

# Saproterin



**Included Products:** Kuvan (saproterin)

Created: 03/13/2012

Revised: 09/12/2013

Reviewed: 11/10/2022

Updated: 12/01/2022

## All Diagnoses

Initial Criteria		If yes	If no
1.	Is prescribed by a metabolic specialist?	Continue to #2.	Do not approve.
2.	Does member have diagnosis of tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)?	Continue to #3.	Do not approve.
3.	Is member currently on a phenylalanine-restricted diet and unable to achieve target blood phenylalanine (Phe) level?	Continue to #4.	Do not approve and recommend a phenylalanine-restricted diet.
4.	Is member's baseline blood Phe level provided in the request?	Continue to #5.	Please request.
5.	Approve for 2 months.		
Renewal Criteria		If yes	If no
1.	Does member have documented one of the following treatment response: a. At least 30% decrease in blood Phe level compared with baseline b. At least 20% decrease in blood Phe level compared with baseline with one of the following: i. Increased dietary Phe tolerance ii. Improved neurocognitive and/or psychosocial functioning iii. Improved blood Phe stability	Continue to #2.	Do not approve.
2.	Approve for life.		