CYCLEVITA™ SUPPORT FOR LIFE

Patient Enrollment Form for CAVHANZA™ (nilotinib) Orally Disintegrating Tablets

CAVHANZA™ (nilotinib) Orally Disintegrating Tablets

To enroll, fax this form at **888 385-8482** or email **hello@cyclevita.life**. Alternatively, for more information call 888 360-8482.

See Important Safety Information, including **Boxed Warning**, on **page 3**.

All required fields are bold and noted with an asterisk*

SERVICES REQUESTED

To be completed by healthcare provider

Select which support option applies*

- ☐ Bridge Program
- ☐ Patient Assistance Program (PAP)
- ☐ Co-Pay Assistance Program
  - Name of Pharmacy _____
  - Date prescription was sent to pharmacy _____
- ☐ Other: _____
- ☐ Reimbursement Support (Benefits Investigation, Prior Authorization and/or Appeals Support)
- ☐ Nurse Educator Support (refill reminders, treatment education, etc.)

Note: Nurse Educator Support is automatically provided for patients enrolled in our Bridge or PAP Programs, and is also available upon request.

PATIENT INFORMATION

Patient Last Name* _____ **Patient First Name*** _____

Date of Birth* _____ **Gender*** ☐ Male ☐ Female ☐ Other

Caregiver Name (if applicable) _____ Relationship to Patient _____

Cell Phone _____ Email _____

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
Primary Insurance Member ID*	Secondary Insurance Member ID

Rx Group*	**RxBIN***	**RxPCN***	Group	BIN	PCN

Prior Authorization Status*

☐ Submitted ☐ Not Submitted ☐ Approved ☐ Denied Approval dates if approval is on file: _____

CLINICAL INFORMATION

Diagnosis ICD-10 code*

- ☐ C92.10: Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission.
- ☐ C92.11: Chronic myeloid leukemia, BCR/ABL-positive, in remission.
- ☐ C92.12: Chronic myeloid leukemia, BCR/ABL-positive, in relapse.
- ☐ Other (please specify): _____

Patient History with Treatment:* Previously prescribed:

☐ Imatinib ☐ Generic nilotinib ☐ Branded nilotinib (please list name below) ☐ Other _____

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 name of any other health conditions the patient currently has (if any): _____

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Patient Full Name*	Date of Birth*

PRODUCT DISPENSING INFORMATION

Select How the Patient Will Receive Their Medication:*

☐ Self-Dispensing Pharmacy

Pharmacy prescription was sent to _____

☐ Specialty Pharmacy Dispensing
(via manufacturer's designated SP channel)

PRESCRIBER INFORMATION

Prescriber Last Name*	**Prescriber First Name***
Prescriber Office/Site/Clinic*	
Prescriber Phone Number*	**Prescriber Fax Number***
Street Address*	
City*	**State*** / **Zip Code***
NPI Number*	**Office Contact Name***
Office Contact Phone Number with Extension*	**Office Email Address***

PRESCRIPTION INFORMATION

☐ CAVHANZA (nilotinib) 60mg (112 tablets)	NDC Number: 70709-191-12
☐ CAVHANZA (nilotinib) 80mg (112 tablets)	NDC Number: 70709-192-12

Only prescriptions filled with the product NDC number listed above will be eligible for Cycle Vita (Eligible Programs)

Quantity per day Supply:* ☐ 112 tablets per 28-day supply ☐ 224 tablets per 56-day supply ☐ 336 tablets per 84-day supply

☐ Other (please enter a number that is a multiple of 112): _____

Number of Refill(s)* _____

Patient Directions (check all that apply)*

☐ Take two 60 mg CAVHANZA (nilotinib) tablets twice a day with or without food, for a total dose of 240 mg /day.

☐ Take two 80 mg CAVHANZA (nilotinib) tablets twice a day with or without food, for a total dose of 320 mg/day.

☐ Take _____ _____ CAVHANZA (nilotinib) tablet(s) twice a day with or without food, for a total dose of _____ mg/day.

☐ **Bridge Program† - "Bridge" is a FREE supply of CAVHANZA (nilotinib) ODT that allows patients with a valid prescription to begin therapy immediately while appropriate benefit verification and authorization is identified. "Bridge" may also be requested for existing patients who are temporarily experiencing disruption in therapy due to insurance coverage.**

By checking the box above for Bridge, 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 for payment/reimbursement for any free CAVHANZA (nilotinib) ODT product(s). I agree and understand that any free CAVHANZA (nilotinib) ODT product(s) provided may not be sold, traded, bartered, transferred, or returned for credit and will only be used for the patient named above on this form. The Bridge program may be modified or terminated without notice at any time.

☐ Urgent ☐ Date needed: _____

†Bridge is at no cost, for eligible patients for medically indicated oncological diseases, and not contingent on purchase of any kind. Bridge is intended to support continuation of prescribed therapy if there is any disruption in therapy due to insurance coverage.

Bridge shipments are available via the manufacturer's specialty pharmacy channel and cannot be dispensed through in-office dispensing

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 CAVHANZA (nilotinib) ODT 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 CAVHANZA (nilotinib) ODT, 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)*

X _____	X _____	_____
Prescriber Signature/Dispense as Written (DAW)*	Prescriber Signature/Substitution Permitted (no stamps or initials)	**Date of Signature*** (MM/DD/YYYY)

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Patient Full Name*	Date of Birth*

Indications and Important Safety Information

Indications

CAVHANZA (nilotinib) is a kinase inhibitor indicated for the treatment of:

- Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
- Adults with CP Ph+ CML or accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy.

Contraindications

CAVHANZA is contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome.

Important Safety Information

Warning: QT Prolongation and Sudden Deaths

- Nilotinib prolongs the QT interval. Monitor for hypokalemia or hypomagnesemia and correct deficiencies. Obtain ECGs to monitor the QTc at baseline on day 7, and periodically thereafter, and following any dose adjustments.
- Sudden deaths have been reported. Avoid use in patients with hypokalemia, hypomagnesemia or long QT syndrome.
- Avoid concomitant drug use with QT-prolonging drugs and strong CYP3A4 inhibitors.

Warnings and Precautions:

- Substitution between nilotinib products requires dose conversion to avoid medication errors.
- Monitor for myelosuppression; manage with dose adjustments or interruptions.
- Cardiovascular and arterial occlusive events have been reported; assess and monitor cardiovascular risk.
- Pancreatitis risk: monitor serum lipase; interrupt dosing if abdominal symptoms occur with lipase elevations.
- Hepatotoxicity has been reported, with higher risk in pediatrics. Monitor liver function tests regularly.
- Correct and monitor electrolyte abnormalities throughout treatment.
- Tumor lysis syndrome has been reported; ensure hydration and correct uric acid before initiating treatment.
- Serious hemorrhage may occur; advise patients to report signs and symptoms of bleeding.
- Monitor for fluid retention and manage accordingly.
- Growth retardation has been reported in pediatric patients. Monitor growth and development.
- Can cause fetal harm; advise use of effective contraception during and 14 days after treatment.
- Monitor BCR-ABL transcript levels in patients discontinuing treatment and manage loss of response appropriately.

Adverse Reactions:

Common non-hematologic adverse reactions include rash, pruritus, headache, nausea, fatigue, alopecia, myalgia, abdominal pain, constipation, diarrhea and vomiting. Hematologic adverse reactions include thrombocytopenia, neutropenia, and anemia. Serious adverse reactions include QT prolongation, sudden deaths, febrile neutropenia, and intracranial hemorrhage. Postmarketing reports include thrombotic microangiopathy, facial paralysis, and osteonecrosis.

Drug Interactions:

Avoid concomitant use with strong CYP3A inhibitors or inducers. Dose reduction is recommended if strong CYP3A inhibitors cannot be avoided. Avoid drugs that prolong the QT interval, including anti-arrhythmics.

Use in Specific Populations:

Pregnancy: CAVHANZA can cause fetal harm when administered to a pregnant woman.
Lactation: Breastfeeding is not recommended during treatment with CAVHANZA and for 14 days after the last dose.
Pediatric use: CAVHANZA is not approved for use in pediatric patients. Monitor growth and development if used.
Due to Novartis Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled with that pediatric information.
Geriatric use: No major differences for safety were observed in patients ≥65 years taking CAVHANZA.

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

To report SUSPECTED ADVERSE REACTIONS, contact Cycle Pharmaceuticals at 1-855-831-5413, or the FDA at: 1-800-FDA-1088 or **www.fda.gov/medwatch**.

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