

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**

**PATIENT:**

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 Te Whatu Ora 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 Te Whatu Ora 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: .....