

Bulevirtide-gmod (HEPCLUDEX) for Chronic Hepatitis D Virus (HDV) Infection Criteria for Use September 2026

VA Pharmacy Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for bulevirtide.

- ☐ Known hypersensitivity to bulevirtide
- ☐ CrCl <15 mL/min
- ☐ Moderate to severe hepatic impairment, defined as Child-Pugh Class B or C
- ☐ Severe cirrhosis-related thrombocytopenia (e.g., platelet count <60,000 cells/mm³)
- ☐ Active or suspected malignancy, history of malignancy, or untreated pre-malignancy disorder within the last 5 years¹

1 Exceptions: successfully treated carcinoma of the cervix in situ, basal cell or squamous cell carcinoma of the skin

Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ Care provided by a VA/VA Community Care Infectious Diseases or Gastroenterology provider
- ☐ Diagnosis of chronic HDV infection established by laboratory testing²
- ☐ Concomitant treatment of underlying HBV infection, as clinically appropriate

2 Positive serum anti-HDV antibody or detectable HDV RNA for at least 6 months prior to treatment initiation

Additional Inclusion Criteria

ONE of the following must be selected to meet criteria.

- ☐ Compensated cirrhosis, staged via histology or non-invasive tests (e.g., transient elastography, fibrosis scores, etc.)
- ☐ Persistently elevated ALT, defined as > 1x ULN but <10x ULN, for at least 3 months

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