Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 13, 2023

Phenylketonuria Treatments

Preferred: N/A

Non-Preferred: Javygtor (sapropterin) oral powder for solution/tablet, Kuvan (sapropterin) oral powder for solution/disintegrating tablet, Palynziq (pegvaliase-pqpz) subcutaneous solution, Sapropterin oral powder for solution/tablet/disintegrating tablet

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be within the FDA approved age limits.
- Patient must have a diagnosis of phenylketonuria (PKU).
- If the request is for generic sapropterin, Kuvan or Javygtor:
  - Patient must have tetrahydrobiopterin- (BH4-) responsive PKU.
- Must submit labs demonstrating elevated blood phenylalanine (Phe) levels.
- Patient must have documentation of failure to phenylalanine-restricted diet as monotherapy.
- Medications must be used in conjunction with a phenylalanine-restricted diet.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response (e.g., decrease in blood Phe levels).
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/