

<b>POLICY NAME</b>	Kuvan, sapropterin pack and tablets	<b>POLICY #</b>	<b>1533P</b>
--------------------	-------------------------------------	-----------------	--------------

## Criteria

### Coverage Criteria for Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-responsive Phenylketonuria (PKU)

- ☐ **1.4** Documented diagnosis of Phenylketonuria (PKU) Treated by a specialist knowledgeable in the management of PKU Documentation that therapy will accompany a strict Phe-restrictive diet  
Baseline Phe level:
  - >6mg/dL (360 micromol/L) if 12 years of age, OR
  - >10 mg/dL (600 micromol/L) if >12 years of age
- ☐ **1.5** For brand Kuvan, documented trial and failure with generic sapropterin tablets/packets

### Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Documented non-response to Kuvan indicated by a failure to reduce baseline Phe level by 30%.
- ☐ **2.2** Kuvan will not be approved if the member is also receiving Palynziq because there is no data available to support the use of concomitant therapy with these medications in the treatment of PKU