

**Pharmacy Policy**

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**Systemic Antibiotics**

**Policy Number:** 9.403

**Version Number:** 1

**Version Effective Date:** 1/1/2021

Product Applicability <input type="checkbox"/> <b>All Plan+ Products</b>	
<b>Well Sense Health Plan</b> <input type="checkbox"/> New Hampshire Medicaid	<b>Boston Medical Center HealthNet Plan</b> <input type="checkbox"/> MassHealth - MCO <input type="checkbox"/> MassHealth - ACO <input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- **Dificid (fidaxomicin)**
- **Xifaxan (rifaximin)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<b>Dificid:</b> 1. A diagnosis of C. difficile infection and treatment with Dificid was started in an inpatient facility; <b>OR</b> 2. A diagnosis of C.difficile infection <b>AND</b> an inadequate response or intolerance to a treatment

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	<p>course of oral vancomycin</p> <p><b>Xifaxan 200mg &gt; 9 tablets a year</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of traveler’s diarrhea caused by non-invasive strains of E.Coli; <b>AND</b></li> <li>2. An inadequate response, intolerance, contraindication or history of resistance to ciprofloxacin and azithromycin</li> </ol> <p><b>Xifaxan 550 mg:</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of hepatic encephalopathy; <b>AND</b> An inadequate response, intolerance or contraindication to lactulose therapy; <b>OR</b></li> <li>2. A diagnosis of diarrhea predominant irritable bowel syndrome with diarrhea (IBS-D); <b>AND</b> An inadequate response, intolerance or contraindication to a trial of an antispasmodic and a tricyclic antidepressant; <b>AND</b> An inadequate response to dietary changes (such as restriction of lactose, fructose, gas-producing foods, or caffeine)</li> </ol>
<b>Age Restriction</b>	Xifaxan 200 mg : 12 years or older Xifaxan 550 mg: 18 years or older
<b>Prescriber Restriction</b>	None
<b>Coverage Duration</b>	Initial: Dificid: C.difficile- maximum of 10 days Xifaxan 200 mg: traveller’s diarrhea- maximum of one treatment course Xifaxan 550 mg: hepatic encephalopathy-Maximum of 1 year ; irritable bowel syndrome- Maximum of two (14 days) treatment courses
<b>Other criteria</b>	None

**Applicable Coding:**

Code	Medication
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**Clinical Background Information and References**

1. Murray BE, Treatment options for infections caused by vancomycin-resistant enterococci — Human studies. Up-to-date Database. Updated periodically. Available at: [http://www.utdol.com/utd/content/topic.do?topicKey=hosp\\_inf/2825](http://www.utdol.com/utd/content/topic.do?topicKey=hosp_inf/2825). Accessed: May 07. 1, 20

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2. Hill D, Ericsson C, Pearson R, et al. The practice of travel medicine: Guidelines by the Infectious Disease Society of America. *Clin Infect Dis*. 2006;43:1499-1539.
3. Thomas D Schiano (2010) Treatment Options for Hepatic Encephalopathy. *Pharmacotherapy: Volume 30, Issue* , pp. 16S-21S
4. Cohen SH, Gerding DN, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults: 2010 Update by the Society of Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol* 2010; 31:431
5. Kelly CP, LaMont JT. Treatment of Clostridium difficile infection in adults. Up to Date® . Accessed Oct 13, 2013. Available from: <http://www.uptodate.com>.
6. Wald A, Treatment of Irritable Bowel Syndrome. Up-To-Date Database. Updated periodically. Available at: <http://www.uptodate.com> Accessed: October 28, 2015
7. Jolley J, High-dose rifaximin treatment alleviates global symptoms of irritable bowel syndrome. *Clin Exp Gastroenterol*. 2011; 4: 43–48.
8. Pimental M, Lembo A, et.al. Rifaximin therapy for patients with irritable bowel syndrome without constipation. TARGET studies. *N Engl J Med*. 2011;364(1):22
9. Difidid® (fidaxomicin) prescribing information. Cubist Pharmaceuticals US, Lexington, MA 02421. April, 2014
10. New Treatment Guidelines for Clostridium Difficile. *Pharmacy Times*. Feb 16, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.108 Systemic Antibiotics Policy retired, new policy created	1/1/2021	P&T Committee

### Next Review Date

2021

### Other Applicable Policies

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## Reference to Applicable Laws and Regulations, If Any

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### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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