Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 13, 2023 March 24, 2025

Phenylketonuria Treatments

Clinical PA required (preferred): Javygtor (sapropterin) tablet, Sapropterin oral powder for solution/tablet

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

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 Kuvan or Javygtor oral powder for solution:
  - Patient must have tetrahydrobiopterin- (BH4-) responsive PKU.
- Patient must have trial and failure to the preferred products (documentation required).
- 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/