

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.**

sapropterin products

Drug Requested: (Select drug below)

<input type="checkbox"/> sapropterin dihydrochloride (generic Kuvan [®])	<input type="checkbox"/> Javygtor[™] (sapropterin dihydrochloride)
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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: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: Initial dose of 10 mg/kg/day is recommended and may be increased to a dose of 20 mg/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 Authorization: 6 months.

- Prescriber is a metabolic geneticist or a physician knowledgeable in the management of PKU
- Member has a diagnosis of hyperphenylalaninemia due to tetrahydrobiopterin (BH4)-responsive phenylketonuria

(Continued on next page)

- Baseline phenylalanine labs must be submitted (**please attach current labs with level**)
- Provider has submitted member's current weight (**please note**): _____
- Member is compliant with a phenylalanine-restricted diet (**please submit chart notes documenting current phenylalanine intake and use of Phe-free medical food supplements**)
- Member does **NOT** have hepatic or renal impairment
- Requested sapropterin dihydrochloride product will **NOT** be used in combination with Palynziq™
- For brand name Kuvan approval: Member has had trial and intolerable life-endangering adverse event with a generic sapropterin dihydrochloride product (**must submit completed MedWatch form and chart notes to document adverse event**)
- Is member a pregnant female? (**please note**): Yes No

Reauthorization: 12 months. 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**)
- Member 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
- Provider has submitted member's current weight (**please note**): _____
- Requested sapropterin dihydrochloride product will **NOT** be used in combination with Palynziq™
- For brand name Kuvan approval: Member has had trial and intolerable life-endangering adverse event with a generic sapropterin dihydrochloride product (**must submit completed MedWatch form and chart notes to document adverse event**)
- Member will be maintained on a dose no greater than the FDA-approved maximum of 20 mg/kg/day

Medication being provided by a Specialty Pharmacy – Proprium Rx

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.****