

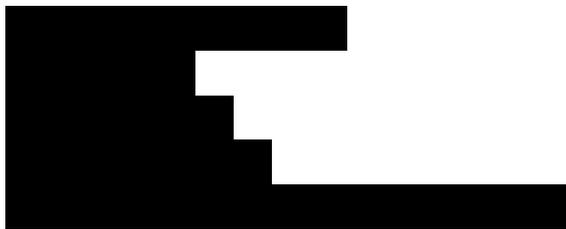
Hepatitis B Foundation UK response to the NICE Entecavir STA

- Hepatitis B Foundation UK is pleased to learn that NICE is minded to recommend entecavir in the e-antigen positive population.
- The Foundation is distressed to hear that NICE is minded to refuse entecavir in the e-antigen negative population.
- The Foundation is concerned that these patients with potentially higher circulating rates of the virus may be denied treatment, as there is no alternative. The aim of therapy is to prevent progression of the disease to cirrhosis and end stage liver disease. If the disease has not progressed to cirrhosis then prevention of progression to advanced fibrosis or cirrhosis is desirable. There is a dearth of economic information concerning treatment of patients who require hospitalisation for cirrhosis and a liver transplant in the UK. However, in the USA costs of the former are estimated to be \$14063 and the latter \$89076. The Department of Health estimates the cost of a liver transplant in 2004 was some £18.370 and the recipient also requires a large number of expensive medicines and outpatient consultations as well as immunotherapy for life. In addition, there is the growing cost of treatment for hepatocellular carcinoma which again can have cost implications in terms of both surgery and chemotherapy. In determining the value of new drugs for the treatment of chronic hepatitis B, drug acquisition must be balanced against expected benefits in morbidity and mortality and cost avoidance from disease progression. Progression can be halted if HBV DNA remains suppressed and resistance or relapse do not occur. It is well known that resistance develops in patients receiving therapy such as lamivudine, with 80% becoming resistant in five years. With the drug adefovir resistance has also developed, with 80% of patients developing resistance within five years.
- For e-negative patients there is little, in fact no, alternative for them if NICE is minded to refuse. This leads to the question of public health and safety when the UK will have a growing number of

individuals not having their HBV DNA suppressed and yet living in the community until they require expensive treatments and therapy

- The Foundation feels that NICE has to consider carefully the economic implications if entecavir is refused for e-negative patients for they will no doubt further down the patient pathway be given other probably less cost effective treatment. Meanwhile the UK continues to run the risk of onward transmission of the disease.

Comments from the trustees and medical advisors of the Hepatitis B Foundation UK for complete list please visit www.hepb.org.uk about us



30th April 2008