imbruvica® By Your Side
Patient Support

Enrollment and Prescription Form

All fields marked with an asterisk (*) are required.

The HCP and the patient or legally authorized person should fill out this form completely before leaving the office. Section 7 not required for enrollment.

PRC-08144

Faxing Instructions:

1. Fax to **IMBRUVICA® By Your Side: 1-800-752-5896**
2. Fax to the patient's preferred Specialty Pharmacy

Questions? Call **1-888-YourSide (1-888-968-7743)**

1 Patient Information* To be completed by the patient or legally authorized person. Please print clearly.

First Name: _____ Last Name: _____

Date of Birth (MM/DD/YYYY): _____ Gender: ☐ M ☐ F

Address: _____ City: _____ State: _____ ZIP: _____

Home Phone: _____ Mobile Phone: _____ Email Address: _____

When did you start treatment? ☐ Not yet started ☐ 0-3 months ago ☐ 4-6 months ago ☐ 7-12 months ago ☐ Over 12 months ago

Optional: I authorize the IMBRUVICA® By Your Side patient support program to contact and communicate with the individual listed here:

Name: _____ Relationship to Patient: _____ Phone Number: _____

Email: _____ Address: _____

City: _____ State: _____ ZIP: _____

By enrolling, you may receive your own IMBRUVICA® By Your Side Ambassador. Ambassadors are provided by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie Company, and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals. For more information about PCYC's Privacy Policy practices or how to opt-out, visit https://www.pharmacyclics.com/privacy-policy.

2 Insurance Information* Please attach insurance cards or fill out information below.

Beneficiary/Cardholder Name: _____ Prescription Insurance: _____

Medical Insurance: _____ Rx Group #: _____

Medical Insurance ID #: _____ Rx ID #: _____

Group #: _____ Rx Bin #: _____ Rx PCN #: _____

Insurance: ☐ Private/Commercial ☐ Medicare ☐ Medicaid ☐ VA Insurance ☐ No Insurance

3

☐ I (the patient) would like to receive news and updates about Pharmacyclics, LLC, an AbbVie Company, and Janssen Biotech, Inc. products, clinical trials, research opportunities, programs, and other information that may be of interest to me.

▼ TO BE COMPLETED BY HEALTHCARE PROFESSIONAL ONLY ▼

4 Diagnosis*

ICD-10 Diagnosis Code: _____

5 Prescriber Information

☐ Receive Benefits Verification Summary ☐ Receive Prior Authorization Form Preferred Method of Contact: ☐ Phone ☐ Fax

Prescriber First Name*: _____ Prescriber Last Name*: _____ NPI #*: _____

Office Address*: _____ City: _____ State: _____ ZIP: _____

Office Contact Name: _____ Office Phone Number*: _____

Prescriber Email: _____ Office Fax Number*: _____

6 Clinical Information

Prior Therapies for Above Indication: _____

Concomitant Drug(s): _____ Allergies: _____

7 Prescription and Pharmacy Information* (REQUIRED FOR PRESCRIPTIONS ONLY)

☐ IMBRUVICA® (ibrutinib) 560-mg tablet ☐ IMBRUVICA® (ibrutinib) 280-mg tablet ☐ IMBRUVICA® (ibrutinib) 140-mg capsule

☐ IMBRUVICA® (ibrutinib) 420-mg tablet ☐ IMBRUVICA® (ibrutinib) 140-mg tablet ☐ IMBRUVICA® (ibrutinib) 70-mg capsule

Directions: _____ Quantity: _____ Refills: _____

Specialty Pharmacy Preference*

☐ In-Office pharmacy name/contact information: _____

☐ Onco360 ☐ Optum Specialty Pharmacy (formerly Avella) ☐ Diplomat

☐ Prescription Faxed to Specialty Pharmacy ☐ Biologics ☐ No preference

Prescriber Certification: I certify that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed IMBRUVICA® (ibrutinib) to the previously identified patient and that I provided the patient with a description of the **IMBRUVICA® By Your Side** Patient Support Program. I authorize **IMBRUVICA® By Your Side** Patient Support Program to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan (if applicable).

Prescriber Signature*: _____ **MM/DD/YYYY*:** _____

I have shared the contents of the enrollment form and PCYC's privacy policy link with the patient.

IMPORTANT INFORMATION: By submitting this form you are referring the above patient to PCYC's patient support program to determine eligibility and receive support related to a PCYC product. Please share this information with your patient. (1) **IMBRUVICA® By Your Side** is a Pharmacyclics, LLC, ("PCYC") and Janssen Biotech, Inc. sponsored program that provides personalized patient support ("By Your Side"). (2) PCYC, its affiliates, collaborators and agents ("PCYC") will use your personal information, including your health information, collected through your enrollment and participation in "By Your Side" to: (1) provide you with support and communications for your prescribed product; and (2) perform research and analytics. For more information about PCYC's Privacy Policy practices or how to opt-out, visit https://www.pharmacyclics.com/privacy-policy.

Please see the accompanying full Prescribing Information or visit IMBRUVICA.com.

imbruvica® (ibrutinib)
560, 420, 280, 140 mg tablets | 140, 70 mg capsules

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(ibrutinib)
560, 420, 280, 140 mg tablets | 140, 70 mg capsules

IMPORTANT SAFETY INFORMATION[1]

WARNINGS AND PRECAUTIONS

Hemorrhage: Fatal bleeding events have occurred in patients who received IMBRUVICA®. Major hemorrhage (≥ Grade 3, serious, or any central nervous system events; e.g., intracranial hemorrhage [including subdural hematoma], gastrointestinal bleeding, hematuria, and post procedural hemorrhage) occurred in 4% of patients, with fatalities occurring in 0.4% of 2,838 patients who received IMBRUVICA® in 27 clinical trials. Bleeding events of any grade including bruising and petechiae occurred in 39%, and excluding bruising and petechiae occurred in 23% of patients who received IMBRUVICA®, respectively.

The mechanism for the bleeding events is not well understood.

Use of either anticoagulant or antiplatelet agents concomitantly with IMBRUVICA® increases the risk of major hemorrhage. Across clinical trials, 3.1% of 2,838 patients who received IMBRUVICA® without antiplatelet or anticoagulant therapy experienced major hemorrhage. The addition of antiplatelet therapy with or without anticoagulant therapy increased this percentage to 4.4%, and the addition of anticoagulant therapy with or without antiplatelet therapy increased this percentage to 6.1%. Consider the risks and benefits of anticoagulant or antiplatelet therapy when co-administered with IMBRUVICA®. Monitor for signs and symptoms of bleeding.

Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections: Fatal and non-fatal infections (including bacterial, viral, or fungal) have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 21% of 1,476 patients who received IMBRUVICA® in clinical trials. Cases of progressive multifocal leukoencephalopathy (PML) and *Pneumocystis jirovecii* pneumonia (PJP) have occurred in patients treated with IMBRUVICA®. Consider prophylaxis according to standard of care in patients who are at increased risk for opportunistic infections.

Monitor and evaluate patients for fever and infections and treat appropriately.

Cytopenias: In 645 patients with B-cell malignancies who received IMBRUVICA® as a single agent, grade 3 or 4 neutropenia occurred in 23% of patients, grade 3 or 4 thrombocytopenia in 8% and grade 3 or 4 anemia in 3%, based on laboratory measurements.

Monitor complete blood counts monthly.

Cardiac Arrhythmias and Cardiac Failure: Fatal and serious cardiac arrhythmias and cardiac failure have occurred with IMBRUVICA®. Grade 3 or greater ventricular tachyarrhythmias occurred in 0.2% of patients, Grade 3 or greater atrial fibrillation and atrial flutter occurred in 4%, and Grade 3 or greater cardiac failure occurred in 1% of 1,476 patients who received IMBRUVICA® in clinical trials. These events have occurred particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of cardiac arrhythmias.

At baseline and then periodically, monitor patients clinically for cardiac arrhythmias and cardiac failure. Obtain an ECG for patients who develop arrhythmic symptoms (e.g., palpitations, lightheadedness, syncope, chest pain) or new onset dyspnea. Manage cardiac arrhythmias and cardiac failure appropriately, and if it persists, consider the risks and benefits of IMBRUVICA® treatment and follow dose modification guidelines.

Hypertension: Hypertension occurred in 19% of 1,476 patients who received IMBRUVICA® in clinical trials. Grade 3 or greater hypertension occurred in 8% of patients. Based on data from 1,124 of these patients, the median time to onset was 5.9 months (range, 0.03 to 24 months).

Monitor blood pressure in patients treated with IMBRUVICA® and initiate or adjust anti-hypertensive medication throughout treatment with IMBRUVICA® as appropriate.

Second Primary Malignancies: Other malignancies (10%), including non-skin carcinomas (4%), occurred among the 1,476 patients who received IMBRUVICA® in clinical trials. The most frequent second primary malignancy was non-melanoma skin cancer (6%).

Tumor Lysis Syndrome: Tumor lysis syndrome has been infrequently reported with IMBRUVICA®. Assess the baseline risk (e.g., high tumor burden) and take appropriate precautions.

Monitor patients closely and treat as appropriate.

Embryo-Fetal Toxicity: Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMBRUVICA® and for 1 month after the last dose. Advise males with female partners of reproductive potential to use effective contraception during the same time period.

ADVERSE REACTIONS

B-cell malignancies: The most common adverse reactions (≥30%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were thrombocytopenia (54.5%)*, diarrhea (43.8%), fatigue (39.1%), musculoskeletal pain (38.8%), neutropenia (38.6%)*, rash (35.8%), anemia (35.0%)*, and bruising (32.0%).

The most common Grade ≥ 3 adverse reactions (≥5%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (20.7%)*, thrombocytopenia (13.6%)*, pneumonia (8.2%), and hypertension (8.0%).

Approximately 9% (CLL/SLL), 14% (MCL), 14% (WM) and 10% (MZL) of patients had a dose reduction due to adverse reactions. Approximately 4-10% (CLL/SLL), 9% (MCL), and 7% (WM [5%] and MZL [13%]) of patients discontinued due to adverse reactions.

cGVHD: The most common adverse reactions (≥20%) in patients with cGVHD were fatigue (57%), bruising (40%), diarrhea (36%), thrombocytopenia (33%)*, muscle spasms (29%), stomatitis (29%), nausea (26%), hemorrhage (26%), anemia (24%)*, and pneumonia (21%).

The most common Grade 3 or higher adverse reactions (≥5%) reported in patients with cGVHD were pneumonia (14%), fatigue (12%), diarrhea (10%), neutropenia (10%)*, sepsis (10%), hypokalemia (7%), headache (5%), musculoskeletal pain (5%), and pyrexia (5%).

Twenty-four percent of patients receiving IMBRUVICA® in the cGVHD trial discontinued treatment due to adverse reactions. Adverse reactions leading to dose reduction occurred in 26% of patients.

*Treatment-emergent decreases (all grades) were based on laboratory measurements.

DRUG INTERACTIONS

CYP3A Inhibitors: Co-administration of IMBRUVICA® with strong or moderate CYP3A inhibitors may increase ibrutinib plasma concentrations. Dose modifications of IMBRUVICA® may be recommended when used concomitantly with posaconazole, voriconazole, and moderate CYP3A inhibitors. Avoid concomitant use of other strong CYP3A inhibitors. Interrupt IMBRUVICA® if strong inhibitors are used short-term (e.g., for ≤ 7 days). See dose modification guidelines in USPI sections 2.3 and 7.1.

CYP3A Inducers: Avoid coadministration with strong CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment (based on Child-Pugh criteria): Avoid use of IMBRUVICA® in patients with severe hepatic impairment. In patients with mild or moderate impairment, reduce recommended IMBRUVICA® dose and monitor more frequently for adverse reactions of IMBRUVICA®.

INDICATIONS

IMBRUVICA® is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion

Reference: 1. IMBRUVICA® (ibrutinib) Prescribing Information. Pharmacyclics LLC. 2020.

Please see the accompanying full Prescribing Information or visit IMBRUVICA.com.