

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: Sephience™ (sepiapterin)

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:

Age	Sephience (mg/kg) per day
Less than 6 months	7.5 mg/kg
6 months to less than 1 year	15 mg/kg
1 year to less than 2 years	30 mg/kg
2 years and older	60 mg/kg

Maximum Daily Dose: 60 mg/kg/day

Quantity Limits:

- 250 mg packets – 3 packets per day
- 1000 mg packets – 6 packets per day

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.

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Initial Authorization: 6 months

- ☐ Member is ≥ 1 month of age with a diagnosis of hyperphenylalaninemia with sepiapterin-responsive phenylketonuria
- ☐ Prescriber is a metabolic geneticist or a physician knowledgeable in the management of PKU
- ☐ Member consistently has phenylalanine levels greater than 360 micromol/L (**please attach previous and current baseline labs with levels**)
- ☐ Provider has submitted member's current weight (**please note**): _____
- ☐ Member is compliant with a protein- and phenylalanine-restricted diet (**please submit chart notes documenting current phenylalanine intake and use of Phe-free medical food supplements**)
- ☐ Requested medication will **NOT** be used in combination with Palynziq® or sapropterin products (Kuvan®, Javygtor™)
- ☐ Member has had trial and intolerable life-endangering adverse event or therapeutic failure with generic sapropterin dihydrochloride (**must submit completed MedWatch form and chart notes/lab test results to document adverse event or therapy failure**)
- ☐ Member will be maintained on a dose no greater than the FDA-approved maximum of 60 mg/kg/day
- ☐ Provider attests that if the member's blood Phe does not decrease after 2 weeks of treatment at the maximum daily dosage of 60 mg/kg, Sephience will be discontinued for lack of biochemical response

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.

- ☐ Member must have reduction in phenylalanine level by at least 30% from baseline level after initial approval, and further reduction or stabilization in phenylalanine level below baseline after subsequent approvals (**please attach current labs with level**)
- ☐ Member remains compliant with a protein- and phenylalanine-restricted diet (**please submit chart notes documenting current phenylalanine intake and use of Phe-free medical food supplements**)
- ☐ Provider attests phenylalanine levels will continue to be measured periodically during therapy
- ☐ Provider has submitted member's current weight (**please note**): _____
- ☐ Requested medication will **NOT** be used in combination with Palynziq® or sapropterin products (Kuvan®, Javygtor™)
- ☐ Member will be maintained on a dose no greater than the FDA-approved maximum of 60 mg/kg/day

Medication being provided by Specialty Pharmacy – Proprium Rx

*****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.****