UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kuvan

Program	Prior Authorization
Medication	Kuvan® (sapropterin dihydrochloride)
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

1. Background:

Phenylketonuria (PKU) is a genetic condition in which patients lack the enzyme phenylalanine hydroxylase which is needed to break down the amino acid phenylalanine (Phe). Phenylalanine is commonly found in foods that contain protein. Phenylalanine build up is toxic to the central nervous system and can result in brain damage. Kuvan (sapropterin dihydrochloride) is indicated to reduce blood levels of Phe in patients with hyperpheylalaninemia (HPA) due to tetrahydrobiopterin-(BH_4) responsive PKU. It is to be used in conjunction with a Phe-restricted diet.

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Kuvan** will be approved based on the following criteria:

   a. Diagnosis of phenylketonuria (PKU)

Authorization will be issued for 12 months.

3. References:

1. Kuvan [package insert], Novato, CA: BioMarin Pharmaceutical Inc.;June 2016.
2. Vockley et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. American College of Medical Genetics and Genomics Practice Guidelines. Genetics in Medicine 2014;16 (2):188-200.

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Program	Prior Authorization - Kuvan® (sapropterin dihydrochloride)
Change Control	
Date	Change
12/2009	Criteria taken from previously approved AmeriChoice policy. Policy was reformatted.
12/2010	Annual Review
12/2011	Annual Review
12/2012	Annual Review
3/2015	Added Kuvan powder for oral solution to product list. No change to clinical criteria.
9/2016	Added requirement for Phe-restricted diet and changed initial authorization duration to 6 months to align with Employer & Individual. Updated policy template and references.
3/2017	Changed initial authorization to 12 months
9/2017	Annual review. No change to coverage criteria.
9/2017	Removed clinical criteria in addition to diagnosis and removed reauthorization criteria to allow for Dx to Rx implementation

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