ARCALYST® (rilonacept) ENROLLMENT FORM

KINIKSA oneconnect™

Instructions for **Healthcare Providers (HCP)**

To prescribe ARCALYST, please follow these steps:

1 Have your patient read the Patient Consent Information form and sign the signature field

Give your patient a copy of the Patient Consent Information form. If the form is not signed at submission, a Patient Access Lead with the Kiniksa OneConnect™ program can subsequently acquire a signature electronically.

2 Complete this enrollment form and download a copy. Please be sure all of the items in this HCP instructions checklist are completed on the enrollment form:

- ☐ **Fill out all required fields;** incomplete fields may delay the start of treatment
- ☐ **Sign and date** the enrollment form in PRESCRIBER CERTIFICATION (section 6)
- ☐ Fully complete the PRESCRIPTION (section 5), **including sterile water, refills, and ancillary supplies**
- ☐ Complete INSURANCE INFORMATION (section 2) and **provide copies of your patient's medical and prescription insurance cards**
- ☐ Upload or attach patient demographic sheet if available
- ☐ If required, please submit a completed Prior Authorization (PA) with the patient's enrollment form

3 Fax the enrollment form to 781-609-7826. Following enrollment:

- A Patient Access Lead with the Kiniksa OneConnect™ program will contact your patient to discuss the next steps to take to get their ARCALYST prescription filled
- The specialty pharmacy will coordinate delivery of the prescription to the address provided in section 1 of the enrollment form

If you have any questions about the Kiniksa OneConnect™ program, please call **833-KINIKSA (833-546-4572)**.
To learn more about ARCALYST, visit **arcalyst.com/HCP**

Instructions for **Patients**

To get started on ARCALYST, please follow these steps:

1 Read the Patient Consent Information and sign the signature field

If unable to sign, a Patient Access Lead with the Kiniksa OneConnect™ program can subsequently acquire a signature electronically

2 Your healthcare provider will complete the enrollment form. Once enrolled:

- A Patient Access Lead with the Kiniksa OneConnect™ program will contact you to discuss the next steps in getting your ARCALYST prescription filled (calls may come from an 833 number, "unknown number," or "no caller ID")
- A Patent Access Lead may also communicate through texting if you prefer this method of communication
- The specialty pharmacy will coordinate delivery of the prescription to the address provided in section 1 of the enrollment form

If you have questions about the Kiniksa OneConnect™ program, please call **833-KINIKSA (833-546-4572)**.
To learn more about ARCALYST, visit **arcalyst.com**.

Please see full Prescribing Information available at ARCALYST.com/PI

For details about how Kiniksa collects and uses personal information, your privacy rights, and specific notices for California residents, please visit: **kiniksapolicies.com/privacy.html**

PATIENT CONSENT INFORMATION

Please read the following, then complete and sign the areas indicated below.

I understand that the Kiniksa OneConnect™ program ("the Program") is a patient support service offered by Kiniksa Pharmaceuticals ("Kiniksa") to help eligible patients who have been prescribed a Kiniksa therapy to obtain financial assistance and access other patient support programs and services provided by the Program.

By signing below, I authorize my healthcare providers and staff (eg, physicians, pharmacies) and my insurance company to disclose in electronic or other form, personal health information about me, including information related to my medical condition and any treatment, my health insurance coverage, and my address, email address, and telephone number (collectively, my "PHI") to Kiniksa, its affiliates, agents, contractors, and representatives, and the Program so that Kiniksa may review, use, and disclose the PHI and information on this form for purposes of: (1) verifying, investigating, assisting with, and coordinating my coverage for the therapy with my healthcare provider or health insurers; (2) assessing my eligibility for co-pay assistance or free drug or referring me to other programs and sources of funding and financial support; (3) coordinating delivery of the therapy to me or my healthcare provider; (4) providing education, information on Kiniksa products, and support services to me related to the therapy; (5) gathering feedback on my therapy and/or disease state; (6) contacting me by mail, email, phone, or text for any of the above purposes; and (7) creating information that does not identify me personally for use other than for the legitimate purposes as set forth in this authorization. I also authorize Kiniksa and my healthcare providers and my insurance company to use my PHI to communicate with me about Kiniksa products and services. I authorize my pharmacy and Kiniksa contractors to receive remuneration from Kiniksa for disclosing or using my PHI and/or for providing support services as outlined in this authorization. I understand that once disclosed pursuant to this authorization, my PHI may no longer be protected under federal or state law and could be disclosed by Kiniksa to others, but I also understand that Kiniksa will make reasonable efforts to keep my PHI private and to disclose it only for purposes set forth in this authorization.

I understand that I do not have to sign this authorization to obtain health care treatment or benefits; however, in order to receive the services and communications described above, I must sign the authorization. I understand that I may cancel my authorization at any time by contacting Kiniksa by fax at 1-781-609-7826, or by mail at Kiniksa OneConnect Program, 100 Hayden Avenue, Lexington, MA 02421. My cancellation of this authorization will be effective for Kiniksa upon receipt, and will be effective for each of my healthcare providers and insurance companies when they are notified of it, but the cancellation will not affect prior uses or disclosures of PHI.

I understand that I have a right to receive a copy of this authorization.

I understand that this authorization will remain valid for 5 years after the date I sign it as shown below, unless I cancel it earlier as described above, or unless a shorter period is required under state or local laws.

If the form is not signed at submission, a Patient Access Lead with the Kiniksa OneConnect™ program can subsequently acquire a signature electronically.

***Required information.**

***PATIENT CONSENT**	**If patient consent on this form during submission is not possible, consent can be acquired electronically.**
I have read, understand, and agree to all the PATIENT CONSENT INFORMATION and verify that the information I have provided in this authorization is complete and accurate.	
*Printed Name of Patient, Legal Guardian, or Personal Representative:	
*Relationship to Patient:	Email:
***Signature of Patient, Legal Guardian, or Personal Representative: _____ *Date: _____**	

Please review the statements below. Checking these boxes is optional.

☐ By checking this box, I consent to receive recurring text messages from the Kiniksa OneConnect™ program, including service updates and medication reminders, to the number I have provided. Message and data rates may apply. I am not required to consent or provide my consent as a condition of receiving any goods or services. I can text STOP to unsubscribe any time. For more details, please visit **kiniksapolicies.com/privacy.html**

☐ By checking this box, I consent to participate in marketing surveys and receive marketing communications and materials from Kiniksa via phone, mail, or email. I understand that I may opt out of receiving such messages at any time by calling **833-KINIKSA (833-546-4572)** or emailing **KiniksaOneConnect@kiniksa.com**

☐ By checking this box, I understand that the personal data I provide on this form may be shared with third parties operating on behalf of Kiniksa to conduct market research. I authorize Kiniksa and these third parties to contact me for market research purposes.

1 *PATIENT INFORMATION

First name:	MI:	Last name:	Suffix:	Sex: ☐ M ☐ F
Home address:		City/State:		ZIP:
Alternate address:		City/State:		ZIP:
Ship treatment to: ☐ Home address ☐ Alternate address				DOB:
Preferred phone: _____ ☐ Home ☐ Mobile ☐ Work			Alternate phone: _____ ☐ Home ☐ Mobile ☐ Work	
Email:		Preferred contact method: ☐ Phone (OK to leave messages: ☐ Y ☐ N) ☐ Text ☐ Email		
Best time to contact: ☐ Weekday mornings ☐ Weekday afternoons ☐ Weekday evenings			Language: ☐ English ☐ Spanish ☐ Other _____	
Alternate contact first name:		Last name:	Relationship to patient:	
Phone:	Email:		OK to leave messages: ☐ Y ☐ N	

MEDICAL HISTORY

Current medications _____

Allergies: ☐ No Known Drug Allergies ☐ Other: _____

2 * INSURANCE INFORMATION

Please provide a copy of the front and back of the patient's medical and prescription insurance cards.

Is the patient enrolled in a government-funded health plan†, qualified health plan (QHP), or plan offered on a state or federal marketplace or exchange? ☐ Yes ☐ No ☐ Patient Does Not Have Health Insurance

†Such as Medicare, Medicare Part D, Medicaid, VA, DoD, TRICARE®.

Primary Insurance:	ID #:	Group #:	Phone #:
Policy Holder:		Relationship to Patient:	
Pharmacy Insurance:	ID #:	Group #:	Phone #:
Policy Holder:		Relationship to Patient:	
RxBIN:		RxPCN:	

3 *PRACTICE AND PRESCRIBER INFORMATION

Office/Clinic/Institution name:		**Contact name:**
Address:	City/State:	ZIP:
Contact email:	Contact phone:	Contact fax:
Prescriber first name:	**Prescriber last name:**	
Address:	City/State:	
NPI #:	License # (and state):	
Tax ID #:		

Please continue enrollment on next page.

ENROLLMENT FORM | *Required information

KINIKSA oneconnect™

4 *DIAGNOSIS

☐ Cryopyrin-associated periodic syndromes (CAPS) ICD-10-CM: _____ ☐ Deficiency of IL-1 receptor antagonist (DIRA) ICD-10-CM: _____ ☐ Other ICD-10-CM: _____

5 *PRESCRIPTION FOR ARCALYST® (rilonacept) injectable sterile powder for reconstitution, 220 mg/vial

Reconstitute each single-dose vial of ARCALYST with 2.3 mL preservative-free sterile water for injection, resulting in 80mg/mL solution.

Patient first name: **Last name:** **DOB: __ /__ /____**

CAPS WEEKLY DOSING

FOR PATIENTS ≥18 YEARS OF AGE for cryopyrin-associated periodic syndromes (CAPS)

LOADING DOSE: Inject 320 mg [given as two x 2 mL (160 mg) injections] subcutaneously on day 1. Inject each dose at a different injection site.

To be administered at: ☐ Practice ☐ Home

Quantity: 2 vials **Refills:** 0

MAINTENANCE DOSE Inject 2 mL (160 mg) subcutaneously once weekly. Rotate injection sites as needed.

To be administered at: ☐ Practice ☐ Home

Quantity: ☐ 1 month (4 vials)

Refills: ☐ 11 ☐ Other _____

FOR PATIENTS 12 TO 17 YEARS OF AGE for cryopyrin-associated periodic syndromes (CAPS)

LOADING DOSE Inject (from LD calculation below) _____ mL (_____ mg) subcutaneously on day 1. If injection volume is greater than 2 mL, split between two syringes at different injection sites. **Loading dose should not exceed 320 mg (4 mL).**

Patient weight: _____ kg x 4.4 mg = Loading Dose (LD): _____ mg ÷ 80 mg/ mL = _____ mL

To be administered at: ☐ Practice ☐ Home **Quantity:** _____ vials **Refills:** 0

MAINTENANCE DOSE Inject (from MD calculation below) _____ mL (_____ mg) subcutaneously once weekly. If injection volume is greater than 2 mL, split between two syringes at different injection sites. **Maintenance dose should not exceed 160 mg (2 mL).** Rotate injection sites as needed.

Patient weight: _____ kg x 2.2 mg = Maintenance Dose (MD): _____ mg ÷ 80 mg/ mL = _____ mL

To be administered at: ☐ Practice ☐ Home

Quantity: ☐ 1 month (4 vials) **Refills:** ☐ 11 ☐ Other _____

DIRA WEEKLY DOSING

FOR ADULT PATIENTS ≥ 18 YEARS OF AGE
for deficiency of IL-1 receptor antagonist (DIRA)

DOSE 4.4 mg/kg up to a maximum of 320 mg, delivered as 1 or 2 injections (2 mL/injection) once weekly. Rotate injection sites as needed.

To be administered at: ☐ Practice ☐ Home

Quantity: ☐ 1 month (4 vials)

Refills: ☐ 11 ☐ Other _____

FOR PEDIATRIC PATIENTS ≤ 17 YEARS OF AGE WEIGHING AT LEAST 10 KG
for deficiency of IL-1 receptor antagonist (DIRA)

DOSE Inject (from Dose calculation below) _____ mL (_____ mg) subcutaneously once weekly. If injection volume is greater than 2 mL, split between two syringes at different injection sites. **Dose to not exceed 320 mg (4 mL).**

Patient weight: _____ kg x 4.4 mg = Dose: _____ mg ÷ 80 mg/ mL = _____ mL

To be administered at: ☐ Practice ☐ Home

Quantity: ☐ 1 month (4 vials) **Refills:** ☐ 11 ☐ Other _____

*REQUIRED PRESCRIPTIONS FOR ADMINISTRATION OF ARCALYST

ADDITIONAL SUPPLIES

☐ **Preservative-free sterile water for injection (5 mL, 10 mL, or whatever is available)** **Quantity:** ☐ **1 month** **Refills:** ☐ **11** ☐ **Other** _____

Ancillary supplies **Quantity:** ☐ **1 month** **Refills:** ☐ **11** ☐ **Other** _____

☐ I request inclusion of the ancillary supplies listed to the right, which are needed to administer ARCALYST. The ancillary supplies will be sent to patients with their ARCALYST treatment **and are included in the cost**. Certain state laws require the physician to include a prescription for ancillary materials. The label for ARCALYST requires the following ancillary materials:

- **10** sterile 3-milliliter (mL) disposable syringes
- **20** sterile disposable needles, 26-gauge, 1/2-in
- **20** sterile blunt beveled needles with needle covers, 18-gauge, 1-in, or 1½-in
- **20** alcohol wipes
- **8** gauze pads
- **1** puncture-resistant container for disposal of used needles, syringes, and vials

Injection training for patient will be conducted by: ☐ Prescriber/Practice (In-Office) ☐ Kiniksa OneConnect™ Program Injection Training Support

6 *PRESCRIBER CERTIFICATION

Please manually sign and date below. No rubber stamps, signature by other office personnel, or computer generated images are allowed.

"Dispense As Written" / Brand Medically Necessary / Do Not Substitute / No Substitution / DAW / May Not Substitute

Prescriber's signature: _____

NPI#: _____ **Date:** _____

If NP or PA, under direction of Dr. _____ **License #:** _____

OR

May Substitute / Product Selection Permitted / Substitution Permissible

Prescriber's signature: _____

NPI#: _____ **Date:** _____

If NP or PA, under direction of Dr. _____ **License #:** _____

CA, MA, NC & PR: Interchange is mandated unless Prescriber writes the words **"No Substitution"** _____

The prescriber is to comply with his/her 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.

By signing above, I certify that (1) the information contained in this application is current, complete, and accurate to the best of my knowledge; (2) the therapy is medically necessary and in the best interest of the patient identified above; (3) I have obtained and provided any consent required under federal and state law for the release and use of the patient's personal health information including diagnosis, treatment, medical information and insurance information contained on this form to Kiniksa Pharmaceuticals ("Kiniksa") and its agents, including commercial and field-based teams, for purposes of benefits verification and coordination of dispensing therapy, or to otherwise assist the patient to initiate or continue the prescribed therapy and/or to evaluate the patient's eligibility for the QuickStart Program, Patient Assistance Program, or other programs for ARCALYST; and (4) I will not seek payment from any payer, patient, or other source for free product provided directly to the patient.
I understand that I am under no obligation to prescribe any Kiniksa therapies, to participate in the Kiniksa OneConnect™ program, and that I have not received, nor will I receive, any benefit from Kiniksa for prescribing a Kiniksa therapy. I certify that I am a legal resident of the United States (or US territories).
I authorize Kiniksa and its agents to convey the above prescription by any means allowed under applicable law to the dispensing pharmacy. Special note: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc.
Noncompliance with state-specific requirements could result in outreach to the prescriber.