

<b>Clinical Policy Title:</b>	sapropterin dihydrochloride
<b>Policy Number:</b>	RxA.787
<b>Drug(s) Applied:</b>	Kuvan®
<b>Original Policy Date:</b>	04/13/2023
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Phenylketonuria (must meet all):

1. Diagnosis of HPA due to PKU;
2. Prescribed by or in consultation with an endocrinologist, metabolic disease specialist, or genetic disease specialist;
3. Recent (within 90 days) phenylalanine (Phe) blood level is > 600 µmols/L;
4. Member is currently on a phenylalanine-restricted diet and will continue this diet during treatment with Palyngiq®;
5. Kuvan® is not prescribed concurrently with Palyngiq®;
6. Dose does not exceed 20 mg/kg per day.

#### Approval Duration

**Commercial:** 3 months

**Medicaid:** 3 months

### II. Continued Therapy Approval

#### A. Phenylketonuria (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as demonstrated by a reduction in Phe blood levels since initiation of therapy;
3. Member is currently on a phenylalanine-restricted diet and will continue this diet during treatment with Kuvan®;
4. If request is for a dose increase, new dose does not exceed 20 mg/kg per day.

#### Approval Duration

**Commercial:** 12 months

**Medicaid:** 12 months

## References

1. Vockly J, Andersson HC, Antshel KM, et al. ACMG practice guidelines: phenylalanine hydroxylase deficiency: diagnosis and management guideline. *Genet Med.* 2014;16(2):188- 200. Available at: <https://pubmed.ncbi.nlm.nih.gov/24385074/>. Accessed January 27, 2023.
2. Camp KM, Parisi MA, Acosta PB, et al. Phenylketonuria scientific review conference: state of the science and future research needs. *Mol Genet Metab.* June 2014;112(2):87-122. Available at:

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<https://pubmed.ncbi.nlm.nih.gov/24667081/>. Accessed January 27, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/27/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023