Prior Authorization Guideline

Guideline Name	Hepcludex

Guideline Note:

Effective Date:	10/1/2026

1 . Criteria

Product Name: Hepcludex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis D infection

AND

2 - Prescribed by or in consultation with one of the following:
2.1 Gastroenterologist

OR

2.2 Hepatologist

OR

2.3 Infectious disease specialist

AND

3 - Patient is 18 years of age or older

AND

4 - Medical record documentation showing detectable serum HDV RNA levels within the last 6 months

AND

5 - Provider attestation of one of the following:
5.1 Clinical failure with peginterferon alfa-2a

OR

5.2 Contraindication to peginterferon alfa-2a therapy

Product Name: Hepcludex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Medical record documentation of one of the following:
1.1 Reduction in HDV RNA levels

OR

1.2 Reduction or normalization of ALT lab values from baseline