

**HEPSERA
(adefovir)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Hepsera (adefovir) is an acyclic nucleotide analog of adenosine monophosphate which is phosphorylated to the active metabolite adefovir diphosphate by cellular kinases. Hepsera inhibits Hepatitis B virus (HBV) DNA polymerase by competing with the natural substrate deoxyadenosine triphosphate and by causing DNA chain termination after its incorporation into viral DNA (1).

Regulatory Status

FDA-approved indication: Hepsera is indicated for the treatment of chronic hepatitis B virus (HBV) infection (1).

Summary

Hepsera (adefovir) is an acyclic nucleotide analog of adenosine monophosphate which is phosphorylated to the active metabolite adefovir diphosphate by cellular kinases. Hepsera inhibits Hepatitis B virus (HBV) DNA polymerase by competing with the natural substrate deoxyadenosine triphosphate and by causing DNA chain termination after its incorporation into viral DNA (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Hepsera while maintaining optimal therapeutic outcomes.

References

1. Hepsera [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2018.