Arcalyst® (rilonacept) For Injection

ARCALYST® (rilonacept) Access and Reimbursement Guide

Navigating Insurance and Support Programs for ARCALYST

We're available Monday through Friday, 8 AM to 8 PM ET.
Call 1-833-KINIKSA (1-833-546-4572) or visit KiniksaOneConnect.com/HCP

Welcome to your guide to ARCALYST® (rilonacept) access and reimbursement

Here you'll find a comprehensive overview of the patient journey and key steps along the way to help you navigate the process for your patients and your office.

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Program support services

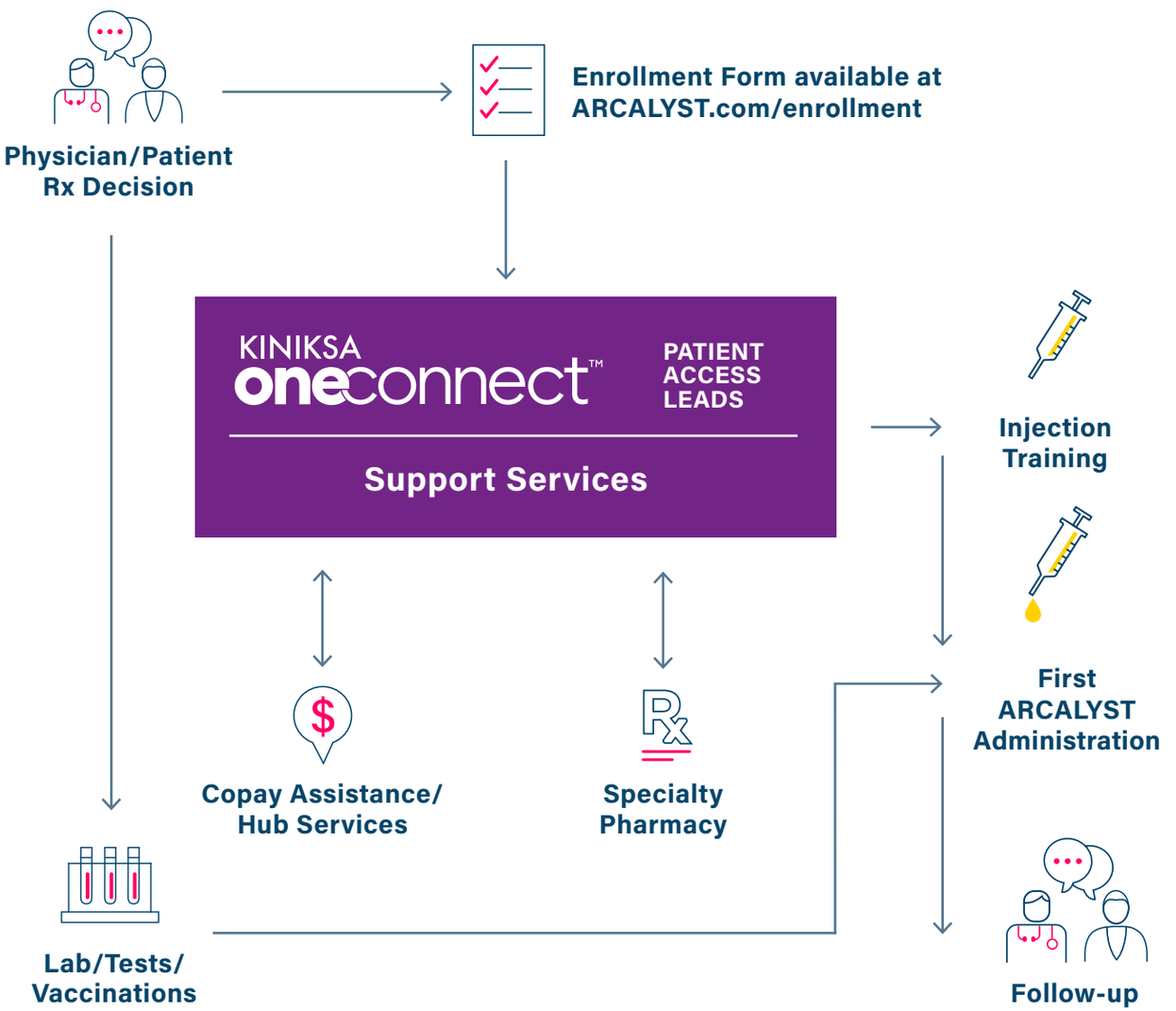
The Kiniksa OneConnect™ program is designed to simplify the treatment experience for your practice and your patients.

- **Dedicated Patient Access Lead point of contact for healthcare providers and patients**
- **Benefits verification**
- **Prior Authorization assistance**
- **Financial assistance for eligible patients**
- **Treatment logistics**
- **Options for injection training with an ARCALYST® (rilonacept) Clinical Educator**
- **Ongoing education and support**

Once your patient is prescribed ARCALYST and enrolled in the Kiniksa OneConnect support program, a dedicated Patient Access Lead will be assigned to you and your patient by geographic location.

The Kiniksa OneConnect™ program provides support throughout the treatment journey

Below is an overview of the patient journey and stepwise process of receiving ARCALYST® (rilonacept). This guide provides an overview of the Kiniksa OneConnect program and explains how your Patient Access Lead can help along the way.



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Reimbursement support

Insurance Coverage and Benefits Investigation

Once your patient is enrolled in the Kiniksa OneConnect™ program, a Patient Access Lead will:

- Complete benefits verification with the insurance provider*
- Inform your office if Prior Authorization is required
- Provide a summary of benefits to your office, including the patient's copay responsibility and specialty pharmacy
- Inform the patient of their coverage benefits, including their copay responsibility, if applicable

*Some payers will not speak with third parties, such as the Kiniksa OneConnect program. If this is the case, the physician office will need to call the insurance company to obtain the patient's benefits and PA requirements.

Prior Authorization (PA) Support

During the benefits investigation, if the Patient Access Lead learns that a PA is required for coverage, she/he will inform your office, including documentation required and how to submit the PA. While your office is required to submit the PA, your Patient Access Lead will track the status of the decision.

See page 6 for helpful reminders when completing and submitting the PA.

Appeals Support

If you receive notification that coverage has been denied, your Patient Access Lead can provide support for submitting a Letter of Appeal to formally document the request to appeal the payer's initial decision to deny coverage.

Download an editable Letter of Appeal template.

Prior Authorization (PA)

To complete the PA:

- Use CoverMyMeds to submit the PA for ARCALYST ® (rilonacept) (if you participate)
- Consider submitting the prior authorization when submitting the Enrollment Form so that the PA is approved when the patient is ready to start treatment. It is important to submit a PA properly in order to avoid delays in ARCALYST initiation.
- Make sure to:
  - Submit all requested PA information to the payer
  - List tests, such as a tuberculosis (TB) test, that the patient has taken in the past year
  - Clearly state why ARCALYST is medically necessary for your patient
  - List all medications the patient has tried for their condition

In case of denial:

- Carefully read and understand why the PA was not approved
- Share the denial reasons and/or denial letter with your Patient Access Lead
- Common reasons for denial:
  - Previous medication(s) for condition not provided
  - Patient testing history, such as TB testing, was not provided
  - Incomplete or inaccurate coding submitted
  - Clinical notes not submitted (if requested)

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Financial assistance

The Kiniksa OneConnect™ program is dedicated to helping your patients get the treatment they need. Patient Access Leads identify financial assistance programs to help make access to treatment more affordable for eligible patients.

Commercial Copay Assistance Program[a]

Eligible, commercially insured patients pay as little as **$0** per month for treatment

Quick Start Program[b]

Supports eligible patients with delay in coverage for treatment initiation

- Program offered for up to 60 days while awaiting PA

Patient Assistance Program (PAP)[c]

Supports eligible patients with limited or no coverage for treatment

- Qualified patients can receive treatment at no cost
- Program offered for up to 12 months
- Patients are uninsured or underinsured
- Monthly shipments

Eligibility requirements, terms and conditions, and restrictions apply.

[a]Copay Assistance Program Terms and Conditions: kiniksapolicies.com/copay
[b]Quick Start Program Terms and Conditions: kiniksapolicies.com/qstart
[c]Patient Assistance Program Terms and Conditions: kiniksapolicies.com/pap

Contact a Kiniksa OneConnect program team member for more information.

Our network of specialty pharmacies delivers ARCALYST® (rilonacept) where you and your patient want it[a]

Specialty pharmacy network

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allianceRx Walgreens Pharmacy

Contact:
866-741-0130

CVS specialty®

Contact:
855-264-3242

Orsini Specialty Pharmacy

Contact:
800-473-3261

Once your patient's insurance coverage is approved, your Patient Access Lead can help ensure timely delivery of ARCALYST. Your Patient Access Lead will work with your office staff and/or patient to coordinate delivery through our limited specialty pharmacy network. Specialty pharmacies are dependent on payer network participation.

PLEASE NOTE: Sending a prescription or the Enrollment Form directly to the specialty pharmacy rather than to the Kiniksa OneConnect™ program may delay the access process, resulting in your patients not being able to immediately obtain support services such as financial assistance or injection training.

[a]Pending individual state pharmacy law and regulation.

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Injection training and ongoing support

Injection training options

The Kiniksa OneConnect™ program offers a variety of injection training options to help ensure that patients feel confident with preparing and injecting their ARCALYST® (rilonacept) treatment.

In-office training by you or your office staff

One-on-one injection training with an ARCALYST Clinical Educator

A Patient Access Lead can coordinate training with an ARCALYST Clinical Educator, who will conduct the training session based on the patient's needs:

Virtual

In person

To further support learning the injection process, patients receive access to a step-by-step administration guide and injection training video. In addition, the ARCALYST Clinical Educator will contact your patient between their first and second dose to reinforce the training and answer any of the patient's questions.

Low out-of-pocket cost and high commercial access

$0

Eligible, commercially insured patients pay as little as **$0 per month** for ARCALYST treatment with the copay assistance program*

≥94%

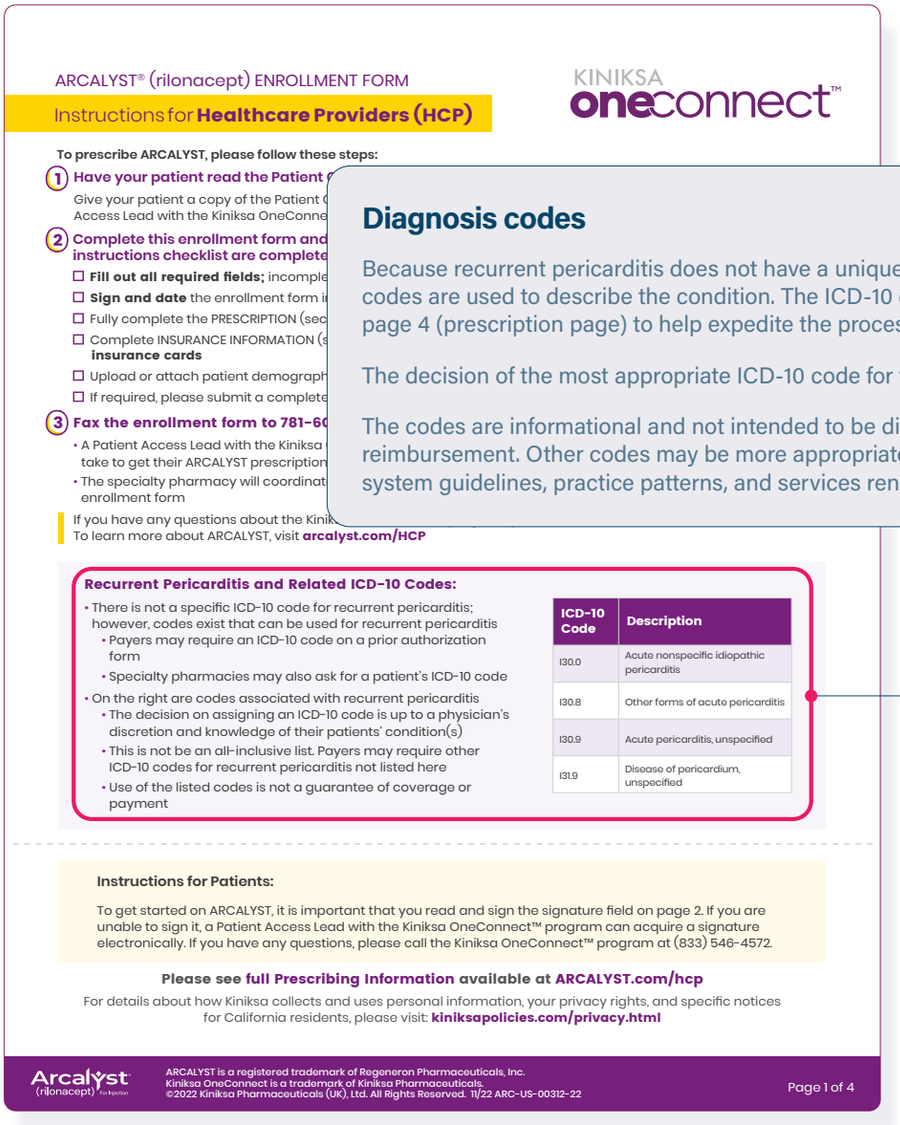
of prior authorization requests have been approved*†

*From approval in March 2021 to June 2023.
†Based on final coverage approval.

Patient Enrollment Form Guide

To ensure the enrollment is processed in a timely manner, please fill out all required fields. The highlighted areas on the following pages are examples of common fields where complete information is not provided, which may result in a delay in patient enrollment.

PAGE 1 Instructions



ARCALYST® (rilonacept) ENROLLMENT FORM

Instructions for **Healthcare Providers (HCP)**

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To prescribe ARCALYST, please follow these steps:

1. **Have your patient read the Patient**
   Give your patient a copy of the Patient
   Access Lead with the Kiniksa OneConne
2. **Complete this enrollment form and instructions checklist are complete**
   - ☐ **Fill out all required fields;** incomple
   - ☐ **Sign and date** the enrollment form i
   - ☐ Fully complete the PRESCRIPTION (sec
   - ☐ Complete INSURANCE INFORMATION (s **insurance cards**
   - ☐ Upload or attach patient demograph
   - ☐ If required, please submit a complete
3. **Fax the enrollment form to 781-60**
   - A Patient Access Lead with the Kiniksa take to get their ARCALYST prescription
   - The specialty pharmacy will coordinat enrollment form

If you have any questions about the Kini
To learn more about ARCALYST, visit **arcalyst.com/HCP**

Recurrent Pericarditis and Related ICD-10 Codes:

- There is not a specific ICD-10 code for recurrent pericarditis; however, codes exist that can be used for recurrent pericarditis
  - Payers may require an ICD-10 code on a prior authorization form
  - Specialty pharmacies may also ask for a patient's ICD-10 code
- On the right are codes associated with recurrent pericarditis
  - The decision on assigning an ICD-10 code is up to a physician's discretion and knowledge of their patients' condition(s)
  - This is not be an all-inclusive list. Payers may require other ICD-10 codes for recurrent pericarditis not listed here
  - Use of the listed codes is not a guarantee of coverage or payment

ICD-10 Code	Description
I30.0	Acute nonspecific idiopathic pericarditis
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I31.9	Disease of pericardium, unspecified

Instructions for Patients:

To get started on ARCALYST, it is important that you read and sign the signature field on page 2. If you are unable to sign it, a Patient Access Lead with the Kiniksa OneConnect™ program can acquire a signature electronically. If you have any questions, please call the Kiniksa OneConnect™ program at (833) 546-4572.

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

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**

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Page 1 of 4

Diagnosis codes

Because recurrent pericarditis does not have a unique ICD-10 code, acute pericarditis codes are used to describe the condition. The ICD-10 code is inserted at the top of page 4 (prescription page) to help expedite the processing of the Enrollment Form.

The decision of the most appropriate ICD-10 code for the patient is up to the physician.

The codes are informational and not intended to be directive or guarantee of reimbursement. Other codes may be more appropriate given prescribers' internal system guidelines, practice patterns, and services rendered.

If you have any questions about filling out the Enrollment Form, please reach out to your Patient Access Lead.

Please see Important Safety Information on last page and full Prescribing Information.

PAGE 2

Patient Consent

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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 disclosure

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 ea 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 subsequen 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 a **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 th on behalf of Kiniksa to conduct market research. I authorize Kiniksa and these third parties to contact research purposes.

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Patient email

Include the patient's email address

Actual or electronic patient signature

If the patient is not present in the office to sign, a Patient Access Lead can obtain the patient's signature electronically.

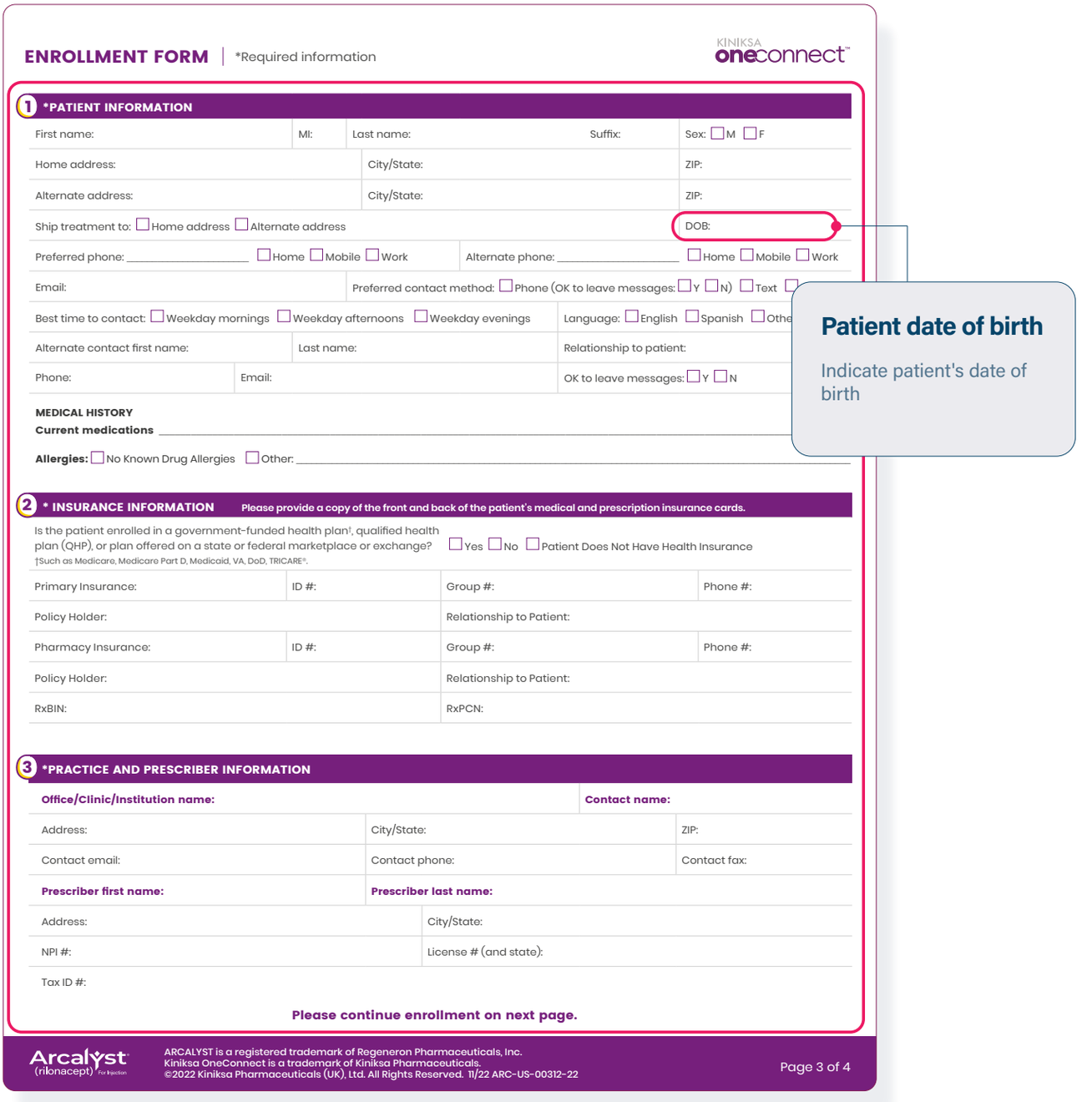
Please see Important Safety Information on last page and full Prescribing Information.

IMPORTANT!

To avoid delays in ARCALYST® access, provide as much information as possible. Completed information allows for faster benefits investigation and patient contact by the Patient Access Lead and specialty pharmacy.

PAGE 3

Patient and Provider Demographics



ENROLLMENT FORM | *Required information

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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 ☐		
Best time to contact: ☐Weekday mornings ☐Weekday afternoons ☐Weekday evenings			Language: ☐English ☐Spanish ☐Othe	
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.

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ARCALYST is a registered trademark of Regeneron Pharmaceuticals, Inc.
Kiniksa OneConnect is a trademark of Kiniksa Pharmaceuticals.
 11/22 ARC-US-00312-22

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Patient date of birth

Indicate patient's date of birth

Please see Important Safety Information on last page and full Prescribing Information.

PAGE 4

Prescription

Diagnosis

- Check the diagnosis box
- Include appropriate ICD-10 code (refer to page 1, if needed)

Patient date of birth

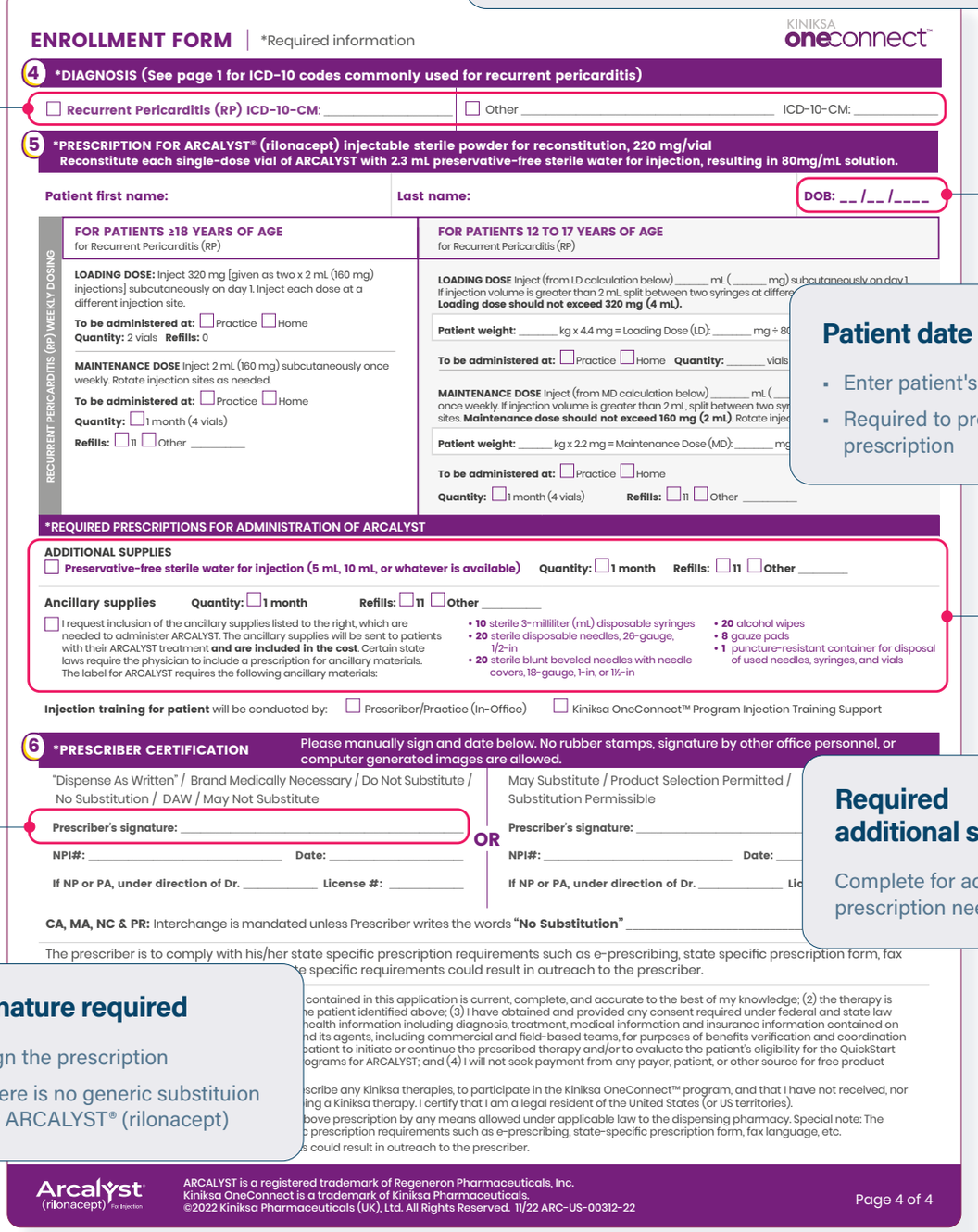
- Enter patient's birthdate
- Required to process prescription

Required additional supplies

Complete for additional prescription needs.

Signature required

- Sign the prescription
- There is no generic substituion for ARCALYST® (rilonacept)



ENROLLMENT FORM | *Required information

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4 *DIAGNOSIS (See page 1 for ICD-10 codes commonly used for recurrent pericarditis)

☐ Recurrent Pericarditis (RP) 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: __ /__ /____**

RECURRENT PERICARDITIS (RP) WEEKLY DOSING

FOR PATIENTS ≥18 YEARS OF AGE
for Recurrent Pericarditis (RP)

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 Recurrent Pericarditis (RP)

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 differe
Loading dose should not exceed 320 mg (4 mL).

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

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

MAINTENANCE DOSE Inject (from MD calculation below) _____ mL (__
once weekly. If injection volume is greater than 2 mL, split between two syr
sites. **Maintenance dose should not exceed 160 mg (2 mL).** Rotate injec

Patient weight: _____ kg x 2.2 mg = Maintenance Dose (MD): _____ mg

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. _____ **Lic**

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
e specific requirements could result in outreach to the prescriber.

contained in this application is current, complete, and accurate to the best of my knowledge; (2) the therapy is
e patient identified above; (3) I have obtained and provided any consent required under federal and state law
health information including diagnosis, treatment, medical information and insurance information contained on
nd its agents, including commercial and field-based teams, for purposes of benefits verification and coordination
patient to initiate or continue the prescribed therapy and/or to evaluate the patient's eligibility for the QuickStart
ograms for ARCALYST; and (4) I will not seek payment from any payer, patient, or other source for free product

scribe any Kiniksa therapies, to participate in the Kiniksa OneConnect™ program, and that I have not received, nor
ing a Kiniksa therapy. I certify that I am a legal resident of the United States (or US territories).
bove prescription by any means allowed under applicable law to the dispensing pharmacy. Special note: The
prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc.
s could result in outreach to the prescriber.

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Kiniksa OneConnect is a trademark of Kiniksa Pharmaceuticals.

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Please see Important Safety Information on last page and full Prescribing Information.

Two Ways to Access Enrollment Forms

1

Download the enrollment form here

2

Contact your Kiniksa Clinical Sales Specialist to request copies for your office

Important Code for ARCALYST® (rilonacept) Reimbursement

NDC code: 73604091404

Please see Important Safety Information on next page and full Prescribing Information.

Navigate ARCALYST® (rilonacept) access and reimbursement with

KINIKSA oneconnect™

We're available Monday through Friday, 8 AM to 8 PM ET.
Call 1-833-KINIKSA (1-833-546-4572) or visit KiniksaOneConnect.com/HCP

INDICATION

ARCALYST is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 or inhibition of tumor necrosis factor (TNF) is not recommended as this may increase the risk of serious infection. Serious, life-threatening infections have been reported in patients taking ARCALYST. Do not initiate treatment with ARCALYST in patients with an active or chronic infection.
- Discontinue ARCALYST if a patient develops a serious infection.
- It is possible that taking drugs such as ARCALYST that block IL-1 may increase the risk of tuberculosis (TB) or other atypical or opportunistic infections.
- Although the impact of ARCALYST on infections and the development of malignancies is not known, treatment with immunosuppressants, including ARCALYST, may result in an increase in the risk of malignancies.
- Hypersensitivity reactions associated with ARCALYST occurred in clinical trials. Discontinue ARCALYST and initiate appropriate therapy if a hypersensitivity reaction occurs.
- Increases in non-fasting lipid profile parameters occurred in patients treated with ARCALYST in clinical trials. Patients should be monitored for changes in their lipid profiles.
- Since no data are available, avoid administration of live vaccines while patients are receiving ARCALYST. ARCALYST may interfere with normal immune response to new antigens, so vaccines may not be effective in patients receiving ARCALYST. It is recommended that, prior to initiation of therapy with ARCALYST, patients receive all recommended vaccinations, as appropriate.

Adverse Reactions

- The most common adverse reactions (≥10%) include injection-site reactions and upper respiratory tract infections.

Drug Interactions

- In patients being treated with CYP450 substrates with narrow therapeutic indices, therapeutic monitoring of the effect or drug concentration should be performed, and the individual dose of the medicinal product may need to be adjusted.

Please see full Prescribing Information for ARCALYST.

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