MEDICATION POLICY:
Hepcludex (bulevirtide-gmod)

Applicable Drugs: Hepcludex (bulevirtide-gmod)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/31/2026

Date Last Reviewed / Revised: 8/31/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documentation of diagnosis of chronic hepatitis D (HDV) and must meet ALL the following criteria:
   A. Documented positive serum anti-hepatitis delta virus (HDV) antibody results or PCR results for serum/plasma HDV RNA.
   B. Documented elevated serum ALT levels (ALT >1 x ULN but <10 x ULN).
   C. Documented baseline serum albumin > 28 g/L.

II. Age requirement: 18 years or older

III. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, hepatologist, or oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Cirrhosis or Child-Pugh hepatic insufficiency >7 points.
- Concurrent HCV.
- Active HIV infection.
- Renal insufficiency with CrCL < 60 mL/min.

OTHER CRITERIA

- Documented treatment failure with Pegasys (pegylated Interferon alfa-2a).

Quantity / Days Supply Restrictions

- Thirty 8.5 mg subcutaneous injections per 30 days supply.

Approval Length

- **Authorization:** 48 weeks
- **Re-Authorization:** 48 weeks, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

References

1. Hepcludex. Prescribing information. Gilead Sciences, Inc; 2026. Accessed August 31, 2026.
2. American Gastroenterological Association. AGA Clinical Practice Update on Management of Hepatitis Delta: Commentary. Gastroenterology. 2025;1063-1069.
3. Wedemeyer H, Aleman S, Brunetto MR, et al. A Phase 3, Randomized Trial of Bulevirtide in Chronic Hepatitis D. N Engl J Med. 2023;389(1):22-32. doi:10.1056/NEJMoa2213429
4. Wedemeyer H, Aleman S, Brunetto M, et al. Bulevirtide monotherapy in patients with chronic HDV: Efficacy and safety results through week 96 from a phase III randomized trial. J Hepatol. 2024;81(4):621-629. doi:10.1016/j.jhep.2024.05.001
5. Abdrakhman A, Ashimkhanova A, Almawi WY. Effectiveness of pegylated interferon monotherapy in the treatment of chronic hepatitis D virus infection: A meta-analysis. Antiviral Res. 2021;185:104995. doi:10.1016/j.antiviral.2020.104995