Ministry of Health
Phone 0800 243 666

APPLICATION FOR WAIVER OF RULE BY SPECIAL AUTHORITY

Form SA0997
September 2010

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: ....
Reg No:	First Names:	First Names: ....
Name:	Surname:	Surname: ....
Address:	DOB:	Address: ....
....	Address:	....
....	....	....
Fax Number:	....	Fax Number: ....

Tenofovir

INITIAL APPLICATION - Drug-Resistant Chronic Hepatitis B
Applications only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

☐ Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months)

and

☐ Patient has had previous lamivudine, adefovir or entecavir therapy

and

Documented drug resistance, defined as both:

☐ ALT greater than upper limit of normal; or ≥ Metavir Stage F3

and

☐ HBV DNA greater than 20,000 IU/mL or increased ≥ 10 fold over nadir

and

☐ Hepatitis B virus resistant to lamivudine with detection of M204I/V mutation

or

☐ Hepatitis B virus resistant to adefovir with detection of A181T/V or N236T mutation

or

☐ Hepatitis B virus resistant to entecavir with detection of I169T, L180M T184S/A/I/L/G/C/M, S202C/G/I, M204V or M250I/V mutation

RENEWAL - Drug-Resistant Chronic Hepatitis B

Current approval Number (if known):..

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

Prerequisites (tick box where appropriate)

☐ The treatment remains appropriate and the patient is benefiting from treatment

Note:

- Tenofovir disoproxil fumarate should be stopped 6 months following HBeAg seroconversion for patients who were HBeAg positive prior to commencing Tenofovir disoproxil fumarate.
- The recommended dose of Tenofovir disoproxil fumarate for the treatment of hepatitis B is 300 mg once daily.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Tenofovir disoproxil fumarate dose should be reduced in accordance with the approved Medsafe datasheet guidelines.
- Tenofovir disoproxil fumarate is not approved for use in children.

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