotene, clindamycin, erythromycin). Combinations of products, if compatible, may be used. Systemic antibiotics are a standard of care in the management of moderate and severe acne and treatment-resistant forms of inflammatory acne. There is evidence to support the use of tetracycline, doxycycline, minocycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, and azithromycin. Doxycycline and minocycline are more effective in reducing *P acnes*. Although erythromycin is effective, use should be limited to those who cannot use the tetracyclines. Trimethoprim-sulfamethoxazole and trimethoprim alone are also effective in instances where other antibiotics cannot be used.⁴⁻⁶

The guidelines state that 4 to 8 weeks of oral antibiotic use are needed before the clinical effects are visible, and maximal response may require 3 to 6 months. Antibiotic use should be limited to short periods and discontinued when there is no further improvement or the improvement is only slight with continuation of topical therapy to maintain control of acne. When possible, the original antibiotic should be used for subsequent courses if patient relapses.⁴⁻⁶

REFERENCES

1. Solodyn [package insert]. Scottsdale, AZ: Medcis, The Dermatology Company; June 2016.
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3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed December 2016.
4. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for Acne Vulgaris Management. *J Am Acad Dermatol*. 2016; 74(5):945-973..
5. Thiboutot D, Gollnick H, Bettoli V, et al. New Insights into the Management of Acne: An update from the Global Alliance to Improve Outcomes in Acne Group. *J Am Acad Dermatol*. 2009;60:S1-50.
6. Eichenfield L, Krakowski A, Piggott C, et al. Evidence-Based Recommendations for the Diagnosis and Treatment of Pediatric Acne. *Pediatrics*. 2013;131:S163–S186.

Written by: UM Development (NB)
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External Review: 09/2010, 06/2011, 06/2012, 06/2013, 04/2014, 04/2015, 02/2016, 02/2017

CRITERIA FOR APPROVAL

1	Is the patient 12 years of age or older with a diagnosis of inflammatory, non-nodular moderate to severe acne vulgaris?	Yes	No
2	Has the patient experienced an inadequate treatment response with generic minocycline extended-release or minocycline or doxycycline extended-release or doxycycline after a trial of at least 30 days? [If yes, then no further questions.]	Yes	No
3	Has the patient experienced an intolerance, contraindication to or a potential drug interaction with generic minocycline extended-release or minocycline AND doxycycline extended-release or doxycycline that would prohibit a 30 day trial?	Yes	No
4	Has the patient experienced an inadequate treatment response with tetracycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, or azithromycin after a trial of at least 30 days?	Yes	No

Mapping Instructions

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Deny	Your plan covers this drug when you meet all of these conditions: – You have inflammatory, non-nodular moderate to severe acne vulgaris – You are 12 years of age or older Your use of this drug does not meet the requirements. This is based on the information we have.
2.	Approve, 12 months	Go to 3	
3.	Go to 4	Deny	Your plan covers this drug when you meet any of these conditions: – You have tried generic minocycline or doxycycline for 30 days and it did not work for you – You cannot use generic minocycline AND doxycycline for 30 days Your use of this drug does not meet the requirements. This is based on the information we have.
4.	Approve, 12 months	Deny	Your plan covers this drug when you meet any of these conditions: – You have tried generic minocycline or doxycycline for 30 days and it did not work for you – You cannot use generic minocycline and doxycycline, and, you have tried tetracycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, or azithromycin for 30 days and it did not work for you Your use of this drug does not meet the requirements. This is based on the information we have.