

Solodyn[®] Prior Authorization Criteria

Brand	Generic	Dosage Form
Solodyn [®] *	minocycline	extended-release tablet

* - generic products are available in 45 mg, 90 mg, and 135 mg strengths; they are not included in this prior authorization (PA) program

FDA APPROVED INDICATIONS¹

The following information is taken from individual drug prescribing information and is provided here as background information only. Not all FDA-approved indications may be considered medically necessary. All criteria are found in the section "Prior Authorization (PA) Criteria for Approval."

Solodyn[®] (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. Solodyn did not demonstrate any effect on non-inflammatory 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.

RATIONALE FOR PRIOR AUTHORIZATION

The intent of the prior authorization (PA) criteria for Solodyn 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 first-line generic agents before use of Solodyn.

The safety and efficacy of Solodyn in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris was assessed in two 12-week, multi-center, randomized, double-blind, placebo-controlled, studies in subjects ≥ 12 years. The mean age of subjects was 20 years and subjects were from the following racial groups: white (73%), Hispanic (13%), black (11%), Asian/Pacific islander (2%), and other (2%). In the two efficacy and safety trials, a total of 924 subjects with non-nodular moderate to severe acne vulgaris received 1 mg/kg of Solodyn or placebo for a total of 12 weeks. The two primary efficacy endpoints were:

1. Mean percent change in inflammatory lesion counts from baseline to 12 weeks
2. Percentage of subjects with an Evaluator's Global Severity Assessment (EGSA) of clear or almost clear at 12 weeks.

Patients on Solodyn had a greater mean percent improvement in inflammatory lesions (43.1% and 45.8% in studies one and two respectively) compared to placebo (31.7% and 30.8%) ($p < 0.05$). Solodyn did not demonstrate any effect on non-inflammatory lesions.¹

There are no clinical studies comparing extended-release minocycline with older immediate-release formulations. Reviews of tetracycline products used in the treatment of acne^{2,3} have found tetracycline, minocycline, and doxycycline all to be effective in the treatment of acne, particularly during the inflammatory stage. One review of seven randomized trials which were set up to compare the efficacy of tetracyclines found no evidence of superiority of one tetracycline over another in reducing acne lesion counts.²

A Medical Letter review of Solodyn⁴ concluded "Solodyn is an expensive new formulation of minocycline labeled for once-daily use. Whether Solodyn is as effective as immediate-release minocycline and less likely to cause vertigo remains to be established."⁴

The 2007 guidelines from the American Academy of Dermatology on treatment of acne vulgaris⁵ include the following recommendations:

1. Topical therapy is a standard of care in acne treatment
 - Topical retinoids, benzoyl peroxide, and antibiotics are strongly recommended.
 - Topical antibiotics used alone can be associated with the development of bacterial resistance.
 - Azelaic acid is effective but some experts consider its efficacy limited.
 - Employing multiple topical agents that affect different aspects of acne pathogenesis can be useful.
2. Systemic antibiotics are a standard of care in moderate and severe acne and treatment-resistant forms of inflammatory acne
 - Doxycycline and minocycline are more effective than tetracycline, and there is evidence that minocycline is superior to doxycycline 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.
3. Other Therapies
 - Estrogen-containing oral contraceptives can be useful in treatment of acne in some women.
 - Spironolactone and cyproterone can be useful, but the strength of recommendation is less
 - Oral isotretinoin is useful for severe recalcitrant nodular acne and also lesser degrees of acne that are treatment-resistant or for acne that is scarring
 - Intralesional corticosteroid injections are effective in the treatment of individual acne nodules

This prior authorization program will limit use of Solodyn to those who are 12 years or older and have already tried and failed, or cannot use, both first-line prescription topical therapy and an oral generic doxycycline or generic minocycline product. Approvals will be limited to one 12-week course of Solodyn per 12 months time frame. This PA program applies to brand Solodyn only; generic products are not included as targets.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

***Solodyn*[®] (minocycline extended-release)**

Initial and Renewal Evaluation

1. Is the patient 12 years of age or older?
If yes, continue to 2. If no, deny.
2. Does the patient have a diagnosis of inflammatory lesions of non-nodular moderate to severe acne vulgaris?
If yes, continue to 3. If no, deny.
3. Has the patient previously tried and failed therapy with a prescription topical acne treatment?
If yes, continue to 5. If no, continue to 4.
4. Does the patient have an allergy, contraindication, or intolerance to prescription topical acne treatment?
If yes, continue to 5. If no, deny.
5. Has the patient previously tried and failed therapy with an oral generic minocycline product or generic doxycycline product?
If yes, approve for 12 weeks. If no, continue to 6.
(Note: PA approvals will be limited to one approval per 12 months.)
6. Does the patient have an allergy, contraindication, or intolerance to an oral generic minocycline product or generic doxycycline product?
If yes, approve for 12 weeks. If no, deny.

(Note: Solodyn will not be approved for patients with an allergy to the drug minocycline.)
(Note: PA approvals will be limited to one approval per 12 months.)

SUMMARY

Solodyn has been approved by the Food and Drug Administration (FDA) for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older; it did not demonstrate any effect on non-inflammatory lesions. The prior authorization program for Solodyn reviews use of this agent for appropriate use based on product labeling and/or clinical studies and/or guidelines. The criteria will approve use of Solodyn in patients 12 years of age or older who have tried and failed both prescription topical acne therapy and oral generic minocycline or doxycycline therapy, or who have an intolerance, allergy or contraindication to these therapies. In this manual review, the prescribing physician provides patient-specific information to be taken into consideration. This PA program applies to brand Solodyn only.

REFERENCES

1. Solodyn prescribing information. Medicis Pharmaceutical Corporation. July 2009.
2. Simonart T, Dramaix M, De Maertelaer V. Efficacy of tetracyclines in the treatment of acne vulgaris: a review. *Br J Dermatol.* 2007;158:208-16.
3. Sapadin AN, Fleischmajer R. Tetracyclines: nonantibiotic properties and their clinical implications. *J Am Acad Dermatol.* 2006;54:258-65.
4. Anon. Extended-release minocycline (Solodyn) for acne. *Med Lett Drugs Ther.* 2006;48(1248):95-96.
5. Strauss JS, Krowchuk DP, Leyden JJ et al. for the American Academy of Dermatology. Guidelines of care for acne vulgaris management. *J Am Acad Dermatol.* 2007;56(4):651-63.

Document History

Original Client Specific criteria, approved by HCSC Corporate Clinical Committee 05/2009
Mid-year Review, clarification of approval duration, approved by HCSC Corporate Clinical Committee 06/2009
Administrative Action (update of Solodyn PI date with new strengths marketed; generic product marketed; note added to criteria question 6) 08/2009