APDSAssist™

Patient Enrollment Form

Fax completed forms to: (833) 850-2737 (APDS)

Joenja leniolisib

Getting Started

Step 1:

Fill out both pages of the Patient Enrollment Form

Page 1

Patient to read and sign the Consent Form

NOTE: Patient signature on Consent Form is required to access APDS Assist support, including clinical educator services, copay assistance, and product assistance for eligible patients. If consent is not submitted with the enrollment form, APDS Assist will work with the patient to obtain consent. Benefit verification will occur without receipt of consent.

Page 2

Provider to fill out and sign the Patient Enrollment Form including a copy of the patient's insurance card.

NOTE: The Patient Enrollment Form provides prescription for both Commercial and Product Assistance.

Step 2:

For prior authorization support, submit Page 1 and 2 of the Patient Enrollment Form to APDS Assist, along with the following documentation:

- **Copy of Genetic Test results confirming the diagnosis of APDS** (required)
- **Patient's medication list** (including allergies) and **current patient weight** (required)
- Clinical **documentation of symptoms, labs, and manifestations** related to APDS (required)
- Any additional clinical information pertaining to **patient's clinical history and diagnosis** (required)
- Any **past or current imaging files (ie, CT/MRI/ultrasound)** related to APDS (optional)

Fax: (833) 850-2737 (APDS)

Questions? Call (877) 796-2737 (APDS) between 8 AM-8 PM ET M-F for additional assistance

Note: Patient support services cannot be provided without the signed Patient Consent Form

Indications and Usage
JOENJA® (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3δ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

Important Safety Information
Verify pregnancy status in females of reproductive potential prior to initiating treatment with JOENJA.

JOENJA may cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus and to use highly effective methods of contraception during treatment with JOENJA and for 1 week after the last dose. Additionally, advise women not to breastfeed during treatment with JOENJA and for 1 week after the last dose.

Live, attenuated vaccinations may be less effective if administered during JOENJA treatment.

JOENJA may cause hypersensitivity reaction(s), including anaphylaxis. Advise patients to discontinue JOENJA and to seek immediate medical attention if they develop any signs and symptoms of serious allergic reactions.

Use of JOENJA in patients with moderate to severe hepatic impairment is not recommended. There is no recommended dosage for patients weighing less than 45 kg.

Avoid co-administration of JOENJA with other medications known to be strong CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, or BCRP, OATP1B1, and OATP1B3 substrates.

The most common adverse reactions (incidence >10%) were headache, sinusitis, atopic dermatitis, and weight gain.

Seven (33%) patients receiving JOENJA developed an absolute neutrophil count (ANC) between 500 and 1500 cells/microL. No patients developed an ANC <500 cells/ microL and there were no reports of infection associated with neutropenia.

Before prescribing JOENJA, please read the full Prescribing Information.

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Patient Consent Form

Patient Name _____ **DOB** _____

Patient Email _____ **Patient Phone (Cell)** _____

Emergency Contact Name _____ **Relationship to Patient** _____

Emergency Contact Phone _____

Emergency Contact I authorize APDS Assist, my doctor, my pharmacist, or any representative attempting to provide me with access to Joenja to contact the emergency contact listed above on my behalf in the event of an emergency.

By signing this Authorization, I authorize my healthcare providers (e.g., physicians, pharmacies, other healthcare professionals, facilities and staff) and insurers (e.g., health insurance plans) to share my protected health information with Pharming Healthcare, Inc., and its agents and representatives ("Pharming") for the purposes of enrolling me in and providing me services through Pharming's APDS Assist ("Program"). I authorize Pharming to receive and use my health information (including information about my medical condition, treatment, and insurance coverage), my contact information and any other information I or my healthcare providers or insurers provide to Pharming ("My Information"). I also authorize my healthcare providers and insurers to receive My Information from the Program. I consent to Pharming enrolling me in the Program and providing me with support related to any of Pharming's products, such as insurance coverage, prescription fulfillment, online support, financial assistance services, adherence, and other therapy support services. I understand that personnel providing support as part of the Program are not employed by my healthcare provider(s). I understand that Pharming may use My Information for: determining my eligibility (or ineligibility) to participate in the Program and providing Program services (such as prescription fulfillment, free product assistance programs, financial assistance services, adherence, insurance coverage assessment, and other therapy support services as further described at www.joenja.com/apds-assist/); evaluating, improving or developing the Program; conducting data analytics and market research; communicating with me; and for Pharming's internal business purposes. Once My Information has been disclosed to Pharming , I understand that federal privacy laws no longer protect the information. Pharming agrees to protect My Information as required by law. I understand that Pharming may remunerate service providers, including pharmacies, in exchange for My Information and/or for therapy support services provided to me. I further understand that my treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my signing this Authorization and I may refuse to sign it; but if I do not sign it or later cancel it, I will not be able to participate in the Program. This Authorization expires five (5) years from the date signed unless a shorter period is required by law, or until I am no longer participating in the Program. My Information that is collected before cancellation may continue to be used for the purposes set forth in this Authorization. I may cancel this Authorization at any time by calling (877) 796-2737 or sending an email to info@pharming.com. Canceling this Authorization will not affect how Pharming uses and shares My Information prior to my cancellation. I understand that I am entitled to a copy of this Authorization after signing below. By providing my contact information to Pharming, I authorize the Program to contact me via any of the contact methods provided by me on this Authorization form to provide me support related to any Program services listed above and/or to provide me with information about insurance coverage, prescription fulfillment, product assistance, financial assistance services, adherence, other therapy support services, relevant disease-related information, potential topics of interest to me, customer surveys, or occasionally for market research purposes. I understand that I may opt out of these communications at any time by contacting Pharming at (877) 796-2737 or replying "STOP" to any text message I receive. For text messages, reply "HELP" for help or "STOP" to opt-out of receiving marketing texts. Message frequency varies (messaging rates may apply).

Consent for Collection and Use of Health Information: By signing below, I consent to the collection and use of my health information, contact information and other identifying information by Pharming, which I, my healthcare providers or others share with Pharming for the purposes described in this form and as further described in the Pharming Privacy Policy at www.pharming.com/privacy-statement.

☐ **Opt-In for Marketing Communications** (Optional) By checking this box, I consent to receive automated and recurring phone calls and text messages from Pharming for the purpose of sending me marketing messages about Pharming products or services. I understand that I am not required to provide this consent as a condition of participating in the Program. For text messages, reply"HELP" for help or "STOP" to opt-out of receiving marketing texts. Message frequency varies (messaging rates may apply).

By signing below, I confirm that I have read and understand the Consent to Share Health Information and Patient Support Services above and agree to the terms.

Printed Patient/Legal Representative Name _____

Patient/Legal Representative Signature _____ Date _____

If Legal Representative, Relationship to Patient _____

Before prescribing Joenja, please read the accompanying full Prescribing Information or go to www.joenja.com

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A Patient Information

Name _____ ☐ Male ☐ Female Last 4 digits of SSN _____

Date of Birth (mm/dd/yyyy) _____ Primary Language: ☐ English ☐ Spanish ☐ Other _____

Check Preferred Phone #: ☐ Cell # _____ ☐ Home # _____ ☐ Other # _____

Email _____

Address _____

City/State/Zip _____

Is the patient currently receiving leniolisib: ☐ Yes ☐ No

Caregiver Name _____

Relationship to Patient _____

☐ OK to leave voicemail

Caregiver Phone _____

B Patient Insurance Information – Please provide front/back copies of the insurance card

Primary Medical Insurance _____

Medical Insurance ID# _____ Insurance Group # _____

Prescription Drug Plan _____ Rx ID # _____

Rx BIN # _____ Rx PCN# _____ Rx Group# _____

☐ If the patient has secondary insurance, please check this box and attach a copy of the insurance card

Policyholder Name _____

Policyholder Date of Birth (mm/dd/yyyy) _____

Policyholder Relationship to Patient _____

C Prescriber Information

Provider Specialty: ☐ Allergy & Immunology ☐ Hematology ☐ Oncology ☐ Pulmonologist ☐ Other _____

Prescriber Name _____ **NPI (required)** _____ State License # _____

Practice Name _____

Address _____

City/State/Zip _____

Phone _____ Fax _____

Accurate office phone and fax required for efficient contact

Office Contact Name _____

Role _____

Contact Phone _____

Contact Email _____

D Prescription Information Required

Diagnosis Code: ☐ D81.82 Activated PI3K Delta Syndrome

Product: ☐ Joenja (leniolisib) 70mg tablets

Directions: ☐ Take one tablet by mouth twice daily

Quantity: 60 tablets

Refills: ☐ 11 ☐ Other _____

Patient weight (kg) _____

Date recorded _____

Date of Genetic Diagnosis

(*Please provide report*) _____

**PIK3CD*:

☐ Pathogenic ☐ Likely Pathogenic ☐ VUS

**PIK3R1*:

☐ Pathogenic ☐ Likely Pathogenic ☐ VUS

E Product Assistance Program

☐ I attest that I am requesting product assistance for a patient having a documented diagnosis of APDS in accordance with the FDA approved indication. Eligibility for the APDS Assist Product Assistance Program is subject to additional program terms and conditions. Pharming reserves the right to rescind, revoke, or amend the program at any time without notice.

Product: ☐ Joenja (leniolisib) 70mg tablets

Directions: Take one tablet by mouth twice daily; up to 30-day supply; up to 60 tablets Refills: 0

F Prescriber Signature

By signing this form, I am indicating a prescribing decision has been made. In addition, I am certifying treatment with Joenja indicated above is medically necessary for this patient, and I have received authorization to release the medical and/or other patient information relating to this therapy to Pharming Healthcare, APDS Assist and its affiliated companies, agents, and representatives (including, but not limited to, PANTHERx Rare Pharmacy) to use and disclose as necessary for prior authorization processing and fulfillment of the prescription. I certify that, to the best of my knowledge, the patient and physician information in this form is complete, accurate, and consistent with applicable privacy regulations.

To indicate the brand is medically necessary, please handwrite "brand medically necessary" on this line. _____

Prescriber Signature (no stamps) _____ **Date:** _____

Prescriber is to comply with their 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 the prescriber.

Before prescribing Joenja, please read the accompanying full Prescribing Information or go to www.joenja.com