UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1057-10
Program	Prior Authorization/Notification
Medication	Kuvan® (sapropterin dihydrochloride)*
P&T Approval Date	4/2008, 4/2009, 3/2010, 3/2011, 1/2012, 2/2013, 10/2013, 10/2014, 10/2015, 9/2016, 9/2017, 7/2018, 7/2019, 7/2020, 7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

1. Background:

Kuvan (sapropterin dihydrochloride) is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older 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>Initial Authorization</u>

1. **Kuvan** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of phenylketonuria (PKU)

   -AND-

   b. Patient is actively on a Phe-restricted diet

   -AND-

   c. Patient is not receiving Kuvan in combination with Palynziq (pegvaliase-pqpz)

Authorization will be issued for 6 months.

B. <u>Reauthorization</u>

1. **Kuvan** will be approved based on **<u>all</u>** of the following criteria:

   a. Patient is actively on a Phe-restricted diet

   -AND-

   b. Blood Phe levels continue to remain lower than baseline level.

   -AND-

   c. Patient is not receiving Kuvan in combination with Palynziq (pegvaliase-pqpz)

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Authorization will be issued for 12 months.

*Brand Kuvan is excluded from coverage for the majority of our benefits

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 also be in place.

4. References:

1. Kuvan [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; February 2021.
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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Change Control	
10/2013	Removed age criterion.
10/2014	Annual review. Updated references.
10/2015	Annual review. Updated authorization period to 6 mo. Updated reauthorization requirement. Background edit. Updated references.
9/2016	Annual review. Updated references.
9/2017	Annual review with no changes to coverage criteria.
7/2018	Added criteria restricting combination use with Palynziq
12/2018	Administrative change to add statement regarding use of automated processes.
7/2019	Annual review with no changes to coverage criteria. Updated reference.
7/2020	Annual review with no changes to coverage criteria. Updated reference.
7/2021	Annual review with no changes to clinical criteria. Updated re-authorization to 12 months. Added statement that Brand Kuvan is excluded from coverage for the majority of our benefits. Updated background and references.

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