

**Arcalyst**<sup>®</sup>  
(rilonacept) For Injection

# ARCALYST 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](https://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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# **The Kiniksa OneConnect™ Program**

# Program support services

The Kiniksa OneConnect<sup>™</sup> 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<sup>®</sup> (rilonacept) Clinical Educator**

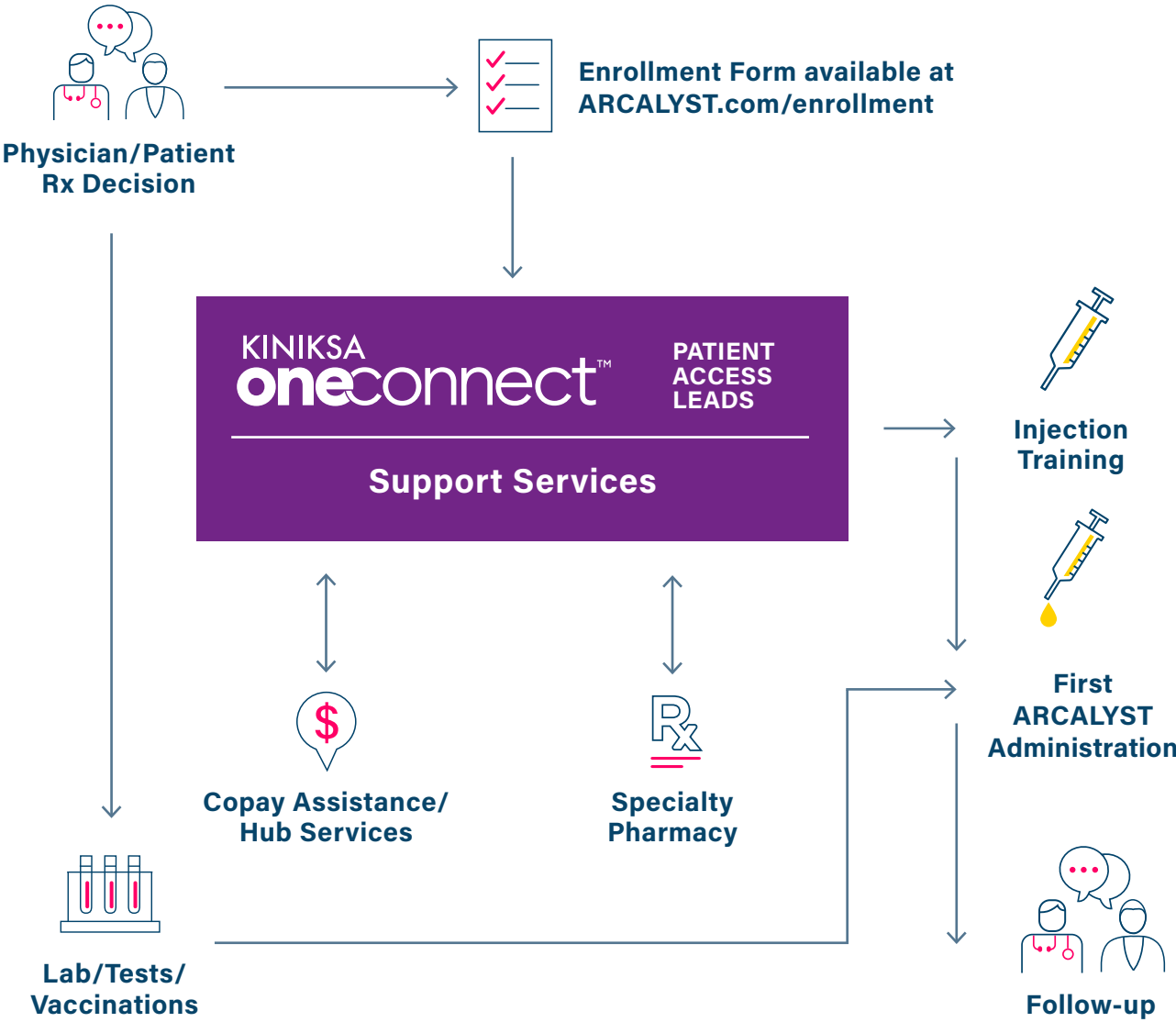


**Ongoing education and support**

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.



# Reimbursement support

## Insurance Coverage and Benefits Investigation

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

- Complete benefits verification with the insurance provider\*
- Inform your office if Prior Authorization (PA) 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 opposite page 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 the Letter of Appeal Guide and Template.](#)**

# Prior Authorization (PA)

## To complete the PA:

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- ✔ Use CoverMyMeds to submit the PA for ARCALYST® (rilonacept) (if you participate). Refer to the CoverMyMeds section in this guide for helpful PA submission instructions.
- 

- ✔ 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:

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- ✔ 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)

# Financial assistance

The Kiniksa OneConnect<sup>™</sup> 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<sup>a</sup>

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

## Quick Start Program<sup>b</sup>

Supports eligible patients with delay in coverage for treatment initiation

- Program offered for up to 60 days while awaiting PA

## Patient Assistance Program (PAP)<sup>c</sup>

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.

<sup>a</sup>Copay Assistance Program Terms and Conditions: [kiniksapolicies.com/copay](https://kiniksapolicies.com/copay)

<sup>b</sup>Quick Start Program Terms and Conditions: [kiniksapolicies.com/qstart](https://kiniksapolicies.com/qstart)

<sup>c</sup>Patient Assistance Program Terms and Conditions: [kiniksapolicies.com/pap](https://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<sup>a</sup>

## Specialty pharmacy network

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**Contact:**  
855-264-3242



**Contact:**  
800-473-3261



**Contact:**  
866-741-0130

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.

<sup>a</sup>Pending individual state pharmacy law and regulation.

# Injection training and ongoing support

## Injection training options

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

# Payer Coverage

# 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\*



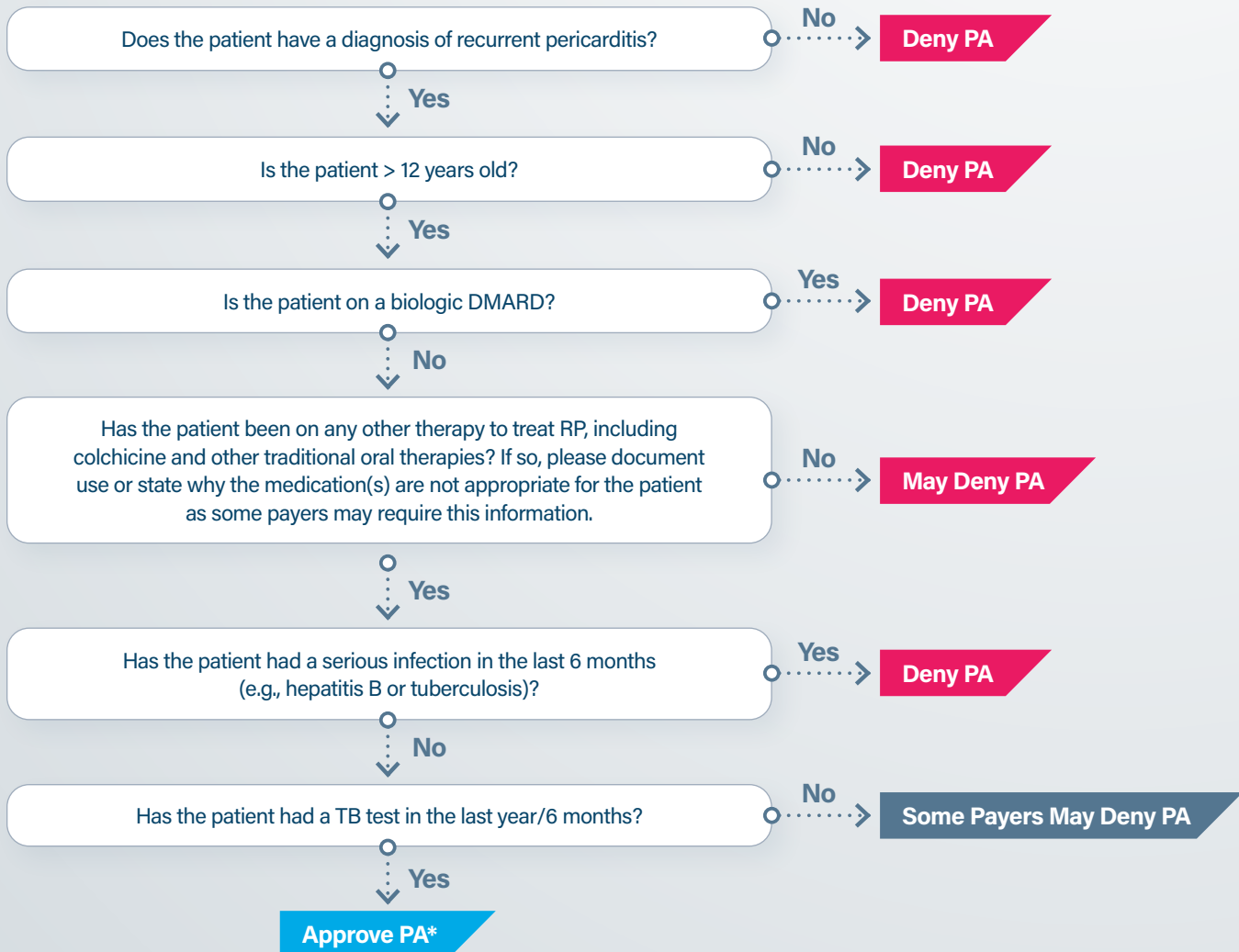
**≥95%**

of prior authorization requests have been approved\*†

\*From approval in March 2021 to September 2024.

†Based on final coverage approval.

# Example of ARCALYST® (rilonacept) Coverage Decision Logic for Recurrent Pericarditis\*



RP = recurrent pericarditis; PA = prior authorization; DMARD = Disease modifying antirheumatic drug; TB = tuberculosis

\*This is an example of common payer coverage decision making; however, each payer may differ in the determination of coverage for ARCALYST. Please refer to specific payer policies on ARCALYST access requirements.

## 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.

Please see Important Safety Information throughout and [full Prescribing Information at ARCALYST.com/PI](https://www.arcalyst.com/PI).

**Arcalyst**<sup>®</sup>  
(rilonacept) For Injection

# CoverMyMeds® Guide



# The Kiniksa OneConnect Program™ Through CoverMyMeds® *User Guide*

## Overview

Located within your CoverMyMeds account, you can access integrated patient support resources following the prescription to start of therapy, helping to consolidate processes and access for patients prescribed ARCALYST® (rilonacept).

If you do not have a CoverMyMeds account, follow the proceeding steps:

### Step 1.

Visit [CoverMyMeds.com](https://www.covermymeds.com) and click “**Create Account**”

### Step 2.

Enter the required information in the form fields

## Need help?

**Access More Patients ARCALYST helpline:** 1-800-705-9613 (Prior Authorization and Appeals team)

**CoverMyMeds Support Center:** 1-866-452-5017 (Technical assistance)

**CoverMyMeds website:** <https://www.covermymeds.com/>

### 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 (continued)

- 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.

**Please see Important Safety Information throughout and [full Prescribing Information](https://www.covermymeds.com/prescribing) at [ARCALYST.com/PI](https://www.covermymeds.com/prescribing)**

This guide is provided for informational purposes and is not intended to provide reimbursement or legal advice. The information is not a guarantee of payment, coverage, reimbursement, or program eligibility. Healthcare providers are ultimately responsible for seeking coverage and reimbursement and ensuring the accuracy and completeness of claim submissions for their patients.

Images throughout are sample depictions only.

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## [25. Frequently Asked Questions](#)

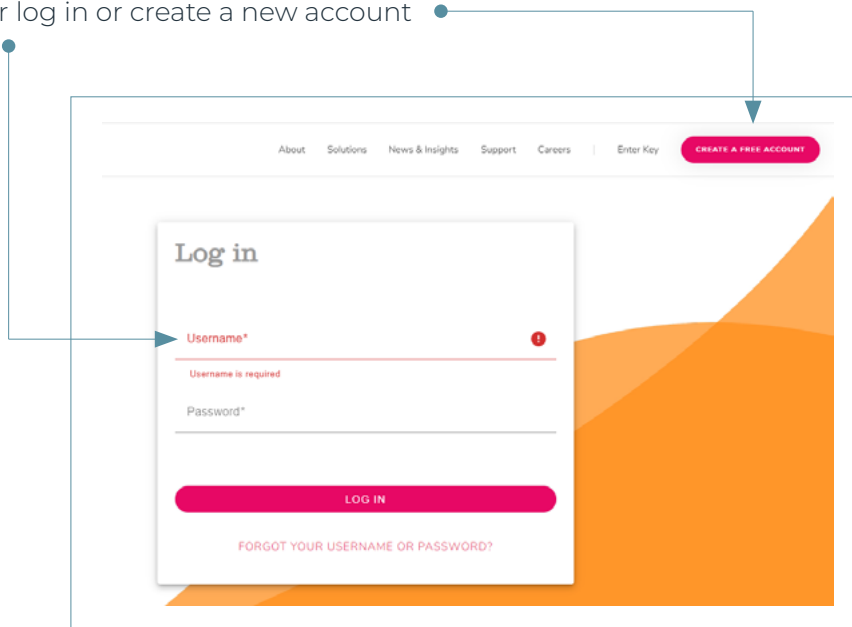
# How to Use CoverMyMeds for ARCALYST® (rilonacept) *Prior Authorizations (PAs)*

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## Getting Started

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- Go to [www.CoverMyMeds.com](http://www.CoverMyMeds.com)
- Either log in or create a new account



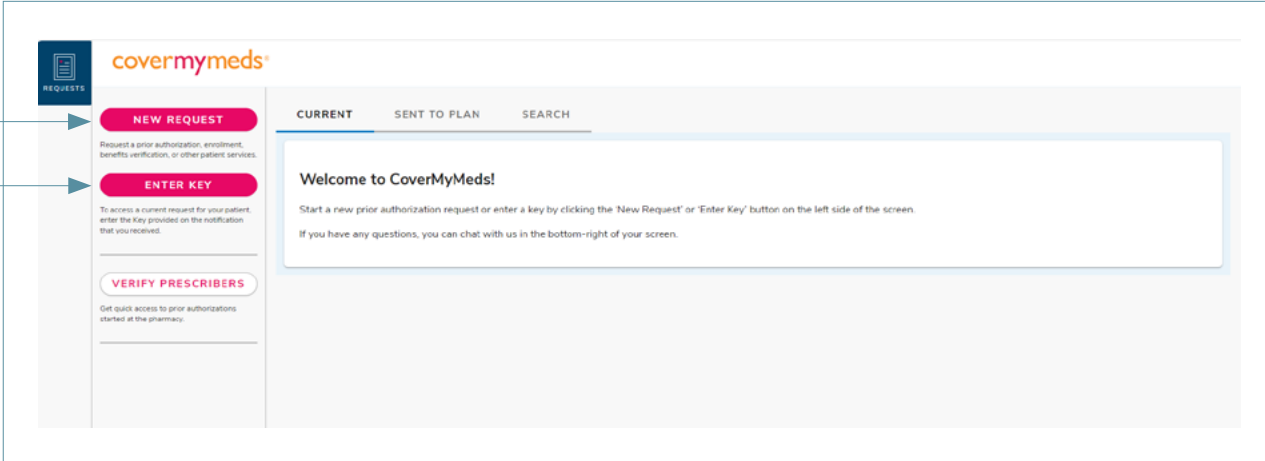
## ARCALYST® (rilonacept) May Require 2 *PA Submissions*

- **Because a loading dose is required** for patients starting ARCALYST treatment, a payer may require separate PAs for the loading dose and the maintenance dose.
- **If the loading dose has been administered**, e.g., patient is on Quick Start, then the PA will be needed only for the maintenance dose.
- **It will be important to understand** where the patient is in the ARCALYST process to determine if one or two PA submissions are required.

## Starting a *PA Request* for ARCALYST® (rilonacept)

Navigate to the Case or Patient for which you would like to initiate ARCALYST.

To create a new patient case, select NEW REQUEST



Sample depiction only

If you have previously accessed cases, you can enter the patient Key from the notification that you received when the PA was initiated.

### IMPORTANT SAFETY INFORMATION (continued)

#### Warnings and Precautions (continued)

- 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.

Please see Important Safety Information throughout and [full Prescribing Information](https://www.arcalyst.com/PI) at [ARCALYST.com/PI](https://www.arcalyst.com/PI)

# Prior Authorization Assistance

As you enter ARCALYST, the name will appear.

**Start a New Request**  
Enter the patient's prescription information and then select a form to start a new request. It's helpful to have the patient's drug insurance information (BIN, PCN, RxGroup) handy for accurate form selection.

**Medication**  
Enter the medication name or NDC (National Drug Code) number.  
Search for medication name or NDC number  
Arcalyst 220MG solution

**IMPORTANT MESSAGE FOR ARCALYST**  
Please note that for initiation of therapy of Arcalyst, plans may require two separate prior authorizations, one for the loading dose and one for the maintenance dose.  
CoverMyMeds has established a business relationship with the pharmaceutical manufacturer that results in a differentiated user experience on CoverMyMeds for the PA process, and may include patient support services. There may be lower cost medications available or preferred on your patient's plan.

**Patient Information**  
Entering the patient information here is optional, but will help with form selection. This information will pre-fill in the form.  
Fields with an \* are required

Patient Address Book Clear

First Name\* Last Name\*

Gender\*  
 Male  Female  Unspecified

Date of Birth\*

Patient Zip Code\* Patient Insurance State\* Alabama

Enter This Later Continue

Sample depiction only

Fill in patient demographic information. If you have previously submitted a PA for your patient in the portal, you can search for them in the Patient Address Book. This will help with identifying the specific PA form needed.

## ARCALYST for Injection

- Each vial contains 220 mg of ARCALYST (rilonacept) in its lyophilized form. After reconstitution, each vial contains 80mg/mL of rilonacept.
- Each single-dose vial of ARCALYST requires reconstitution with 2.3 mL of preservative-free Sterile Water for Injection prior to subcutaneous administration of the drug and will result in 2.7mL of solution.
- The resulting 80 mg/mL solution is sufficient to allow a withdrawal volume of up to 2 mL (160 mg) for subcutaneous administration.

For complete Dosage and Administration, see the accompanying **full Prescribing Information**.

### IMPORTANT SAFETY INFORMATION (continued)

#### Warnings and Precautions (continued)

- Hypersensitivity reactions associated with ARCALYST occurred in clinical trials. Discontinue ARCALYST and initiate appropriate therapy if a hypersensitivity reaction occurs.

Please see Important Safety Information throughout and [full Prescribing Information](https://www.covermymeds.com/ARCALYST.com/PI) at ARCALYST.com/PI

# Enter *Insurance* Information

**Patient Insurance** [MORE INFO](#)

Enter the patient's drug insurance ID card to find the most accurate form. Alternatively, you can enter a patient's insurance plan or PBM name.

**Option 1: Drug Insurance ID card**

Patient Insurance State  
Arizona

RxBIN

For best results, enter the insurance BIN number. Or, search by plan name

RxPCN Number

RxGroup

**Option 2: Insurance plan or PBM name**

Patient Insurance State  
Arizona

Plan or PBM Name

*Sample depiction only*

**Choose the Patient Insurance State** in the drop-down list under Option 2. Then type in Plan or PBM Name.

- If multiple forms appear, select the correct form or use the More Information link. Additional forms may also be available by opening the Show More Forms tab

**You may also enter the patient's drug ID card information (Option 1):**

- Sometimes located on front or back of the patient's insurance card
- Patients may have a separate pharmacy benefit card
- Call the patient's pharmacy where they normally pick up their prescriptions for this information

# Select *Correct* Form

Option 2: Insurance plan or PBM name



Patient Insurance State  
Arizona

Plan or PBM Name  
test plan

---

### Select a Form

---

|  |  |                  |                      |
|--|--|------------------|----------------------|
|   | <p>PHARMACY BENEFIT<br/><b>Pseudo 4-part</b><br/>Classic version of 4-part ePA test form</p> | <p>MORE INFO</p> | <p>START REQUEST</p> |
|  | <p>MEDICAL BENEFIT<br/><b>Pseudo 4-part</b><br/>Classic version of 4-part ePA test form</p>  | <p>MORE INFO</p> | <p>START REQUEST</p> |

*Sample depiction only*

## Selecting the correct PA form

- Choose the Patient Insurance State in the drop-down list. Then type in Plan or PBM Name.
- If multiple forms appear and you are not sure which form to select, please call **1-800-705-9613** and a CoverMyMeds support specialist will assist you.

# For ARCALYST® (rilonacept) *Loading Dose* PA Requests

Use when patient HAS NOT obtained a loading dose. We suggest filling out as many of these fields as possible. Quantity and dosage should be input in milligrams.

The below are **suggestions only** to account for the loading dose and possible PA requirements

- **Quantity and dosage form:** should be indicated in vials.
- **Refills:** no refills are needed for the Loading dose.

Both Loading and Maintenance dose information can be found on the ARCALYST Enrollment Form or in the accompanying Prescribing Information.

Sample depiction only

Loading Dose suggestion per the ARCALYST Enrollment Form:

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

**ARCALYST is dispensed as 4 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

Dosing quantity and days supply is at your discretion.

**Diagnosis Codes:** Although there is no code for RP, these codes may be used for recurrent pericarditis. This is not a complete list and choice of diagnosis is at the physician's discretion.

| ICD-10 Code | Description                               |
|-------------|---|
| I30.0       | Acute nonspecific idiopathic pericarditis |
| I30.9       | Acute pericarditis, unspecified           |
| I31.9       | Disease of pericardium, unspecified       |

Arcalyst is not indicated to treat acute pericarditis or diseases of the pericardium other than recurrent pericarditis.

## IMPORTANT SAFETY INFORMATION (continued)

### Warnings and Precautions (continued)

- 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.

Please see Important Safety Information throughout and [full Prescribing Information](https://www.amlpharm.com/ARCALYST.com/PI) at [ARCALYST.com/PI](https://www.amlpharm.com/ARCALYST.com/PI)

# Attaching Documentation: *Helpful Tips*

Please upload additional documentation using the 'Upload or Manage Attachments' link at the bottom of this request.

---

**Rationale**

|                      |                      |
|----------------------|----------------------|
| Other criteria       |                      |
| Explanation          | <input type="text"/> |
| Patient Drug History |                      |

---

**Upload Additional Documentation (0)**

|                    |  |
|--------------------|--|
| Upload Attachments | Upload test results or other medical information that you would like attached to your request.<br><a href="#">Upload or Manage Attachments</a> |
|--------------------|--|

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[Send to Plan](#)

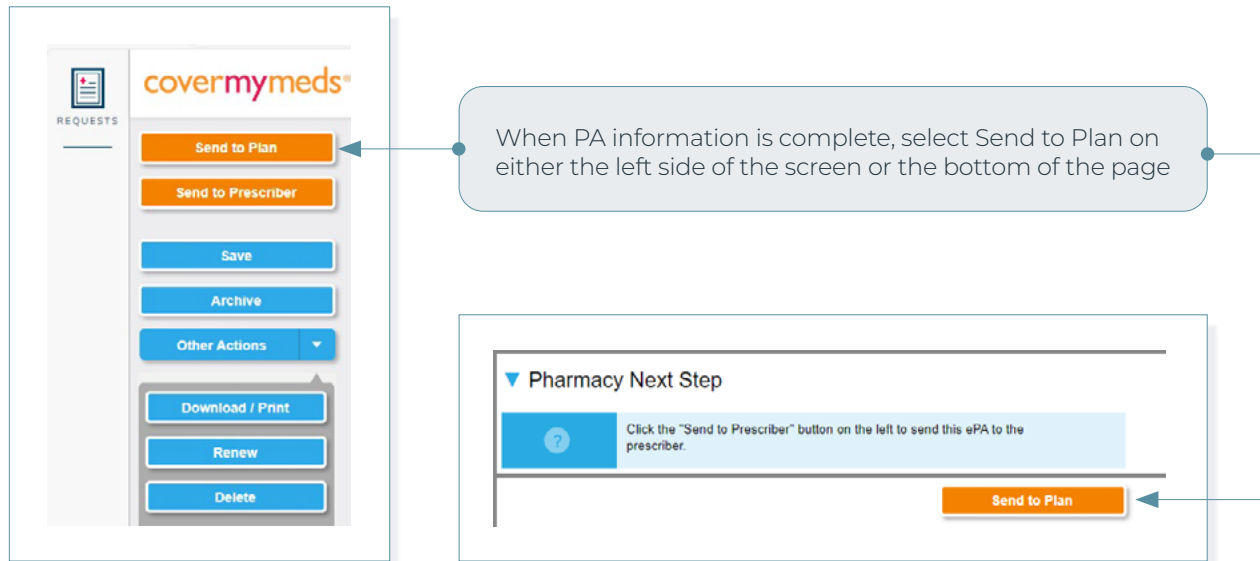
[Click to Chat with CoverMyMeds ^](#)

Sample depiction only

## Attaching Documentation

- **Only one document may be uploaded.** If a plan requires additional documentation, combine supporting documents into a single file (up to 5mb)
- Alternately, additional documentation may be faxed to CoverMyMeds®
  - Ensure the PA is completed. Save PA in your portal, but do not click “Send to Plan.”
  - Select “Click to Chat”
  - Tell the team member the PA key and number of pages you are faxing that will need to be attached
  - Write the PA key and number of pages on the top of page 1 and fax to **888-965-1415**.
  - Upon receipt, CoverMyMeds will attach the documents and you will receive confirmation by chat or email.
  - Upon confirmation, verify the documents are attached by refreshing your browser and clicking print/download on the left side of the screen.
  - When all documents are attached, click “Send to Plan”

## Submitting Request

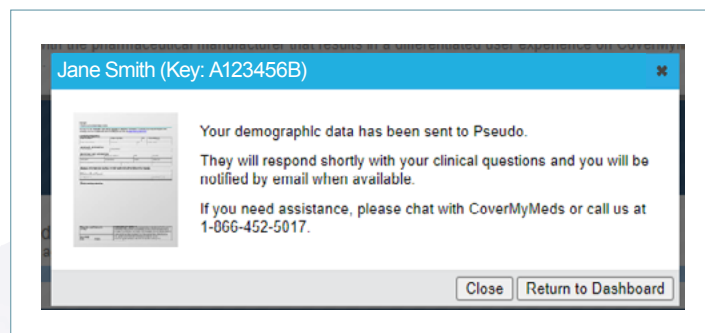


Sample depiction only

## PA Confirmation

Upon submitting the prior authorization request, a confirmation that the request has been sent to the plan will pop up on the screen. If no response is received, CoverMyMeds will follow up with the plan, as applicable.

**Note:** The status of the prior authorization can be found in the patient's case.



Sample depiction only

# For ARCALYST® (rilonacept) *Maintenance Dose* PA Requests

Submit a maintenance dose request separately from a loading dose request. If a loading dose has already been administered to the patient, submit a PA for the maintenance dose only.

We suggest filling out as many of these fields as possible.

- **Quantity and dosage form:** should be indicated in vials.

Dosing information can be found on the ARCALYST Enrollment Form or in the accompanying Prescribing Information.

Maintenance Dose suggestion per the ARCALYST Enrollment Form:

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

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

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

**Refills:**  12     Other \_\_\_\_\_

Dosing quantity and days supply is at your discretion.

Refer to pages 8-9 for the remaining steps to complete the PA submission process for the Maintenance dose.

### IMPORTANT SAFETY INFORMATION (continued)

#### Warnings and Precautions (continued)

- 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.

Please see Important Safety Information throughout and [full Prescribing Information](http://ARCALYST.com/PI) at [ARCALYST.com/PI](http://ARCALYST.com/PI)

**Diagnosis Codes:** Although there is no code for RP, these codes may be used for recurrent pericarditis. This is not a complete list and choice of diagnosis is at the physician's discretion.

| ICD-10 Code | Description                               |
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| I30.0       | Acute nonspecific idiopathic pericarditis |
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# Frequently Asked Questions

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## What dosing information is needed for the Loading and the Maintenance doses?

**Answer:** For the Loading dose PA, you may indicate that 4 vials are needed for 21 days since 2 injections of 160 mg each are needed for the adult Loading dose and ARCALYST® (rilonacept) is shipped in packs of 4. For the Maintenance dose, 4 vials are needed for a 28-day supply.

## Are two separate submissions required for Loading and Maintenance doses in CoverMyMeds?

**Answer:** Yes

## What ICD-10 codes are most appropriate for recurrent pericarditis?

**Answer:** Recurrent pericarditis does not have a unique ICD-10 descriptive code. Examples of acute pericarditis ICD-10 codes are located on page 7 of this guide. Choosing the most accurate diagnostic code for your patient is left up to your clinical judgement. If a code is chosen which is not associated with the FDA-approved indication, then the PA may be denied.

## Can I speak with somebody live at CoverMyMeds?

**Answer:** Yes, you may call the CoverMyMeds helpline at 1-800-705-9613

## What is the importance of the CoverMyMeds Key?

**Answer:** The eight-character CoverMyMeds Key is a unique identifier to a specific patient request. Knowing this Key will allow you to narrow your search quickly to the exact PA for a particular patient. If the specific Key is not known, you may type in the patient's name in the Search tab on your dashboard and find all cases created for this patient; however, the patient name search is at a higher level than that of a search with the Key.

### **IMPORTANT SAFETY INFORMATION (continued)**

#### **Adverse Reactions**

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

**Please see Important Safety Information throughout and [full Prescribing Information](https://www.arcalyst.com/PI) at [ARCALYST.com/PI](https://www.arcalyst.com/PI)**

# Frequently Asked Questions

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## Do I need to enter the Pharmacy Location Details, e.g., the pharmacy's zip code?

**Answer:** This information is needed if you have a preferred specialty pharmacy (SP) you would like to service the patient. Please note that ARCALYST is distributed by only 3 specialty pharmacies and the Kiniksa OneConnect™ program contact will determine which ARCALYST-providing SP is in your patient's insurance network.

## Do I need to enter ARCALYST's J-code?

**Answer:** In most cases, no, since ARCALYST is mostly covered by the patient's pharmacy benefit.

## Will ARCALYST be covered by the payer if my patient is on other biologic or injectable medications?

**Answer:** It will depend on the individual payer policy. In some instances, ARCALYST may not be covered if the patient is on another biologic. It will be important to understand the individual payer coverage policy for ARCALYST.

## covermy meds® *is Here to Help*

Dedicated representatives are ready to take your call or live chat  
**Monday - Friday, 8 a.m. - 11 p.m. ET and Saturday 8 a.m. - 6 p.m.**

**PA and Appeals Phone: 1.866.452.5017**

### IMPORTANT SAFETY INFORMATION (continued)

#### 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 Important Safety Information throughout and [full Prescribing Information](https://www.kiniksa.com/ARCALYST.com/PI) at [ARCALYST.com/PI](https://www.kiniksa.com/ARCALYST.com/PI)

# Two Ways to Access ARCALYST® (rilonacept) Enrollment Forms

1



[Download the enrollment form here](#)

2



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

**ARCALYST NDC Code  
for Your Reference:  
73604091404**

# Navigate ARCALYST® (rilonacept) access and reimbursement with



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](https://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 ( $\geq 10\%$ ) 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 Important Safety Information throughout and [full Prescribing Information at ARCALYST.com/PI](https://KiniksaOneConnect.com/PI)



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