Clinical Policy Title:	sapropterin dihydrochloride
Policy Number:	RxA.787
Drug(s) Applied:	Kuvan®
Original Policy Date:	04/13/2023
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	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 Palynziq®;
5. Kuvan® is not prescribed concurrently with Palynziq®;
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:

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