



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service  
Prior Authorization Criteria

**KUVAN<sup>®</sup> (sapropterin)**  
**[Prior Authorization Request Form](#)**

Kuvan is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4)- responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

**Criteria for Approval**

- 1) Diagnosis of phenylketonuria; **AND**
- 2) Documentation that the patient is adhering to a Phe-restricted diet, and continues to have baseline PHE levels above 360  $\mu\text{mol/L}$ ; **AND**
- 3) Prescriber must submit patient's baseline weight and phenylalanine levels at initiation of therapy for a thirty (30) day supply. Initial dosing will be calculated for 10mg/kg/day; **AND**
- 4) Additional authorization of a thirty (30) day supply at a dose of 20mg/kg/day will be granted if patient does not respond adequately to initial dosing; **AND**
- 5) Re-authorization for one (1) six (6) month period will be issued with documentation of reduced phenylalanine levels within goal range (120-360  $\mu\text{mol/L}$ ) and documentation of patient compliance. Subsequent authorizations may be issued for up to twelve (12) months depending on patient compliance.  
Doses exceeding 20mg/kg/day will not be authorized.

**References**

- 1) Lexi-Comp Clinical Application 05/06/2015
- 2) Kuvan. Clinical Pharmacology. Tampa (FL): Gold Standard. Retrieved from <http://clinicalpharmacology.com/Forms/search.aspx?s=kuvan> on 4/20/2015.
- 3) Kuvan [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; 2014.
- 4) Vockley J, Andersson HC, Antshel KM, et al. "Phenylalanine Hydroxylase Deficiency: Diagnosis and Management Guideline" *ACMG Practice Guideline*. 2014. Accessed 4/20/2015.