KINIKSA oneconnect®

ARCALYST® (rilonacept) ENROLLMENT FORM

Instructions for **Healthcare Providers (HCPs)**

To prescribe ARCALYST, please follow these steps:

1 Have your patient read the Patient Consent Information form on page 2 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. Please be sure all of the items below 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).
- ☐ Complete INSURANCE INFORMATION (section 2) and **provide copies of your patient's medical and prescription insurance cards**
- ☐ Include a patient demographic sheet if available
- ☐ Submit a completed Prior Authorization (PA) directly to the payer, if required
- ☐ Please do NOT send clinical notes and medical records

3 Fax the enrollment form to 1-781-609-7826. Following enrollment:

- A Kiniksa OneConnect Patient Access Lead will confirm enrollment with your office via efax, and contact the patient with next steps for prescription fulfillment
- The specialty pharmacy will deliver the prescription to the address provided in section 1 of the enrollment form

CAPS and DIRA ICD-10 Codes:

- Payers may require an ICD-10 code on a prior authorization
- Specialty pharmacies may also ask for a patient's ICD-10 code

On the right are codes associated with CAPS and DIRA

- The decision to assign an ICD-10 code is up to a physician's discretion and knowledge of the patient's condition(s)
- This is not an all-inclusive list. Payers may require other ICD-10 codes not listed here
- Use of the listed codes is not a guarantee of coverage or payment

ICD-10 Code	Description
M04.2	Cryopyrin-Associated Periodic Syndrome (CAPS)
M04.8	Deficiency of Interleukin 1 Receptor Antagonist (DIRA)

Please see full Prescribing Information available at ARCALYSThcp.com

Complete and fax/efax pages 2-4 of this enrollment form to 1-781-609-7826.

Please call the Kiniksa OneConnect program at **1-833-546-4572** if you have any questions.

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PATIENT AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

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

I understand Kiniksa OneConnect™ ("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.

By signing below, I authorize my healthcare providers, pharmacies, health plan and insurers to share my Protected Health Information ("PHI"), including but not limited to information related to my medical condition, treatment, care management, health insurance, medication history, prescriptions and all information provided on this form with Kiniksa and its affiliates, and partners so they can provide the following support services:

- Assess my eligibility for financial assistance and help coordinate insurance coverage in order for me to receive my medication.
- Communicate with me about my medication, treatment, possible financial assistance, and if enrolled, administer my participation in any sponsored financial assistance program.
- Help me take part in the Program, support ongoing Program activities, and provide educational services.
- Improve service quality, handle business operations, and ask for my feedback about the services or my treatment.

I authorize my pharmacy and Kiniksa Partners to receive payment from Kiniksa for sharing or using my PHI and/or for providing support services described in this form. I understand that once my PHI is shared under this authorization, it may no longer be protected under federal law and could be shared by Kiniksa with others. I also understand that Kiniksa will make reasonable efforts to keep my PHI private and to only process it for the purposes set forth in this authorization.

I understand that I do not have to sign this form to receive health care treatment or benefits. However, I must sign it to receive the services and communications described above. 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 10 years after the date I sign it as shown below, unless I cancel it earlier as described above, or if a shorter period is required under state or local laws. If the form is not signed at submission, a Patient Access Lead with the Program can subsequently acquire a signature electronically.

***Required information. A signature and consent to use and disclose personal and consumer health data are required to receive Kiniksa OneConnect services.**

PATIENT AUTHORIZATION

Printed Name of Patient, Legal Guardian, or Personal Representative:

Relationship to Patient: | Email:

Please specify any additional contacts with whom Kiniksa OneConnect is allowed to discuss patient's information.

Additional Contact Name: | Relationship to Patient:

***(Required for services) Signature of Patient, Legal Guardian, or Personal Representative:** _____

Date: _____

☐ ***(Required for services) PATIENT CONSENT TO USE AND DISCLOSE PERSONAL AND CONSUMER HEALTH DATA**

By checking the box above, I'm agreeing to the use, disclosure and other related processing of my Personal and Consumer Health Data by Kiniksa for the purposes of participating in the Program as described below.

Kiniksa will process your Personal Data, including data that may be considered Consumer Health Data under certain privacy laws (e.g., name, email address, phone number, health information), in accordance with their Privacy Policy: **https://kiniksapolicies.com/privacy**.

By participating in the Program, you agree to the collection, use and disclosure of your Personal and Consumer Health Data to (1) facilitate participation and assist in the general administration of the Program, (2) conduct any additional services related to the Program, including clinical and educational services, and (3) to receive communications, including education, support, product information, and other related information determined to be relevant to your participation in the Program; communications may be customized based on your Personal and Consumer Health Data. You may withdraw your consent to participate in the Program at any time by contacting **privacy@kiniksa.com**.

☐ **I WOULD LIKE TO RECEIVE TEXT MESSAGES**

By checking the box above, I am opting 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 provide my consent as a condition to receiving any goods or services. I can text STOP to unsubscribe any time. For more details, please visit **https://kiniksapolicies.com/privacy**.

☐ **I WOULD LIKE TO RECEIVE MARKETING COMMUNICATIONS**

By checking the box above, I am opting to participate in marketing surveys and receive marketing communications and materials from Kiniksa via phone, mail, or email. 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 also authorize Kiniksa and these third parties to contact me for market research purposes. I understand that I may opt out of receiving such messages at any time by clicking on the unsubscribe link in any email or emailing **privacy@kiniksa.com**.

ENROLLMENT FORM

KINIKSA oneconnect®

1 PATIENT INFORMATION *REQUIRED FIELDS

*First name:	MI:	*Last name:	*DOB:
*Address:	*City:	*State:	*ZIP:
Ship treatment to: ☐ Home address ☐ Alternate address:			Gender: ☐ M ☐ F
*Phone: ☐ Home ☐ Mobile ☐ Work		*Email:	
Preferred language, if not English:			
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 *REQUIRED FIELDS

Please provide both medical and pharmacy insurance information. Also, **submit a copy of the front and back of the patient's medical and prescription insurance cards** with the completed enrollment form.

	Pharmacy Insurance		Medical Insurance
*Insurance Provider:			
*Insurance Phone #:			
*Cardholder Name : (if not the patient)			
*Relationship to Patient:			
*Cardholder DOB:			
*Member ID #:			
Group #:			
RxBIN / RxPCN:	Rx Bin:	RxPCN:	

Employer Sponsor:

3 *PRACTICE AND PRESCRIBER INFORMATION

Office/Clinic/Institution name:

Address:	City:	State:	ZIP:

Enrollment Form/Office Contact			Prior Authorization Office Contact (if different from Enrollment Form/Office Contact)		
First Name:	Last Name:		First Name:	Last Name:	
Email:			Email:		
Direct Phone: Ext		Fax:	Direct Phone: Ext		Fax:

Prescriber first name:	**Prescriber last name:**	
Address:	City:	State:
NPI #:	Tax ID #:	

ENROLLMENT FORM

*Required information

KINIKSA oneconnect®

4 *DIAGNOSIS FOR ARCALYST® (rilonacept) TREATMENT

! ☐ M04.2 **Cryopyrin-associated periodic syndromes (CAPS)**

☐ M04.8 **Deficiency of IL-1 receptor antagonist (DIRA)**

Other Diagnosis for ARCALYST Treatment Diagnosis _____

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. See full Prescribing Information for complete Dosing and Administration instructions.

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

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

ARCALYST is dispensed as 4 single-dose vials per carton.

☐ **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.
Then inject 2 mL (160 mg) for maintenance dose subcutaneously once weekly thereafter. Rotate injection sites.

Quantity: 4 vials **Days Supply:** 21 **Refills:** 0

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

Quantity: 4 vials **Days Supply:** 28

Refills: ☐ 12 ☐ Other _____

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

ARCALYST is dispensed as 4 single-dose vials per carton.

☐ **LOADING DOSE** Inject (from LD calculation below) _____ mL (_____ mg) subcutaneously on day 1. If injection volume is greater than 2 mL, administer as two injections at different injection sites. **Loading dose should not exceed 320 mg (4 mL).** Then inject maintenance dose for weekly dosing thereafter (from MD calculation below).

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

Quantity: _____ vials **Refills:** 0

☐ **MAINTENANCE DOSE** Inject (from MD calculation below) _____ mL (_____ mg) subcutaneously once weekly. **Maintenance dose should not exceed 160 mg (2 mL).** Rotate injection sites.

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

Quantity: 4 vials **Days Supply:** 28

Refills: ☐ 12 ☐ Other _____

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

DOSE Inject 320 mg subcutaneously once weekly, given as two x 2 mL (160 mg) injections. Administer each Injection at a different site.

Quantity: 8 vials **Days Supply:** 28

Refills: ☐ 12 ☐ 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

Quantity: ☐ 4 vials ☐ 8 vials **Days Supply:** 28 **Refills:** ☐ 12 ☐ Other _____

Include supplies listed below for administration of ARCALYST for CAPS. Supply amounts may be adjusted (up to double) for patients with DIRA.

Preservative-free sterile water for injection
- **4** vials (5 mL or whatever is available) for loading/initial maintenance doses

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

☐ **QUICK START:** Up to 60 days supply of free drug for eligible patients while awaiting payer determination. **Prior authorization submission required.** Terms and conditions apply.

Injection training for patient: ☐ Kiniksa OneConnect™ Program Injection Training Support ☐ Conducted by prescriber; no program support needed

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 #:** _____

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. **ATTN: New York and Iowa providers, please submit electronic prescriptions for ARCALYST (rilonacept) AND sterile water.**

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.