

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	Solosec (secnidazole)
POLICY #	11111
INDICATIONS	Solosec (secnidazole) is indicated for the treatment of Bacterial vaginosis (BV) in adult females
CRITERIA	<p>ConnectiCare, Inc. considers Solosec to be medically necessary for the treatment of bacterial vaginosis in adult females who meet the following criteria:</p> <ul style="list-style-type: none">A. Patient is at least 18 years old <p style="text-align: center;">AND</p> <ul style="list-style-type: none">B. Provider must submit documentation (which may include office chart notes and/or lab results) supporting clinical diagnosis of bacterial vaginosis <p style="text-align: center;">AND</p> <ul style="list-style-type: none">C. Patient has experienced a treatment failure [documentation required] for a previous course of infection with at least one of the following: metronidazole tablets, tinidazole tablets, metronidazole/vandazole 0.75 % vaginal gel)
LIMITATIONS	<p>Duration of treatment will be limited to 30 days</p> <p>Exclusion Criteria:</p> <ul style="list-style-type: none">1. Hypersensitivity to nitroimidazole derivatives (metronidazole, tinidazole)2. Prior failure of metronidazole or tinidazole for the current course of infection
REFERENCES	<ul style="list-style-type: none">1. Solosec [package insert]. Newark, NJ; Symbiomix Therapeutics LLC; September 2017.2. CDC. Bacterial Vaginosis Statistics. Available at: https://www.cdc.gov/std/bv/stats.htm. Accessed November 29, 2017.3. Schwebke JR, Morgan FG Jr, Koltun W, et al. A phase-3, double-blind, placebo-controlled study of the effectiveness and safety of single oral doses of secnidazole 2 g for the treatment of women with bacterial vaginosis. Am J Obstet Gynecol 2017. doi: 10.1016/j.ajog.2017.08.017.4. Centers for Drug Evaluation and Research. Summary Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000SumR.pdf. Accessed November 29, 2017.5. Bohbot JM, Vicaut E, Fagnen D, et al. Treatment of bacterial vaginosis: A multicenter,

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	double-blind, double-dummy, randomised phase III study. Comparing Secnidazole and Metronidazole. Infect Dis Obstet Gynecol. 2010. doi: 10.1155/2010/705692.
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REVISION RECORD	1/18