SENTARA HEALTH PLANS

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 1-800-750-9692**. 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)

❑ **sapropterin dihydrochloride** (generic Kuvan®)	❑ **Javygtor™** (sapropterin dihydrochloride)

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

Member Name: _____

Member Sentara #: _____ **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.****

***Approved by Pharmacy and Therapeutics Committee**: 10/15/2015
REVISED/UPDATED/REFORMATTED: ~~12/21/2016; 8/4/2017; 9/15/2017; 1/16/2019; 3/2/2019; 3/8/2021; 10/11/2021; 10/24/2023;~~ **12/20/2024**