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| POLICY NAME | Palynziq (pegvaliase-pqpz) | POLICY # | 2652P |
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Criteria

Coverage Criteria for Phenylketonuria (PKU)

- ☐ Documented diagnosis of Phenylketonuria with a phenylalanine level of > 600 micromoles/liter on a PKU diet which includes an average of 65 grams of protein daily (combined natural food and medical food content) Age 18 years or older Treated by a specialist knowledgeable in the management of PKU Documentation that therapy will accompany a strict Phe-restrictive diet

Exclusion Criteria – Any of the following prevents coverage

- ☐ Palynziq will not be approved if the member is also receiving Kuvan because there is no data available to support the use of concomitant therapy with these medications in the treatment of PKU.
- ☐ Documented non-response to Palynziq indicated by a failure to reduce baseline Phe levels by 20%