BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Systemic Antibiotics

Policy Number: 9.403
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☒ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

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

Prior Authorization Policy

Products Affected:

- Dificid (fidaxomicin)
- Xifaxan (rifaximin)
- linezolid
- Sivextro (tedizolid)

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

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	**Dificid:** 1. A diagnosis of C. difficile infection and treatment with Dificid was started in an inpatient facility; ***OR*** 2. A diagnosis of C.difficile infection ***AND*** an inadequate response or intolerance to a treatment course of oral vancomycin

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Xifaxan 200mg > 9 tablets a year

1. A diagnosis of traveler's diarrhea caused by non-invasive strains of E.Coli; ***AND***

2. An inadequate response, intolerance, contraindication or history of resistance to ciprofloxacin and azithromycin

Xifaxan 550 mg:

1. A diagnosis of hepatic encephalopathy; ***AND***

   An inadequate response, intolerance or contraindication to lactulose therapy; **OR**

2. A diagnosis of diarrhea predominant irritable bowel syndrome with diarrhea (IBS-D); ***AND***
   An inadequate response, intolerance or contraindication to a trial of an antispasmodic and a tricyclic antidepressant; ***AND***
   An inadequate response to dietary changes (such as restriction of lactose, fructose, gas-producing foods, or caffeine)

linezolid (IV, suspension, tabs):

Oral Therapy

1. Member has been receiving intravenous therapy with vancomycin, linezolid, Synercid®, Cubicin®, or Tygacil® for a confirmed infection with methicillin-Resistant Staphylococcus aureus (MRSA) or vancomycin–resistant enterococcus (VRE) ***AND*** is being or has been switched over from intravenous antibiotic therapy to oral therapy upon hospital discharge; ***OR***

2. A diagnosis of suspected or confirmed community-acquired MRSA skin infection with documented failure or intolerance to at least one of the following oral antibiotics:
   - sulfamethoxazole/trimethoprim
   - tetracycline antibiotic (doxycycline, tetracycline)
   - clindamycin; ***OR***
3. A diagnosis of community-acquired pneumonia that is resistant to all of the following individual antibiotics or antibiotic classes:

   - Macrolides (e.g. azithromycin, clarithromycin)
   - Fluoroquinolones (e.g. levofloxicin, moxifloxacin)
   - Beta-Lactams (e.g. amoxicillin, amoxicillin/clavulonate)
   - Doxycycline

IV Therapy

1. There is a confirmed infection of methicillin-resistant staphylococcus aureus (MRSA) or vancomycin–resistant enterococcus (VRE) supported by provider documentation; ***AND***

	2. Inability to take oral medications **Sivextro:** **Oral Therapy** 1. Member has been receiving intravenous therapy with vancomycin, Sivextro™, linezolid , Synercid®, Cubicin®, or Tygacil® for a confirmed infection with methicillin-Resistant Staphylococcus aureus (MRSA) or other Sivextro™ susceptible bacteria AND is being or has been switched over from intravenous antibiotic therapy to oral therapy upon hospital discharge; OR 2. A diagnosis of confirmed community-acquired skin or skin structure infections caused by methicillin-resistant staphylococcus aureus (MRSA) or susceptible bacteria with documented susceptibility and failure or intolerance to at least one of the following oral antibiotics: • sulfamethoxazole/trimethoprim • tetracycline antibiotic (doxycycline, tetracycline) • clindamycin; ***AND*** 3. An inadequate response, intolerance, or contraindication to linezolid **IV Therapy** 1. There is a confirmed infection of methicillin-resistant staphylococcus aureus ***(***MRSA) or susceptible bacteria supported by provider documentation; AND 2. Inability to take oral medications; AND 3. An inadequate response, intolerance, or contraindication to linezolid
Age Restriction	Xifaxan 200 mg : 12 years or older Xifaxan 550 mg: 18 years or older Sivextro: 18 years or older
Prescriber Restriction	None
Coverage Duration	Initial: Dificid: C.difficle- 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 Linezolid tab, IV, or suspension: MRSA infections and Community acquired Pneumonia:-maximum of 14 days; VRE infections: maximum of 28 days
Other criteria	None

Applicable Coding:

Code	Medication
J2020	Linezolid injection
J3090	Tedizolid injection

Clinical Background Information and References

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12. Thomas D Schiano (2010) Treatment Options for Hepatic Encephalopathy. Pharmacotherapy: Volume 30, Issue , pp. 16S-21S
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15. Wald A, Treatment of Irritable Bowel Syndrome. Up-To-Date Database. Updated periodically. Available at: http://www.uptodate.com Accessed: October 28, 2015
16. World Gastroenterology Organisation (WGO). World Gastroenterology Organisation Global Guideline: irritable bowel syndrome: a global perspective. Munich (Germany): World Gastroenterology Organization (WGO); 2009 Apr 20. 20 p.
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19. Lui C, et al. Clinical practice guidelines by the infectious diseases society of America for the treatment of methicillin-resistant staphylococcus aureus infections in adults and children. Clin Infect Dis. 2011 Feb 1;52(3):e18-55
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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

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, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

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.