

# APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER Reg No:** .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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Fax Number: .....      Fax Number: .....

## Lamivudine

### INITIAL APPLICATION

Applications only from a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 1 year.

#### Prerequisites (tick boxes where appropriate)

HBsAg positive for more than 6 months

and

HBeAg positive or HBV DNA positive defined as > 100,000 copies per ml by quantitative PCR at a reference laboratory

and

ALT greater than twice upper limit of normal or bridging fibrosis or cirrhosis (Metavir stage 3 or 4 or equivalent) on liver histology  
clinical/radiological evidence of cirrhosis

or

HBV DNA positive cirrhosis prior to liver transplantation

or

HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant

or

Hepatitis B surface antigen positive (HbsAg) patient who is receiving chemotherapy for a malignancy, or who has received such treatment within the previous two months

and

No continuing alcohol abuse or intravenous drug use

and

Not coinfecting with HCV or HDV

and

Neither ALT nor AST greater than 10 times upper limit of normal

and

No history of hypersensitivity to lamivudine

and

No previous lamivudine therapy with genotypically proven lamivudine resistance

#### Use next page for: Renewal

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....

Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131

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**Lamivudine - continued**

**RENEWAL**

Current approval Number (if known):.....

Applications only from a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 2 years.

**Prerequisites** (tick boxes where appropriate)

**Renewal for patients who have maintained continuous treatment and response to lamivudine**

Have maintained continuous treatment with lamivudine  
**and**  
 Most recent test result shows continuing biochemical response (normal ALT)  
**and**  
 HBV DNA <100,00 copies per ml by quantitative PCR at a reference laboratory

or

**Renewal when given in combination with adefovir dipivoxil for patients with cirrhosis and resistance to lamivudine**

Lamivudine to be used in combination with adefovir dipivoxil  
**and**  
 Patient is cirrhotic  
**and**  
**Documented resistance to lamivudine, defined as:**  
 Patient has raised serum ALT (> 1 x ULN)  
**and**  
 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir  
**and**  
 Detection of M204I or M204V mutation

or

**Renewal when given in combination with adefovir dipivoxil for patients with resistance to adefovir dipivoxil**

Lamivudine to be used in combination with adefovir dipivoxil  
**and**  
**Documented resistance to adefovir, defined as:**  
 Patient has raised serum ALT (> 1 x ULN)  
**and**  
 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir  
**and**  
 Detection of N236T or A181T/V mutation

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....