Iowa Department of Human Services

FAX Completed Form To
1 (800) 574-2515

Provider Help Desk
1 (877) 776-1567

Request for Prior Authorization

Sapropterin Dihydrochloride (Kuvan)

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

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.

Non-Preferred

☐ Kuvan

Strength	Dosage Instructions	Quantity	Day's Supply

Request for Prior Authorization

Sapropterin Dihydrochloride (Kuvan)

(PLEASE PRINT – ACCURACY IS IMPORTANT)

Diagnosis:_____

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.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.*