

**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: .....

**Saproterin 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 saproterin is required to support management of PKU during pregnancy

and  Saproterin to be administered at doses no greater than a total daily dose of 20 mg/kg

and  Saproterin to be used alone or in combination with PKU dietary management

and  Total treatment duration with saproterin 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 saproterin 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 saproterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy

and

Patient continues to be pregnant and treatment with saproterin will not continue after delivery

or  Patient is actively planning a pregnancy and this is the first renewal for treatment with saproterin

or  Treatment with saproterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy

and  Saproterin to be administered at doses no greater than a total daily dose of 20 mg/kg

and  Saproterin to be used alone or in combination with PKU dietary management

and  Total treatment duration with saproterin 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 Health New Zealand, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)