

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:

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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz