

## PHARMACY PRE-AUTHORIZATION CRITERIA



<b>DRUG (S)</b>	Solosec (secnidazole)
<b>POLICY #</b>	11111
<b>INDICATIONS</b>	Solosec (secnidazole ) is indicated for the treatment of Bacterial vaginosis (BV) in adult females
<b>CRITERIA</b>	<p>ConnectiCare, Inc. considers <b>Solosec</b> 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"> <li>A. Patient is at least 18 years old</li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>B. Provider must submit documentation (which may include office chart notes and/or lab results) supporting clinical diagnosis of bacterial vaginosis</li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>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)</li> </ul>
<b>LIMITATIONS</b>	<p>Duration of treatment will be limited to 30 days</p> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>1. Hypersensitivity to nitroimidazole derivatives (metronidazole, tinidazole)</li> <li>2. Prior failure of metronidazole or tinidazole for the current course of infection</li> </ul>
<b>REFERENCES</b>	<ol style="list-style-type: none"> <li>1. Solosec [package insert]. Newark, NJ; Symbiomix Therapeutics LLC; September 2017.</li> <li>2. CDC. Bacterial Vaginosis Statistics. Available at: <a href="https://www.cdc.gov/std/bv/stats.htm">https://www.cdc.gov/std/bv/stats.htm</a>. Accessed November 29, 2017.</li> <li>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.</li> <li>4. Centers for Drug Evaluation and Research. Summary Review. Available at: <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000SumR.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000SumR.pdf</a>. Accessed November 29, 2017.</li> <li>5. Bohbot JM, Vicaut E, Fagnen D, et al. Treatment of bacterial vaginosis: A multicenter,</li> </ol>

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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.
<b>P&amp;T REVIEW HISTORY</b>	1/18
<b>REVISION RECORD</b>	1/18