Louisiana Medicaid
Sapropterin Dihydrochloride (Kuvan®, Javygtor™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sapropterin dihydrochloride (Kuvan®, Javygtor™).

Additional Point-of-Sale edits may apply.

*The~~i~~se agents may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria (to initiate treatment)

- The recipient is 1 month of age or older on the date of the request; **AND**
- The recipient has a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive phenylketonuria (PKU); **AND**
- The recipient is following a phenylalanine- (Phe-) restricted diet; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Sapropterin dihydrochloride (Kuvan®, Javygtor™) is prescribed by, or in consultation with, a healthcare provider experienced in the management of PKU; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of authorization approval when initiating treatment or increasing dosage to determine response to therapy: 2 months

Reauthorization Criteria (for responders to sapropterin dihydrochloride)

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy by a decreased blood Phe from baseline.

Duration of reauthorization approval after response to therapy has been determined: 12 months

References

Javygtor (sapropterin dihydrochloride) [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc; January 2022. https://javygtor.com/JAVYGTOR_DIGITAL_PI.pdf

Kuvan (sapropterin dihydrochloride) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; February 2021. https://www.kuvan.com/hcp/wp-content/file/KUVAN_Prescribing_Information1.pdf

Revision / Date	Implementation Date
Policy created	December 2019
Formatting changes, updated references / February 2022	July 2022
Added Javygtor™, updated references / January 2023	April 2023