AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Hepcludex	Page:	1 of 2
Effective Date:	8/28/2026	Last Review Date:	7/13/2026
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☐Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Hepcludex under the patient's prescription drug benefit.

Description:

FDA-approved Indications
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 a decrease in HDV RNA and alanine aminotransferase (ALT) normalization. An improvement in disease-related clinical outcomes has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Hepcludex

Policy/Guideline:

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis D virus infection.

Coverage Criteria

Chronic Hepatitis Delta Virus (HDV) Infection
Authorization of 12 months may be granted for treatment of chronic HDV infection in adults without cirrhosis or with compensated cirrhosis when ALL of the following criteria are met:

- Diagnosis of chronic HDV infection is confirmed by ALL of the following criteria:
  - A positive serum anti-HDV antibody result.
  - A positive polymerase chain reaction (PCR) result for HDV RNA within the past 6 months.
  - The HDV infection has been present for greater than 6 months.
- Member has a pretreatment elevated serum alanine aminotransferase (ALT) level.
- No current or previous decompensated liver disease (e.g., coagulopathy, hepatic encephalopathy, ascites, esophageal varices hemorrhage).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic HDV infection who achieve or maintain positive clinical response (e.g., decreased HDV RNA level, alanine aminotransferase [ALT] normalization).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: 8.5mg single dose vial – 30 vials per 30 days

References:

1. Hepcludex [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2026.
2. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on hepatitis delta virus. J Hepatol. 2023 Aug;79(2):433-460. doi: 10.1016/j.jhep.2023.05.001. Epub 2023 Jun 24.
3. Pan C, Gish R, Jacobson IM, Hu KQ, Wedemeyer H, Martin P. Diagnosis and Management of Hepatitis Delta Virus Infection. Dig Dis Sci. 2023 Aug;68(8):3237-3248. doi: 10.1007/s10620-023-07960-y. Epub 2023 Jun 20. Erratum in: Dig Dis Sci. 2023 Oct;68(10):4062-4063.
4. Wedemeyer H, Aleman S, Brunetto MR, Blank A, Andreone P, Bogomolov P, Chulanov V, Mamonova N, Geyvandova N, Morozov V, Sagalova O, Stepanova T, Berger A, Manuilov D, Suri V, An Q, Da B, Flaherty J, Osinusi A, Liu Y, Merle U, Schulze Zur Wiesch J, Zeuzem S, Ciesek S, Cornberg M, Lampertico P; MYR 301 Study Group. A Phase 3, Randomized Trial of Bulevirtide in Chronic Hepatitis D. N Engl J Med. 2023 Jul 6;389(1):22-32.
5. World Health Organization (WHO). Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. https://www.who.int/publications/i/item/9789240090903. Published March 29, 2024. Accessed June 1, 2026.