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CONTAINS CONFIDENTIAL PATIENT INFORMATION

Sapropterin Dihydrochloride (Kuvan)
Prior Authorization of Benefits (PAB) Form

Complete form in its entirety and fax to:
Prior Authorization of Benefits Center at 1-844-512-9004
Provider Help Desk 1-800-454-3730

1. Patient information	2. Physician information
Patient name: _____	Prescribing physician: _____
Patient ID #: _____	Physician address: _____
Patient DOB: _____	Physician phone #: _____
Date of Rx: _____	Physician fax #: _____
Patient phone #: _____	Physician specialty: _____
Patient email address: _____	Physician DEA: _____
	Physician NPI #: _____
	Physician email address: _____

3. Medication	4. Strength	5. Directions	6. Quantity per 30 days
	_____	_____	Specify: _____

7. Diagnosis: _____

8. Approval criteria: CHECK ALL BOXES THAT APPLY

Note: Any areas not filled out are considered not applicable to your patient and MAY AFFECT THE OUTCOME of this request.

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA-approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1) Patient has a diagnosis of phenylketonuria (PKU); and
2) Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and
3) Patient has a baseline blood Phe level ≥ 360 micromol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sapropterin therapy (attach lab results); and
4) Patient's current weight is provided; and
5) Request is for an FDA-approved starting dose (10mg/kg/day for patients 1 month to 6 years and 10-20mg/kg/day for patients 7 years and older); and
6) Blood Phe levels will be measured after 1 week of therapy and at least one other time during the first month of therapy.

Initial requests will be considered for 1 month to assess response to therapy. Continuation of therapy will be considered when the following criteria are met:

1) Patient's current weight is provided; and
2) Patient continues on a Phe restricted diet; and
3) For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for 1 month to assess response to therapy.
4) For patients initiated at a dose of 20mg/kg/day or those increased to this dose after 1 month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease after 1 month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.
5) Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at 6 month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

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Prior Authorization of Benefits Center at 1-844-512-9004

Patient name:_____ **Patient ID #:** _____

Initial requests:

Has patient been on a phenylalanine (Phe) restricted diet prior to sapropterin therapy?
☐ Yes ☐ No

If yes, provide baseline blood Phe level while following the Phe restricted diet (attach results obtained within 2 weeks of initiation of sapropterin therapy):_____ Date obtained: _____

If yes, will patient continue on Phe restricted diet throughout sapropterin therapy? ☐ Yes ☐ No

Patient's weight (kg):_____ Date obtained: _____

Will blood Phe levels be measured after 1 week of therapy and at least one other time during the first month of therapy?
☐ Yes ☐ No

Requests for continuation of therapy:

Patient's weight (kg):_____ Date obtained: _____

Is patient currently on a phenylalanine (Phe) restricted diet?
☐ Yes ☐ No

Current blood Phe level (attach results):_____ Date obtained: _____

For patients who initiated dose of 10mg/kg/day:
Did patient experience at least a 30% reduction in Phe level from baseline? Yes ☐ No ☐
If no, is dose increase being requested? Yes ☐ No ☐

For patients who initiated dose at or tapered dose to 20mg/kg/day:
Did patient experience at least a 30% reduction in Phe level from baseline after 1 month of therapy at a dose of 20mg/kg/day?
Yes ☐ No ☐

Attach lab results and other documentation as necessary.

Patient name:_____ **Patient ID #:** _____

9. Physician signature

_____ _____
Prescriber or authorized signature Date

Prior Authorization of Benefits is not the practice of medicine or the substitute for the independent medical judgment of a treating physician. Only a treating physician can determine what medications are appropriate for a patient. Please refer to the applicable plan for the detailed information regarding benefits, conditions, limitations, and exclusions. The submitting provider certifies that the information provided is true, accurate, and complete and the requested services are medically indicated and necessary to the health of the patient.

Note: Payment is subject to member eligibility. Authorization does not guarantee payment.