SENTARA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Zinplava® (bezlotoxumab) **(J0565) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Quantity Limits:

A. Length of Authorization:

- Coverage limited to a single dose of 10 mg/kg administered as an intravenous infusion over 60 minutes

B. Units (per dose and over time) [HCPCS Unit]:

- 1,000 mg/40 mL single-dose vial: 100 billable units

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is 1 year of age or older
- ❑ Medication must be prescribed by or in consultation with **ONE** of the following specialists:
  - ❑ Infectious Disease Specialist
  - ❑ Gastroenterologist Specialist
- ❑ Member has a diagnosis of Clostridium difficile infection (CDI) confirmed by **BOTH** of the following:
  - ❑ Diarrhea (3 or more loose bowel movements within 24 hours or less)
  - ❑ Positive stool test for toxigenic C. difficile from a stool sample collected no more than 7 days prior
- ❑ This episode of CDI is a recurrence (total of at least 2 episodes) in the past 6 months with previous treatment (e.g., vancomycin, fidaxomicin, including a pulsed vancomycin regimen)
- ❑ Member will receive or is currently receiving concomitant antibacterial drug treatment for CDI (e.g., vancomycin, fidaxomicin)
- ❑ Member is considered "high risk" for initial CDI defined as any of the following **(check all that apply)**:
  - ❑ Age ≥ 65 years
  - ❑ History of 1 or more CDI episodes within the previous six months
  - ❑ Compromised immunity
  - ❑ Documentation of hypervirulent strain (strains 027, 078, 244)
  - ❑ Clinically severe CDI (defined by a Zar score of ≥ 2 points): Age > 60 years (1 point); Body temperature > 38.3°C (1 point); Albumin level 2.5 mg/dL (1 point); Peripheral white blood cell count > 15,000 cells/mm^3 within 48 hours (1 point); Endoscopic evidence of pseudomembranous colitis (2 points); Treatment in Intensive Care Unit (2 points)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.