

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT</b> NHI: .....	<b>REFERRER</b> 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](mailto:customerservice@health.govt.nz)