



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 8, 2012 May 12, 2015

KUVAN® (sapropterin dihydrochloride)

LENGTH OF AUTHORIZATION:

INITIATION: THREE MONTHS

CONTINUATION: UP TO ONE YEAR

REVIEW CRITERIA:

Initiation of therapy:

- Patient must be \geq 1 month old
- Must have a diagnosis of Phenylketonuria (PKU).
- Must submit labs demonstrating elevated blood phenylalanine (Phe) levels.

Continuation of therapy:

- Patient must be \geq 1 month old
- Must have a diagnosis of Phenylketonuria (PKU).
- Must submit labs demonstrating a decrease in blood phenylalanine (Phe) levels.

DOSING & ADMINISTRATION:

- Starting dose for one month to 6 years of age is 10mg/kg once daily
- Starting dose for 7 years of age and older is 10 to 20mg/kg once daily. Dose titration may be increased to 20mg/kg/day in one month if phenylalanine levels do not decrease. If no response is observed after 1 month with 20 mg/kg/day, discontinue use.

Kuvan (sapropterin dihydrochloride) is available as an oral tablet or powder for oral suspension. The powder must be dissolved in 4 to 8 ounces (120 to 240 mL) of water or apple juice. For infants weighing 10 kg or less, dissolve 1 or 2 packets in 5 or 10 mL of water or juice and administer the calculated dosage using an oral syringe. The tablets may be swallowed whole or dissolved in 4 to 8 ounces (120 to 240 mL) of water or apple juice. Stirring or crushing may help the tablets dissolve faster. If the tablets do not dissolve completely, patients may swallow the small remaining pieces with additional water or juice to ensure the entire dose is ingested. The tablets may also be crushed and mixed into soft foods such as applesauce or pudding. Kuvan (sapropterin dihydrochloride) should be taken with food at approximately the same time each day. If dissolving the dose in water or apple juice, administer the tablets within 15 minutes of dissolution and the powder within 30 minutes of dissolution.

DOSAGE FORM: 100mg tablet, 100mg powder packet