Bulevirtide

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards & & Governance	N/A

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1. Abstract

1.1 For Members

Bulevirtide is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult and paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease

1.2 For Medical Professionals

Bulevirtide acetate is an antiviral medication for the treatment of chronic hepatitis D (in the presence of hepatitis B). Bulevirtide works by attaching to and blocking a receptor (target) through which the hepatitis delta and hepatitis B viruses enter liver cells. By blocking the entry of the virus into the cells, it limits the ability of HDV to replicate and its effects in the body, reducing symptoms of the disease.

Dosage and Administration

- Recommended dosage: 2 mg once daily (every 24 hours ± 4 hours) by subcutaneous injection.
- The recommended dose of bulevirtide in paediatric patients is based on weight as detailed in the Table below.

Body Weight (Kg)	Dosing of reconstituted bulevirtide 2 mg powder for solution for injection (ml)	Bulevirtide Daily Dose
10 kg to < 25 kg	0.5 ml	1 mg
25 kg to < 35 kg	0.75 ml	1.5 mg
35 kg and above	1 ml	2 mg

• It can be given as monotherapy or in co-administration with a nucleoside/nucleotide analogue for treatment of underlying hepatitis B virus (HBV) infection.

Missed dose

• If an injection has been omitted and less than 4 hours have elapsed since the scheduled time, the injection must be performed as soon as possible.

• If an injection has been missed and more than 4 hours have elapsed since the scheduled time, the missed dose should not be administered. The next injection will take place according to the usual schedule (injection of the prescribed dose without doubling), at the appointed time the next day.

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Bulevirtide. It also highlights the medical criteria for coverage and re-fill.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

- It is intended for use under the guidance of a healthcare provider.
- Patient should have no prior history of anaphylaxis, to other agents, such as foods, drugs, biologics, etc. including Bulevirtide.
- Bulevirtide is indicated for adult and paediatric patients ≥3 years of age weighing ≥10 kg with compensated liver disease.
- Bulevirtide is covered only in policies where all hepatitis treatments are covered (Premium and Thiqa).

Initial Approval Criteria

Chronic Hepatitis D Infection including all criteria below:

- Diagnosis of chronic HDV infection as evidenced by detectable serum HDV RNA levels by quantitative assay in the last 6 months.
- Two elevated alanine transaminase (ALT) lab values within the past 12 months (≥ 70IU/L for men, ≥ 50 IU/L for women)
- Child-Pugh hepatic insufficiency score < 7 (Child-Pugh Class A)
- No previous (within the last 2 years) or current decompensated liver disease, including coagulopathy, hepatic encephalopathy.
- Dose does not exceed 2 mg (1 vial) per day.

Continued Therapy

- Member is responding positively to therapy as evidenced by both of the following.
- A reduction in HDV RNA levels or undetectable HDV RNA levels by quantitative assay.
- Child-Pugh hepatic insufficiency score < 7 (Child-Pugh Class A).
- A reduction or normalization (≤ 35 IU/L for men, ≤ 25 IU/L for women) of ALT lab values
- If request is for a dose increase, new dose does not exceed 2 mg (1 vial) per day.

3.2 Requirements for Coverage

- Failure to submit the medical reports upon request or when requesting a clinical history, indication for the need for refill will result in rejection of claim.
- Kindly code the ICD-10 and the drug codes to the highest level of specificity.
- Bulevirtide has plan-wise coverage and can be billed based on medical necessity.
- Bulevirtide is covered only in policies where all hepatitis treatments are covered (Premium and Thiqa).
- This drug is listed under indicator for Abu Dhabi governmental products.
- Eligible clinician specialities are as follows:

Eligible Specialties
Gastroenterology
Tropical Medicine/Gastroenterology and Hepatology
Internal Medicine
Haematology
Tropical Medicine
Infectious Diseases

3.3 Non-Coverage

- Not covered for Visitor plan and Basic plan.
- For less than 3 years of age and less than 10kg weight
- Ineligible ordering or prescribing clinicians.
- Not covered for patients with non-compensated Liver disease
- For Enhanced plans, Hepatitis D as a standalone diagnosis is not covered except Premier plan. If the drug has a direct impact on Hepatitis B treatment , then it is covered as per the benefit of Viral hepatitis on the schedule of benefits.

3.4 Payment and Coding Rules

- Kindly apply regulator payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by Daman to the providers.

Code	Code Description
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

https://www.ema.europa.eu/en/medicines/human/EPAR/hepcludex

https://www.medicines.org.uk/emc/product/13482/smpc#gref

Hepcludex, INN-bulevirtide (europa.eu)

https://www.ema.europa.eu/en/medicines/human/EPAR/hepcludex

5.2 Revision History

Date	Version No.	Change (s)
15/04/2024	V1.0	Release of V1.0
25/12/2024	V2.0	Release of V2.0
12/12/2025	V3.0	Guideline review/ Age rule and Dose Updated