



CLINICAL RELEVANCE

Bulevirtide is conditionally approved by EMA and it has been shown to be an efficacious and well-tolerated treatment for the management of chronic HDV. Today, it is the only approved specific treatment for HDV. It needs to be injected subcutaneously every day for an undefined period.



SERVICE DELIVERY ENABLERS

Bulevirtide is approved as monotherapy or in combination with nucleos(t)ide analogues for hepatitis B management. The diagnosis of HDV is challenging in most LMICs. When diagnosed with active HDV infection, people will need to attend an appropriately equipped health care facility (cold chain) to receive the reconstituted daily injection provided by trained medical staff.



MANUFACTURING

The product has a medium complexity associated with chemical manufacture of synthetic peptide (47 AA). The product is lyophilised. Aseptic processing is required. Shelf life is 2 years under refrigeration.



DISEASE BURDEN

Globally, hepatitis delta virus (HDV) affects nearly 5% of people who have a chronic infection with HBV (HBV infections were estimated by WHO to be 296 million in 2019). HDV co-infection is associated with worse outcomes and could explain about 1 in 5 cases of liver disease and liver cancer in people with HBV infection.



INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on bulevirtide is granted in key countries of manufacture such as India, China, Brazil and South Africa and is expected to expire in 2028. Secondary patents on long-acting formulations may be filed.



REGULATORY

Bulevirtide is approved by the European Medicines Agency. Potential sublicensees of bulevirtide could rely on the EU-M4all mechanism for quality assurance. Comparative analytical characterization of the active pharmaceutical ingredient will be required, along with physicochemical comparison of formulation for bioequivalence. Biowaiver could be possible with qualitative and quantitative similarity (Q1/Q2).



MARKET

Access plans for bulevirtide in LMICs are unknown. For its oral hepatitis C medicines, Gilead had issued voluntary licensing agreements to multiple manufacturers. It is unclear whether a similar approach would be taken for this medicine.

BULEVIRTIDE



VIRAL HEPATITIS
Hepatitis D virus

Gilead