

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

PRESCRIBER

Name: Name:

Ward: NHI:

Sapropterin dihydrochloride

INITIATION

Re-assessment required after 1 month

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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 that the above details are correct:

Signed: Date: