Defibrotide (Defitelio®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration HCPCS: J3490 NDC: • 68727-800-01: 200 mg/2.5 mL, single use vial • 68727-800-02: 200mg/2.5ml, case size of 10 single use vials

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

- Hepatic veno-occlusive disease (VOD)
  - Treatment
  - Prophylaxis and prevention

AHFS therapeutic class: Antithrombotic
Mechanism of action: Profibrinolytic agent

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via f.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Defitelio® (defibrotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hepatic veno-occlusive disease (VOD)

1. Being used for the prophylaxis/prevention or treatment of hepatic VOD with renal or pulmonary dysfunction, **AND**
2. 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, and
      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)

   AND
3. Not being covered under the case rate

Covered Dose
Prophylaxis/Prevention in Children:
Up to 40 mg/kg/day 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/day 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 IV every 6 hours for up to 60 days post-HSCT

Coverage Period
2 months

ICD-10:
K76.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Defitelio® (defibrotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How Supplied:
200 mg/2.5 mL (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- 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.
- Defitelio (defibrotide sodium) [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals. 12/2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update
Date of last review: 1Q2024
Date of next review:1Q2025
Changes from previous policy version:
- No clinical change to policy following routine annual review.