CYCLE VITA™
Support for life

Patient Enrollment Form for JAVYGTOR™ (Sapropterin Dihydrochloride) Tablets or Powder for Oral Solution

Phone: +1 (888) 360-8482 FAX: +1 (888) 385-8482

Javygtor™
(sapropterin dihydrochloride)
Tablets or Powder for Oral Solution

To Enroll, Fax this form:
+ 1 (888) 385-8482

Or email: hello@cyclevita.life

All required fields are purple and noted with an asterisk*

PATIENT INFORMATION

Patient Last Name*		Patient First Name*
Date of Birth*	Gender* ☐ Male ☐ Female ☐ Other	Parent/Guardian Name *(if patient is a minor)*
Street Address*		Suite/Floor/Apt #
City*	State*	Zip code*

Preferred Method of Contact (please specify)*

☐ Cell Phone ☐ Alternate Phone

☐ Email

Language Preferred: ☐ English ☐ Spanish ☐ Other (please specify):

INSURANCE INFORMATION

Please attach a copy of the prescription insurance benefit card, front and back, or complete the following*

☐ Prescription insurance benefit card attached. ☐ Patient does not have insurance.

Primary Insurance Company Name*		Secondary Insurance Company Name	
Primary Insurance Company Phone Number*		Secondary Insurance Company Phone Number	
Name of Primary Cardholder*		Name of Primary Cardholder	
Primary Insurance Member ID*	Group ID*	Secondary Insurance Member ID	Group ID
BIN*	PCN*	BIN	PCN

CLINICAL INFORMATION

Diagnosis ICD-10-CM* : _____

Please specify: _____

☐ JAVYGTOR Tablets for Oral Use and Powder for Oral Solution are indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). JAVYGTOR is to be used in conjunction with a Phe-restricted diet.

☐ Other Diagnosis *(please specify)*: _____

Baseline Blood Phenylalanine (Phe) Levels (*before trial*):

Date: _____

I am prescribing JAVYGTOR for this patient and is medically necessary for the following reasons:

☐ To reduce blood Phe levels ☐ Other (please specify) _____

Additional Comments: _____

Patient Allergies*:

☐ No Known ☐ Known *(please list known allergies)*:

_____

Patient Medications*:

☐ None ☐ Please list the names of other medications the patient is currently taking *(if any)*:

_____

Patient Health Conditions*:

☐ No Known ☐ Please list the names of any other health conditions the patient currently has *(if any)*:

_____

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Patient Full Name:	Date of Birth:

PRESCRIBER INFORMATION

Prescriber Last Name* :	Prescriber First Name* :	Prescriber Specialty: ☐ Genetics ☐ Internal Medicine ☐ Other *(please specify)*:	
Prescriber Office/Site/Clinic*		Office Contact	Office Contact Phone Number
Prescriber Phone Number*		Prescriber Fax Number*	
Street Address*			
City*		State*	Zip Code*
NPI Number*			

PRESCRIPTION INFORMATION

☐ New Patient Free Trial - Cycle Vita will provide a 30-day supply of JAVYGTOR for patients new to therapy in an effort to prove clinical effectiveness as measured by HCP administered labs and appropriate lab results.

By checking this box, I, as the prescriber, with my signature below on this form, agree and attest that I will not submit a claim to or seek payment from the patient or any third-party payer (e.g., Medicaid, Medicare, private insurance, etc.) for payment/reimbursement for any free product(s) provided by Cycle Vita. I agree and understand that any free product provided by Cycle Vita may not be sold, traded, bartered, transferred, or returned for credit and will only be used for the patient named above on this form.

Current weight _____kg. Dose per kg body weight: ☐10 mg/kg ☐20 mg/kg ☐Other _____mg/kg Number of days' supply/prescription: ☐ 30 days ☐ 90 days	Refill(s): ☐ One (1) Year
☐ JAVYGTOR, *Tablet 100 mg*	NDC Number: 43598-096-04
☐ JAVYGTOR, *Powder for Oral Solution / 100 mg (Carton of 30 Unit Dose Packets)*	NDC Number: 43598-097-30 *(Carton of 30 Unit Dose Packets)*
☐ JAVYGTOR, *Powder for Oral Solution / 500 mg (Carton of 30 Unit Dose Packets)*	NDC Number: 43598-162-30 *(Carton of 30 Unit Dose Packets)*

Only prescriptions filled with product NDC numbers listed above shall be eligible for Cycle Vita (Eligible Products).

Patient Directions *(check all that apply)*:	Shipping Instructions *(check if applicable)*:
☐ Please contact your physician before starting use of the medication. ☐ Take _____100 mg JAVYGTOR (powder) once daily, as directed, with a meal, for a total dose of _____ mg/day. Note: JAVYGTOR powder for oral solution should be dissolved as directed by the physician before taking. ☐ Take _____100 mg JAVYGTOR (tablet) once daily, as directed, with a meal, for a total dose of _____mg/day. ☐ Take _____500 mg JAVYGTOR (powder) once daily, as directed, with a meal, for a total dose of _____ mg/day. Note: JAVYGTOR powder for oral solution should be dissolved as directed by the physician before taking. ☐ Other: _____	☐ Dispensing pharmacy to notify prescriber when initial shipment is scheduled.

☐ Quick Start† - "Quick Start" is a FREE supply of JAVYGTOR that allows patients to begin therapy immediately while Cycle Vita secures appropriate benefit verification and authorization. "Quick Start" may also be requested for existing patients who are temporarily experiencing disruption in therapy due to insurance coverage.

By checking the box above for Quick Start, I, as the prescriber, with my signature below on this form, agree and attest that I will not submit a claim to or seek payment from the patient or any third-party payer (e.g., Medicaid, Medicare, private insurance, etc.) for payment/reimbursement for any free product(s) provided by Cycle Vita. I agree and understand that any free product provided by Cycle Vita may not be sold, traded, bartered, transferred, or returned for credit and will only be used for the patient named above on this form. Cycle Vita reserves the right to modify or terminate the program without notice at any time.

† Quick Start is at no cost, for eligible patients within labeled indication only, and not contingent on purchase of any kind. Quick Start is intended to support continuation of prescribed therapy if there is any disruption in therapy due to insurance coverage.

PRESCRIBER DECLARATION

Prescriber Declaration: I understand and agree that, as the prescriber, I will comply with my state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me, as the prescriber. I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed JAVYGTOR based on my professional judgment of medical necessity. I authorize Cycle Vita, its affiliates, agents, and contractors (collectively, "Cycle Vita" to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the above-named patient utilizing their benefit plan. I authorize Cycle Vita, its affiliates, agents and contractors to perform any steps necessary to secure reimbursement for JAVYGTOR, including but not limited to insurance verification and case assessment. I understand that Cycle Vita may need additional information, and I agree to provide it as needed for the purposes of securing reimbursement.

Prescriber Signature *(please select one of the options below)**	Date*:
Prescriber Signature/Dispense as Written (DAW) (no stamps or initials)	Prescriber Signature/Substitution Permitted (no stamps or initials)

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Patient Full Name:	Date of Birth:

INDICATION

JAVYGTOR is indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). JAVYGTOR is to be used in conjunction with a Phe-restricted diet.

IMPORTANT SAFETY INFORMATION

Treatment with JAVYGTOR should be directed by physicians knowledgeable in the management of PKU. All patients with PKU who are being treated with JAVYGTOR should also be treated with a Phe-restricted diet, including dietary protein and Phe restriction. Prolonged exposure to elevated blood Phe levels can result in severe neurologic damage in PKU patients.

During treatment with JAVYGTOR, monitor blood Phe levels frequently to ensure adequate blood Phe level control, especially in pediatric patients. Also, active management of dietary Phe intake is required to ensure adequate Phe control and nutritional balance. Biochemical response to JAVYGTOR treatment should be determined through a therapeutic trial.

Patients should be advised to notify their physicians in cases of overdose.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions Including Anaphylaxis:** JAVYGTOR is not recommended in patients with a history of anaphylaxis to SAPROPTERIN DIHYDROCHLORIDE. Hypersensitivity reactions, including anaphylaxis and rash, have occurred. Signs of anaphylaxis include wheezing, dyspnea, coughing, hypotension, flushing, nausea, and rash. Discontinue JAVYGTOR treatment in patients who experience anaphylaxis, and initiate appropriate medical treatment. Continue dietary protein and Phe restrictions in patients who experience anaphylaxis.
- **Upper Gastrointestinal Mucosal Inflammation:** Gastrointestinal (GI) adverse reactions suggestive of upper GI mucosal inflammation have been reported with JAVYGTOR. Serious adverse reactions included esophagitis and gastritis. If left untreated, these could lead to severe sequelae including esophageal stricture, esophageal ulcer, gastric ulcer, and bleeding, and such complications have been reported in patients receiving SAPROPTERIN DIHYDROCHLORIDE. Monitor patients for signs and symptoms of upper GI mucosal inflammation.
- **Hypophenylalaninemia:** Some patients receiving SAPROPTERIN DIHYDROCHLORIDE have experienced hypophenylalaninemia (low blood Phe) during treatment. Children younger than 7 years old treated with JAVYGTOR doses of 20 mg/kg per day are at an increased risk for low levels of blood Phe compared with older patients.
- **Monitoring Blood Phe Levels During Treatment:** Prolonged elevations of blood Phe levels in patients with PKU can result in severe neurologic damage, including severe intellectual disability, developmental delay, microcephaly, delayed speech, seizures, and behavioral abnormalities. Conversely, prolonged levels of blood Phe that are too low have been associated with catabolism and endogenous protein breakdown, which has been associated with adverse developmental outcomes. Active management of dietary Phe intake while taking sapropterin dihydrochloride is required to ensure adequate Phe control and nutritional balance. Monitor blood Phe levels during treatment to ensure adequate blood Phe level control. Frequent blood monitoring is recommended in the pediatric population.
- **Lack of Biochemical Response to JAVYGTOR:** Not all patients with PKU respond to treatment with JAVYGTOR. Biochemical response to JAVYGTOR treatment cannot generally be pre-determined by laboratory testing (e.g., molecular testing), and should be determined through a therapeutic trial (evaluation) of JAVYGTOR response.
- **Interactions with Levodopa:** There have been reports of interactions with levodopa causing seizures, exacerbation of seizures, over-stimulation, and irritability. Monitor patients who are receiving levodopa for a change in neurologic status during treatment with JAVYGTOR.
- **Hyperactivity:** There have been post-marketing reports of hyperactivity with administration of SAPROPTERIN DIHYDROCHLORIDE. Monitor patients for hyperactivity.

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ADVERSE REACTIONS

- **Most common:** The most common adverse reactions (incidence ≥4%) were headache, rhinorrhea, pharyngolaryngeal pain, diarrhea, vomiting, cough, and nasal congestion.

The following adverse reactions have been reported during post-approval use of sapropterin dihydrochloride:

- **Hypersensitivity reactions** including anaphylaxis and rash. Most hypersensitivity reactions occurred within several days of initiating treatment;
- **Gastrointestinal reactions**: esophagitis, gastritis, oropharyngeal pain, pharyngitis, esophageal pain, abdominal pain, dyspepsia, nausea, and vomiting;
- **Hyperactivity**

DRUG INTERACTIONS

- **Levodopa** – JAVYGTOR may increase the availability of tyrosine, a precursor of levodopa. Neurologic events were reported post-marketing in patients receiving sapropterin and levodopa concomitantly for a non-PKU indication. Monitor patients for a change in neurologic status.
- **Inhibitors of Folate Synthesis** - Drugs that inhibit folate synthesis may decrease the bioavailability of endogenous BH4 by inhibiting the enzyme dihydrofolate reductase, which is involved in the recycling (regeneration) of BH4. This reduction in net BH4 levels may increase Phe levels. Frequently monitor blood Phe levels when co-administering JAVYGTOR with medications known to inhibit folate synthesis, such as methotrexate, valproic acid, phenobarbital, trimethoprim.
- **Drugs Affecting Nitric Oxide-Mediated Vasorelaxation** – Both JAVYGTOR and PDE-5 inhibitors (such as sildenafil, vardenafil, or tadalafil) may induce vasorelaxation. A reduction in blood pressure could occur. Monitor patients for hypotension when co-administering JAVYGTOR with medications known to affect nitric oxide–mediated vasorelaxation such as PDE-5 inhibitors.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are no well-controlled clinical studies of Sapropterin Dihydrochloride in pregnant women.
- **Lactation:** There are insufficient data to assess the presence of sapropterin in human milk and no data on the effects on milk production.
- **Pediatric Use:** Pediatric patients with PKU, ages 1 month to 16 years, have been treated with sapropterin dihydrochloride in clinical trials. The efficacy and safety of sapropterin dihydrochloride have not been established in neonates.
- **Geriatric Use:** Clinical studies of sapropterin dihydrochloride in patients with PKU did not include patients aged 65 years and older. It is not known whether these patients respond differently than younger patients.

For more detailed information, please refer to the full Prescribing Information at: www.JAVYGTOR.com/PI

To report SUSPECTED ADVERSE REACTIONS, contact Dr. Reddy's Laboratories, Inc. at 1-888-375-3784 or by email: medinfo@drreddys.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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