

Clostridioides difficile-Associated Infection, Prevention of Recurrence

Goal(s):

- To optimize appropriate prevention of recurrent *Clostridioides difficile*-associated infection (CDI). Recurrent CDI is defined by Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) as an episode of CDI that occurs less than 8 weeks after the onset of a previous CDI episode, if CDI symptoms from the previous episode were resolved.

Length of Authorization:

- Bezlotoxumab (ZINPLAVA): One-time infusion
- Fecal microbiota, live-jslm (REBYOTA): One-time rectal administration
- Oral fecal microbiota spores, live-brpk (VOWST): 4 capsules once daily x 3 days (12 capsules total)

Requires PA:

- Drugs approved to prevent recurrence of CDI:
 - Bezlotoxumab for intravenous infusion (physician administered and pharmacy claims)
 - Fecal microbiota, live-jslm suspension for rectal administration (physician administered and pharmacy claims)
 - Oral fecal microbiota spores, live-brpk (pharmacy claims)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Does the indication match the FDA-approved indication?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the request for an FDA approved-age?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Is the request for bezlotoxumab?	Yes: Go to #5	No: Go to #8

Approval Criteria

<p>5. Is this recurrent of <i>Clostridioides difficile</i>-associated infection (CDI) within 6 months of CDI OR Is the patients presenting with a primary CDI episode and has other risk factors for CDI recurrence (such as age \geq65 years, immunocompromised host, or severe CDI on presentation)? *</p> <p>*Per 2021 IDSA/SHEA guidance¹</p>	<p>Yes: Go to #6</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>6. Has the patient received either the fecal microbiota rectal suspension or a 3 day-course of the oral fecal microbiota spores?</p>	<p>Yes: Go to #7</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>7. Is the patient currently receiving vancomycin or fidaxomicin?</p>	<p>Yes: Approve one dose</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Is this the second or more recurrence of a <i>Clostridioides difficile</i>-associated infection?*</p> <p>*Per 2021 ACG and 2022 NICE guidance^{2,3}</p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>9. Will the patient have recently completed a 10-day course of vancomycin or fidaxomicin prior to starting therapy?</p>	<p>Yes: Approve for 1 course of treatment (see Length of Authorization)</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

1. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults. Clin Infect Dis. 2021; 73(5):1029-e1044.
2. Kelly CR, Fischer M, Allegretti JR, et al. American College of Gastroenterology Clinical Guidelines: Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections. The American Journal of Gastroenterology. 2021; 116(6):1124-1147.
3. National Institute for Health and Care Excellence (NICE): Fecal microbiota transplant for recurrent *Clostridioides difficile* infection. August 31, 2022. <https://www.nice.org.uk/guidance/mtg71> Accessed February 27, 2023.

P&T / DUR Review: 8/23 (DM); 6/23
Implementation: 9/1/23; 7/1/23