

Pharmacy Policy

Systemic Antibiotics

Policy Number: 9.403
Version Number: 2.0
Version Effective Date: 6/1/2021

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| Product Applicability <input type="checkbox"/> All Plan+ Products | |
| <p>Well Sense Health Plan</p> <input type="checkbox"/> New Hampshire Medicaid | <p>Boston Medical Center HealthNet Plan</p> <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <input 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

Products Affected:

- **Dificid (fidaxomicin)**
- **Xifaxan (rifaximin)**
- **linezolid**
- **Sivextro (tedizolid)**
- **Sirturo (Bedaquiline)**
- **Pretomanid**

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

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| Covered Use | All FDA approved indications not otherwise excluded |
| Exclusion Criteria | None |
| Required | |

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| <p>Medical Information</p> | <p>Dificid:</p> <ol style="list-style-type: none"> 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 <p>Xifaxan 200mg:</p> <ol style="list-style-type: none"> 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 <p>Xifaxan 550 mg:</p> <ol style="list-style-type: none"> 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) <p>linezolid (IV, suspension, tabs):</p> <p>Oral Therapy</p> <ol style="list-style-type: none"> 1. Member has been receiving intravenous therapy with vancomycin, linezolid, 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 skin infections caused by methicillin-resistant staphylococcus aureus (MRSA) and treatment failure, intolerance or a clinical reason why at least one of the following oral antibiotics would not be appropriate: <ul style="list-style-type: none"> • sulfamethoxazole/trimethoprim • tetracycline antibiotic (doxycycline, minocycline) • clindamycin; OR 3. A diagnosis of community-acquired pneumonia that is resistant to all of the following individual antibiotics or antibiotic classes, or a clinical reason why the following oral antibiotics would not be appropriate: <ul style="list-style-type: none"> • Macrolides (e.g. azithromycin, clarithromycin) • Fluoroquinolones (e.g. levofloxacin, moxifloxacin) • Beta-Lactams (e.g. amoxicillin, amoxicillin/clavulonate) |
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- Doxycycline: **OR**

4. A diagnosis of pulmonary extensively drug-resistant (XDR-TB) or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis (MDR-TB); **AND**
 - a. Prescribed in combination with pretomanid and bedaquiline; **AND**
 - b. Prescribed by or in consultation with an infectious disease specialist; **AND**
 - c. Member is 17 years of age or older

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, 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 to Sivextro and treatment failure, intolerance to, or clinical reason why at least one of the following oral antibiotics would not be appropriate :
 - sulfamethoxazole/trimethoprim
 - tetracycline antibiotic (doxycycline, minocycline)
 - 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

Sirturo:

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| | <p>1. Diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB); AND</p> <p>a. Prescribed by or in consultation with an infectious disease specialist or pulmonologist; AND</p> <p>b. Member is 5 years of age or older; AND</p> <p>c. Prescribed in combination with at least 3 other anti-tuberculosis agents; OR</p> <p>2. Diagnosis of pulmonary extensively drug-resistant (XDR-TB) or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis (MDR-TB); AND</p> <p>a. Prescribed in combination with pretomanid and linezolid; AND</p> <p>b. Prescribed by or in consultation with an infectious disease specialist; AND</p> <p>c. Member is 17 years of age or older</p> <p>Pretomanid:</p> <p>1. Diagnosis of pulmonary extensively drug-resistant (XDR-TB) or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis (MDR-TB); AND</p> <p>a. Prescribed in combination with bedaquiline and linezolid; AND</p> <p>b. Prescribed by or in consultation with an infectious disease specialist; AND</p> <p>c. Member is 17 years of age or older</p> |
| Age Restriction | <p>Xifaxan 200 mg : 12 years or older Xifaxan 550 mg: 18 years or older Sivextro: 18 years or older</p> |
| Prescriber Restriction | <p>None</p> |
| Coverage Duration | <p>Initial:</p> <p>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 Linezolid tab, IV, or suspension:</p> <ul style="list-style-type: none"> • MRSA infections and Community acquired Pneumonia:-maximum of 14 days; • VRE infections: maximum of 28 days • Tuberculosis: maximum of 6 months <p>Sirturo and Pretomanid:</p> <ul style="list-style-type: none"> • Tuberculosis: maximum of 6 months |

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| Other criteria | None |
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Applicable Coding:

| Code | Medication |
|-------|---------------------|
| J2020 | Linezolid injection |
| J3090 | Tedizolid injection |

Clinical Background Information and References

1. Thomas M File, Jr, MD. Treatment of community-acquired pneumonia in adults in the outpatient setting. Up-to-Date. Available at <http://www.uptodate.com>, Accessed: Oct 13, 2013
2. Franklin D Lowy, MD. Treatment of skin and soft tissue infections due to methicillin-resistant staphylococcus aureus in adults. Up-to-Date. Available at <http://www.uptodate.com>, Accessed: Oct 20, 2014
3. 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. Accessed: May 07. 1, 20
4. Zyvox® (linezolid) prescribing information. Pharmacia & Upjohn Company, division of Pfizer Inc. New York, NY 10017. July 2015.
- 5.
6. Thomas D Schiano (2010) Treatment Options for Hepatic Encephalopathy. Pharmacotherapy: Volume 30, Issue , pp. 16S-21S
7. 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
8. Kelly CP, LaMont JT. Treatment of Clostridium difficile infection in adults. Up to Date® . Accessed Oct 13, 2013. Available from: <http://www.uptodate.com>.
9. Wald A, Treatment of Irritable Bowel Syndrome. Up-To-Date Database. Updated periodically. Available at: <http://www.uptodate.com> Accessed: October 28, 2015
10. Jolley J, High-dose rifaximin treatment alleviates global symptoms of irritable bowel syndrome. Clin Exp Gastroenterol. 2011; 4: 43–48.
11. 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
12. 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
13. Sivextro™ (tedizolid) prescribing information. Cubist Pharmaceuticals US, Lexington, MA 02421. June 2014
14. Dificid® (fidaxomicin) prescribing information. Cubist Pharmaceuticals US, Lexington, MA 02421. April, 2014
15. New Treatment Guidelines for Clostridium Difficile. Pharmacy Times. Feb 16, 2018.

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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 |

| 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 |
| 2/11/2021 | P&T Review: Minor criteria updates for MRSA, VRE and skin infection indications for linezolid and Sivextro; added criteria for MDR –TB and XDR-TB for linezolid; added drug specific approval criteria for Sirturo and Pretomanid | 06/1/2021 | P&T Committee |

Next Review Date

2/2022

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

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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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