UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kuvan

Program	Prior Authorization
Medication	Kuvan® (sapropterin dihydrochloride) tablet and powder
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

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.

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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Kuvan [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; March 2020.

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.
7/2018	Annual review. No updates to criteria.
7/2019	Annual review. Revised background to align with package insert. Updated references.
7/2020	Annual review with no changes to coverage criteria. Added Clinical Rules section. Update reference.