Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Kuvan® (sapropterin)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product:
- ☐ Kuvan 100mg tablet
- ☐ Kuvan 100mg powder for solution
- ☐ Kuvan 500mg powder for solution

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Drug cost information

The wholesale acquisition cost for Kuvan 100mg tablet is $36.90. The annual cost of treatment with this drug will vary depending on the patient's circumstances but may be estimated to average $150,000.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Diagnosis of phenylketonuria
2. Age 1 month and older
3. Current adherence to dietary restriction of phenylalanine
    a. Phenylalanine restricted diet defined as:
        i. Adherence to phenylketonuria diet which includes an average of 65 grams of protein per day (from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods)
    b. Must continue phenylalanine-restricted diet if approved for Kuvan
4. Tetrahydrobiopterin (BH4) deficiency has been ruled out
5. The prescribing physician is a metabolic disease specialist
6. Baseline blood phenylalanine levels must be provided

Initial approval is limited to a maximum of 2 months.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 08/2018

Last reviewed 09/2019

For continuation and subsequent 12-month approval, the patient must meet the following requirements:

1. Documented compliant maintenance therapy on Kuvan
2. Continued adherence to a phenylalanine-restricted diet
3. Achieved a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

New request
Priority Health Precertification Documentation *(provide supporting documentation)*

A. What condition is this drug being requested for?

☐ phenylketonuria
☐ *Other – the patient's condition is:* _____
Rationale for use: _____

B. Has the patient adhered to and will continue to adhere to a phenylalanine-restricted diet?

☐ Yes
☐ No

C. Has Tetrahydrobiopterin (BH4) deficiency has been ruled out?

☐ Yes
Please provide DHPR (dihydropteridine reductase) activity testing and biopterin/neopterin concentrations.
☐ No

D. The provider is a metabolic disease specialist?

☐ Yes
☐ No

E. Patient's baseline phenylalanine level

Date:_____ Blood Phe level (mcmol/L):_____

Request to continue a previously authorized approval
Priority Health Precertification Documentation *(provide supporting documentation)*

A. Has the patient maintained compliant therapy on Kuvan?

☐ Yes
☐ No

B. Has the patient adhered to a phenylalanine-restricted diet?

☐ Yes
☐ No

C. Has the patient achieved at least a 30% reduction in blood phenylalanine concentration from baseline?

☐ Yes
Baseline blood Phe level (mcmol/L):_____ Date:_____
Current blood Phe level (mcmol/L):_____ Date:_____
☐ No

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Last reviewed 09/2019

Additional information

Coverage Limitations:

- Kuvan is not covered in combination with Palynziq.
- When approved, the dosage of the above drug is limited to the FDA-approved dosing found within the package insert.
- Kuvan must be ordered from a network specialty pharmacy.
- Maximum of a 31-day supply per dispensing.

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Last reviewed 09/2019