



Final Appraisal Recommendation

Advice No: 0715 – March 2015

**Entecavir (Baraclude®) 0.5 mg and 1 mg film coated tablets,
0.05 mg/ml oral solution**

**Submission by
Bristol-Myers Squibb Pharmaceuticals Ltd**

Recommendation of AWMSG

Entecavir (Baraclude®) is recommended as an option for use within NHS Wales for the treatment of chronic hepatitis B virus (HBV) infection in:

- **adults with decompensated liver disease;**
- **nucleoside naive paediatric patients from 2 to < 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase (ALT) levels, or histological evidence of moderate to severe inflammation and/or fibrosis.**

Additional note(s):

- This advice incorporates and replaces the existing AWMSG recommendation for entecavir (Baraclude®) for the treatment of chronic hepatitis B virus infection in adults with decompensated liver disease (advice number 0212, originally published February 2012).
- Please refer to the Summary of Product Characteristics for the full licensed indication.
- Please refer to the NICE website for recommendations on the use of entecavir for other indications.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference numbers 438 and 2546), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.



Marketing authorisation holder on first issue	Bristol-Myers Squibb Pharmaceuticals Ltd
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