HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

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: .....

Ward: .....

PATIENT:

Name: .....

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: .....