UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2422-1
Program	Prior Authorization/Medical Necessity
Medication	Hepcludex® (bulevirtide-gmod)
P&T Approval Date	6/2026
Effective Date	9/1/2026

1. Background:

Hepcludex is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

This indication is approved under accelerated approval based on participants who achieved a decrease in HDV RNA and alanine aminotransferase (ALT) normalization. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Hepcludex** will be approved based upon **all** of the following criteria:

   a. Diagnosis of **chronic** hepatitis delta virus (HDV) infection

   -AND-

   b. Submission of medical records (e.g., chart notes, laboratory results) documenting detectable HDV RNA within the past 6 months

   -AND-

   c. Submission of medical records (e.g., chart notes, laboratory values) documenting active liver disease as confirmed by **one** of the following within the past 12 months:

      (1) ALT above the upper limit of normal (ULN)
      (2) Evidence of hepatic fibrosis by noninvasive testing (e.g., transient elastography)
      (3) Liver biopsy demonstrating hepatic fibrosis or active inflammation

   -AND-

   d. **One** of the following:

      (1) Patient is without cirrhosis

      -OR-

      (2) Patient has compensated cirrhosis

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Gastroenterologist
(2) Hepatologist
(3) Infectious disease specialist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Hepcludex** will be approved based upon **both** of the following criteria:

a. Documentation of positive clinical response (e.g., ALT normalization, improvement in or stabilization of fibrosis, undetectable HDV RNA level)

-AND-

b. Prescribed by or in consultation with **one** of the following:

(1) Gastroenterologist
(2) Hepatologist
(3) Infectious disease specialist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Hepcludex [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2026.
2. 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
3. Wedemeyer H, Aleman S, Blank A, et al. 144 Weeks of bulevirtide monotherapy for chronic hepatitis D: Final and posttreatment results from a Phase 3 randomized trial. *J Hepatol*. Published online April 9, 2026. doi:10.1016/j.jhep.2026.03.046
4. Asselah T, Chulanov V, Lampertico P, et al. Bulevirtide Combined with Pegylated Interferon for Chronic Hepatitis D. *N Engl J Med*. 2024;391(2):133-143. doi:10.1056/NEJMoa2314134

5. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67(4):1560-1599. doi:10.1002/hep.29800
6. Kushner T, Cohen SM, Ahn J, Wong RJ. AGA Clinical Practice Update on Management of Hepatitis Delta: Commentary. *Gastroenterology*. 2025;169(5):1063-1069. doi:10.1053/j.gastro.2025.07.037
7. Cornberg M, Zoulim F, Gish R, et al. Best practices for screening, testing, diagnosing, and treating patients with hepatitis D (delta) virus based on global expert review and recent guidelines. *Antivir Ther*. 2025;30(4):13596535251349380. doi:10.1177/13596535251349380
8. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on hepatitis delta virus. *J Hepatol*. 2023;79(2):433-460. doi:10.1016/j.jhep.2023.05.001
9. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on the management of hepatitis B virus infection. *J Hepatol*. 2025;83(2):502-583. doi:10.1016/j.jhep.2025.03.018

Program	Prior Authorization/Medical Necessity - Hepcludex
Change Control	
6/2026	New program.