APDSAssist™

Joenja® leniolisib

# Patient Enrollment Form

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

## Getting Started

### Step 1:
### Fill out both pages of the 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*

#### Page 2

**Provider to fill out and sign the Enrollment Form** including a copy of the patient's insurance card
***NOTE:*** *The Enrollment Form provides prescription for both Commercial and Free Goods Programs*

### Step 2:
### Submit Page 1 and 2 of the Enrollment Form to APDS Assist, along with the following documentation:

- **Patient's current weight and full medication list**, including drug and other allergies
- Copy of **genetic testing results** confirming the clear indication of APDS diagnosis code
- **Copy of complete** blood count with differential, chemistry panel, and any other **pertinent labs**
- Clinical **notes documenting patient signs, symptoms, and manifestations** of APDS
- Any additional clinical information pertaining to **patient's clinical history that supports the APDS diagnosis**
- Any **past or current imaging files (ie, CT/MRI/ultrasound)** and associated reports related to APDS
- Documentation of **other therapies used to treat symptoms of APDS**

**This requested documentation will help APDS Assist to support your office with coverage authorizations when allowed by an insurance company. There may be occasions where the insurer will request additional documentation and/or mandate that your office submit the coverage requests. If this is the case, your office will be informed on a subsequent fax or phone call from the APDS Assist support team.**

### Step 3:
### Let your patient know you are sending in a referral for them and that APDS Assist will be calling them for their first contact point

**Fax:**
**(833) 850-2737 (APDS)**
**Preferred method**

**OR**

ePrescribe*:
PANTHERx Specialty Pharmacy
24 Summit Park Drive
Pittsburgh, PA 15275
NPI: 1316213531

***If ePrescribe is used, you still need to fax the Patient Consent Form and the items listed in Step 2. It is recommended that you search for PANTHERx Specialty Pharmacy ePrescribe using the address or NPI listed above.**

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

**INDICATIONS AND USAGE**
JOENJA® (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) 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 of JOENJA.

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

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.

The most common adverse reactions (incidence >10%) seen in clinical trials were headache, sinusitis, and atopic dermatitis.

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 accompanying full Prescribing Information or go to www.joenja.com**

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## Patient Consent Form

**Patient Name:** _____ **DOB:** _____

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

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

**Emergency Contact Phone:** _____

**Consent to Share Health Information:** By signing this Consent, I authorize my healthcare provider, my health insurance company, and my pharmacy providers ("Healthcare Entities") to disclose to APDS Assist Program ("Program") operated by Pharming Healthcare and companies working with Pharming Healthcare, health information relating to my medical condition, treatment, and insurance coverage for Pharming Healthcare to provide me with (i) support services (and related information and materials) related to any of Pharming Healthcare's products, including but not limited to insurance coverage, prescription fulfillment, online support, financial assistance services, adherence, and other therapy support services; and (ii) information about Pharming Healthcare's products, services, and programs. I understand that Pharming may use my health information to conduct data analytics, market research, and other internal business activities. Once my health information has been disclosed to Pharming Healthcare, I understand that federal privacy laws no longer protect the information. However, Pharming Healthcare agrees to protect my health information by using and disclosing it only for purposes authorized in this Consent or as required by law or regulations. I understand that my pharmacy provider may receive remuneration from Pharming Healthcare in exchange for the health information and/or for any therapy support services provided to me. I understand that I may refuse to sign this Consent. I further understand that my treatment (including with a Pharming Healthcare product), payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my agreement to sign this Consent; but if I do not sign it or later cancel it, I will not be able to receive Pharming Healthcare's patient program support. I may cancel this consent at any time by calling (877) 796-2737. Canceling this Consent will end my consent to further disclosure of my health information to Pharming Healthcare by my Healthcare Entities after they are notified of my cancellation but will not affect previous disclosures by them pursuant to this Consent. Canceling this Consent will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance. This Consent expires five (5) years from the date signed unless a shorter period is required by state law.

**Patient Support Services:** I authorize APDS Assist to contact me to provide me support related to any of Pharming Healthcare's products, including but not limited to insurance coverage, prescription fulfillment, financial assistance services, adherence, and other therapy support services, relevant disease-related information, as well as any information or materials related to such services. I understand that any personnel providing support as part of the APDS Assist is not employed by my healthcare professional. APDS Assist or Pharming Healthcare may contact me by mail, email, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I also authorize Pharming Healthcare to use my health information in connection with the services and programs, including, without limitation, sharing such information with my Healthcare Entities.

**Opt-in for Other Resources:** By signing below, I authorize Pharming Healthcare, and companies working with Pharming Healthcare, to contact me by mail, email, fax, text messaging, and/or telephone regarding other potential topics of interest to me, customer surveys, or occasionally for market research purposes. I understand that I am not required to provide this consent as a condition of receiving any Pharming Healthcare medicine or Patient Support Services. Note that Pharming Healthcare will not sell or trade my personal data to any unrelated third party.

☐ I would like to **opt out** of receiving other resources

**Emergency Contact:** By providing emergency contact information above, I authorize the licensed pharmacy PANTHERx to speak with the named person and accept medications requests/orders from the named person in the event that I am unable to speak with PANTHERx myself.

**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.**

Patient Sign

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 ☐ Other _____

**Patient's weight** _____kg _____lbs Date recorded _____

Product: Joenja (leniolisib) 70 mg tablets

Directions: ☐ One tablet twice daily; 30-day supply; 60 tablets

☐ Other _____

Refills _____

Date of Genetic Diagnosis (*Please provide report*) _____

**PIK3CD*: ☐ Pathogenic ☐ Likely Pathogenic ☐ VUS

**PIK3R1*: ☐ Pathogenic ☐ Likely Pathogenic ☐ VUS

## E Starter Program

Patients who are prescribed Joenja (leniolisib) in accordance with the FDA-approved indication may be eligible for the APDS Assist Starter Program while insurance coverage is being pursued.

☐ Yes, enroll my patient in the APDS Assist Starter Program, if eligible

Product: Joenja (leniolisib) 70 mg tablets Directions: One tablet 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) 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.

***For Starter Program:*** *I understand that this medication is being provided free to the named patient by Pharming and agree that neither I nor the patient will bill an insurer or any government healthcare program for the cost of this medication. The program may not be combined with another offer and is not eligible to patients without insurance or whose insurer has made a final coverage determination. Patients must be residents of the US and have a US mailing address.*

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

MD Sign

**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**