

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Phenylketonuria (PKU)

AND ALL of the following:

1. Blood phenylalanine concentration > 600 micromol/L after a trial of sapropterin dihydrochloride (Kuvan)
2. Physician agrees to assess patient tolerability, blood phenylalanine concentration, and dietary protein and phenylalanine intake throughout treatment
3. Prescriber and patient must be enrolled with the Palynziq REMS Program
4. Auto-injectable epinephrine has been prescribed and the patient or caregiver has been instructed in its use
5. **NOT** to be used in combination with sapropterin dihydrochloride (Kuvan)

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Phenylketonuria (PKU)

1. **NOT** to be used in combination with sapropterin dihydrochloride (Kuvan)
2. Auto-injectable epinephrine has been prescribed and the patient or caregiver has been instructed in its use
3. Patient had adequate response to treatment

Prior - Approval *Renewal* Limits

Duration 12 months