



Prior Authorization Approval Criteria

Kuvan (sapropterin)

Generic name:	Sapropterin
Brand name:	Kuvan
Medication class:	Endocrine metabolic agent
FDA-approved uses:	To reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4-) responsive phenylketonuria (PKU).
Available dosage forms:	100 mg disintegrating tablet (equivalent to 76.8 mg sapropterin)
Usual dose range:	10-20 mg/kg/day. The tablets are dissolved in water or apple juice and taken 15 minutes after it has dissolved with food.
Duration of therapy:	Indefinite
Approximate monthly cost:	\$6400 as of 12/14/2007. <i>(based on AWP 2007)</i>

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin-responsive phenylketonuria.
- Must be seeing a physician with knowledge and experience in metabolic disease.
- Must have failed phenylalanine restricted diet alone despite strict compliance.
- Phe levels must be greater than 6 mg/dL for neonates through 12 years of age.
- Phe levels must be greater than 15 mg/dL* on average after the age of 12.
- Goal of therapy must be to reduce the risk of neurological damage.

Criteria for continuation of therapy:

- Must have a drop in Phe levels by at least 30% within 8 days to indicate the patient is responsive to Kuvan.
- Must maintain Phe levels below baseline levels.

Cautions:

- Patients with hepatic impairment which is associated with impaired phenylalanine metabolism

Monitoring: Phenylalanine blood levels

Contraindications: None known at this time.

Not approved if: Above criteria are not met.

Notes: 0.0167 mg/dL = 1 umol/L

** NIH Consensus Statement October 2000*

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 3/12/08

Revised: 6/18/08