AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: sapropterin dihydrochloride (Kuvan®)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosing: Initial dose of 10mg/kg/day is recommended, and may be increased to a dose of 20mg/kg/day after 1 month of treatment if phenylalanine levels do not decrease below baseline levels.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval: 6 months.

- ❑ Prescriber is a metabolic geneticist or a physician knowledgeable in the management of PKU
- ❑ Patient has a diagnosis of hyperphenylalaninemia due to tetrahydrobiopterin (BH4)-responsive phenylketonuria
- ❑ Baseline phenylalanine labs must be submitted **(please attach current labs with level)**
- ❑ Patient's current weight **(please note)**: _____

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- ❑ Patient is compliant with a phenylalanine-restricted diet **(please submit chart notes documenting current phenylalanine intake and use of Phe-free medical food supplements)**
- ❑ Patient does **not** have hepatic or renal impairment
- ❑ sapropterin dihydrochloride (Kuvan®) will **NOT** be used in combination with Palynziq™
- ❑ For brand name Kuvan approval: Member has had trial and intolerable life-endangering adverse event with generic sapropterin dihydrochloride (must submit completed MedWatch form and chart notes to document adverse event)
- ❑ Is patient a pregnant female? **(please note)**: ❑ Yes ❑ No

Reauthorization Approval: 1 year. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Phenylalanine levels have decreased by at least 30% from baseline levels and have remained below baseline **(please attach current labs with level)**
- ❑ Patient remains compliant with a phenylalanine-restricted diet **(please submit chart notes documenting current phenylalanine intake and use of Phe-free medical food supplements)**
- ❑ Phenylalanine levels will continue to be measured periodically during therapy
- ❑ Patient's current weight: _____
- ❑ sapropterin dihydrochloride (Kuvan®) will **NOT** be used in combination with Palynziq™
- ❑ For brand name Kuvan approval: Member has had trial and intolerable life-endangering adverse event with generic sapropterin dihydrochloride (must submit completed MedWatch form and chart notes to document adverse event)
- ❑ Patient will be maintained on a dose no greater than the FDA-approved maximum of 20mg/kg/day

****Length of authorization will be for 1 year if approved for continuation.**

Yearly reauthorization will be required.**

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 10/15/2015
REVISED/UPDATED/REFORMATTED: ~~10/23/2015; 12/22/2015; 9/22/2016; 12/21/2016; 8/4/2017; 9/15/2017; 1/16/2019; 3/2/2019; 3/8/2021;10/11/2021;~~ **10/27/2023**