

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:

Sapropterin dihydrochloride

Initial application
Applications only from a metabolic physician. Approvals valid for 1 month.
Prerequisites(tick boxes where appropriate)

Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant
and Treatment with sapropterin is required to support management of PKU during pregnancy
and Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg
and Sapropterin to be used alone or in combination with PKU dietary management
and Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

Renewal
Current approval Number (if known):.....
Applications only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy
or On subsequent renewal applications, the patient has previously demonstrated response to treatment with sapropterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy

and

Patient continues to be pregnant and treatment with sapropterin will not continue after delivery
or Patient is actively planning a pregnancy and this is the first renewal for treatment with sapropterin
or Treatment with sapropterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy

and Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg
and Sapropterin to be used alone or in combination with PKU dietary management
and Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

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 – email: customerservice@health.govt.nz