POLICY AND PROCEDURE

POLICY TITLE: Kuvan (**Sapropterin Dihydrochloride)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2008 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Kuvan (sapropterin dihydrochloride).

Kuvan (Sapropterin dihydrochloride) is the cofactor of a metabolic enzyme indicated to reduce blood phenylalanine levels in patients with hyperphenylalaninemia due to tetrahydrobiopterin responsive Phenylketonuria.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Kuvan (Sapropterin dihydrochloride), is subject to the prior authorization process

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of phenylketonuria (PKU)
- Must have a documented baseline serum phenylalanine level

Reauthorization Criteria:

- A laboratory reassessment is conducted after an initial one month trial to determine if authorization may be extended.
    - Patients on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These patients are approved for another 1 month trial at the higher dose.
    - Patients on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment with Kuvan is discontinued in these patients.
    - Patients responding to therapy receive additional authorization at 1-year intervals.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 month
Reauthorization	Case-by-case basis

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Sapropterin dihydrochloride (Kuvan) package insert. Biomarin; December 2007.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*