Field Name	**Field Description**
Prior Authorization Group Description	**Palynziq**
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "other criteria"
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	**INITIAL AUTHORIZATION:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU); **AND** • Documentation the member's blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days) • Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum) • Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. **DOSE INCREASES:** • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen:

	○ For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control ○ For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control • The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). **<u>REAUTHORIZATION:</u>** • Documentation of recent blood Phe level results (within the previous 90 days); **AND** • The medication is being prescribed at an FDA approved dose; **AND** • Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline.. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date: 4/2023	