

SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Hepcludex[®] (bulevirtide-gmod)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: SUBQ: 8.5 mg once daily.

Quantity Limit: 1 vial per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ☐ Member is 18 years of age or older
- ☐ Prescribed by or in consultation with an infectious disease specialist, hepatologist, gastroenterologist or liver transplant specialist

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- ☐ Member has had coinfection with hepatitis B and hepatitis D for at least 6 months, as confirmed by **ALL** the following (**please provide test results**):
 - ☐ Positive HDV antibody test or HDV RNA polymerase chain reaction (PCR) test completed at least 6 months prior to start of treatment
 - ☐ Current HDV RNA detected in serum by PCR test
 - ☐ Current alanine aminotransferase (ALT) level of > 1 to < 10 -times the upper limit of the normal range (ULN)
- ☐ Member is currently established on treatment for hepatitis B infection according to standard of care and will continue to receive treatment for hepatitis B infection
- ☐ Member does **NOT** have diagnosis of decompensated cirrhosis (Child-Pugh Class B or C) (**please provide test results documenting compensated cirrhosis or absence of cirrhosis**)
- ☐ Provider attests that hepatic function will be monitored closely for at least 6 months in members who discontinue Hepcludex

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ Member continues to meet diagnostic criteria in initial authorization section above
- ☐ Member has a documented positive response to therapy as evidenced by **ONE** of the following (**please provide current supporting lab test results**):
 - ☐ $A \geq 2 \log_{10}$ decline in hepatitis D virus (HDV) RNA from baseline
 - ☐ Undetectable HDV RNA level
 - ☐ Normalization of alanine aminotransferase level
- ☐ Member is currently receiving and will continue to receive treatment for hepatitis B infection according to standard of care
- ☐ Member does **NOT** have diagnosis of decompensated cirrhosis (Child-Pugh Class B or C) (**please provide test results documenting compensated cirrhosis or absence of cirrhosis**)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****