

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1523-1
Program	Prior Authorization/Notification
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 **both** of the following criteria:

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

-AND-

b. **One** of the following:

(1) Patient is without cirrhosis

-OR-

(2) Patient has compensated cirrhosis

Authorization will be issued for 12 months.

B. Reauthorization

1. **Hepcludex** will be approved based upon the following criterion:

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

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 and/or Medical Necessity may be in place.

4. References:

1. Hepcludex [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2026.

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