

## Sapropterin (Kuvan and Javygtor)

### Coverage Criteria:

1. Prescribed by a metabolic disease specialist; and,
2. Patient has a diagnosis of tetrahydrobiopterin-(BH4-) responsive phenylketonuria (PKU); and
3. The requested medication is prescribed as an adjunct to dietary restriction of protein and phenylalanine; and,
4. The requested drug will not be used in combination with pegvaliase (Palynziq); and,
5. For brand requests, patient has had a documented allergic reaction to generic sapropterin; and,
6. The requested medication is prescribed within the FDA-approved weight-based dosing regimen.

### Renewal Criteria:

1. Patient has been seen by the prescriber in the previous 12 months; and,
2. Patient shows evidence of positive clinical response on therapy per chart documentation (e.g., reduction in blood phenylalanine levels from baseline); and,
3. Patient continues to be adherent to dietary phenylalanine restriction; and,
4. For brand requests, patient has had a documented allergic reaction to generic sapropterin; and,
5. The requested drug will not be used in combination with pegvaliase (Palynziq); and,
6. The requested medication is prescribed within the FDA-approved weight-based dosing regimen.

### Coverage Duration:

Initial authorizations will be provided for 3 months.

Reauthorizations will be provided for 12 months.