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30 March 2005

To: All Pharmaceutical Suppliers, Medical Groups and Interested Parties

CONSULTATION ON WIDENING ACCESS TO LAMIVUDINE

PHARMAC proposes to widen access to lamivudine from 1 June 2005. Hepatitis B surface antigen positive (HbsAg) patients who are receiving chemotherapy for a malignancy would be able to access fully subsidised lamivudine from commencement and up to two months after chemotherapy treatments have ceased. Patients must meet the other relevant Special Authority criteria for access to fully subsidised lamivudine.

The Special Authority would be as indicated on page 2.

This proposal will be considered by the PHARMAC Board or by the Chief Executive under Delegated Authority in April 2005. If you have comments to make on this proposal and would like those comments to be considered by the PHARMAC Board or the Chief Executive then please send them to Deepti Chotai at PHARMAC **by 5 p.m. on 13 April 2005**. The Board will consider all comments submitted by this date.

Yours sincerely



Wayne McNee
Chief Executive

INITIAL APPLICATION

Applications only from a relevant specialist. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

<input type="checkbox"/> HBsAg positive for more than 6 months and <input type="checkbox"/> HBeAg positive or HBV DNA positive defined as >0.6 pg/ml by quantitative PCR at reference laboratory and <input type="checkbox"/> ALT greater than twice upper limit of normal or stage 3 or 4 fibrosis, or liver histology or clinical/radiological evidence of cirrhosis
or <input type="checkbox"/> HBV DNA positive cirrhosis prior to liver transplantation
or <input type="checkbox"/> HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant
or <input type="checkbox"/> Hepatitis B surface antigen positive (HbsAg) patient who is receiving chemotherapy for a malignancy, or who has received such within the previous two months

and

<input type="checkbox"/> No continuing alcohol abuse or intravenous drug use and <input type="checkbox"/> Not coinfectd with HCV, HDV, or HIV and <input type="checkbox"/> Neither ALT nor AST greater than 10 times upper limit of normal and <input type="checkbox"/> No known or suspected hepatocellular carcinoma (AFP > 100 or liver mass on imaging) unless awaiting liver transplantation or curative treatment and <input type="checkbox"/> Not pregnant or breast feeding and <input type="checkbox"/> No history of hypersensitivity to lamivudine and <input type="checkbox"/> No previous lamivudine therapy with breakthrough (presumed YMDD mutant)
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RENEWAL

Current approval Number:.....

Applications only from a relevant specialist. Approvals valid for 2 years.

Prerequisites (tick boxes where appropriate)

<input type="checkbox"/> Have maintained continuous treatment with lamivudine and
<input type="checkbox"/> Most recent test result shows continuing biochemical response (normal ALT) or <input type="checkbox"/> HBeAg negative or <input type="checkbox"/> HBV DNA negative defined as < 0.6 pg/ml by quantitative PCR at reference laboratory
and
<input type="checkbox"/> Have had less than three years of access to treatment with lamivudine or <input type="checkbox"/> There is evidence of cirrhosis