defibrotide (Defitelio)

Commercial Medical Benefit Drug Policy

Place of Service
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: Profibrinolytic agent
HCPCS:
J3490:Unclassified drugs
How Supplied:
200 mg/2.5 mL (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Hepatic Veno-Occlusive Disease (VOD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Hepatic Veno-Occlusive Disease (VOD)
Meets medical necessity if all the following are met:

1. Being used for the prophylaxis/prevention or treatment of hepatic VOD with renal or pulmonary dysfunction
2. Meets ONE of the following:
   a. For VOD prophylaxis and all the following:
      i. Started up to 30 days prior to hematopoietic stem cell transplantation (HSCT) with conditioning therapy
      ii. Being used up to 30 days post-HSCT
   b. For VOD treatment and all the following:
      i. Being used following hematopoietic stem-cell transplantation (HSCT)
3. Not being covered under the case rate

Covered Doses:
Prophylaxis/Prevention in Children:
Up to 40 mg/kg given intravenously daily for up to 60 days total treatment (Up to 30 days prior to HSCT and up to 30 days post-HSCT)
Prophylaxis/Prevention in Adults:
Up to 1600 mg given intravenously daily for up to 60 days total treatment (Up to 30 days prior to HSCT and up to 30 days post-HSCT)
Treatment: up to 6.25 mg/kg given intravenously every 6 hours for up to 60 days post-HSCT

Coverage Period:
2 months

ICD-10:
K76.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Bonifazi F, Sica S, et al. Veno-occlusive Disease in HSCT Patients: Consensus-based Recommendations for Risk Assessment, Diagnosis, and Management by the GITMO Group. Transplantation. 2021 Apr 1;105(4):686-694.
3. Defitelio (defibrotide sodium) Prescribing Information. Jazz Pharmaceuticals, Palo Alto, CA: 12/2022.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee