

Palynziq (pegvaliase-pqpz)

Initial Coverage Criteria:

1. Prescribed by a metabolic disease specialist; and,
2. Patient has a diagnosis of phenylketonuria (PKU); and
3. Patient has an elevated blood phenylalanine concentration of greater than 600 micromol/L for 6 months prior to treatment despite a phenylalanine-restricted diet; and
4. The requested medication is prescribed as an adjunct to dietary restriction of protein and phenylalanine; and,
5. Patient has documentation of a trial and failure, intolerance, or medical contraindication to generic sapropterin; and,
6. The requested drug will not be used in combination with sapropterin (Kuvan, Javygtor); and,
7. The requested medication is prescribed within the FDA-approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by prescriber within the past 12 months; and
2. Patient shows evidence of positive clinical response on therapy per chart documentation of ONE of the following:
 - a. Patient has had at least a 20% decrease in blood phenylalanine levels from baseline; or
 - b. Patient's blood phenylalanine level is 600 micromol/L or less; and,
3. Patient continues to be adherent to dietary phenylalanine restriction; and,
4. Patient has documentation of a trial and failure, intolerance, or medical contraindication to generic sapropterin; and,
5. The requested drug will not be used in combination with sapropterin (Kuvan, Javygtor); and,
6. The requested medication is prescribed within the FDA-approved dosing regimen, and meets ONE of the following:
 - a. Patient has NOT been titrated to the maximum allowed dose of 60 mg once daily; or,
 - b. Patient has received less than 16 weeks of continuous treatment at the maximum dose of 60 mg once daily.

Coverage Duration:

Initial authorizations will be for 6 months.

Re-authorization will be provided for 12 months.