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 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

- 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.

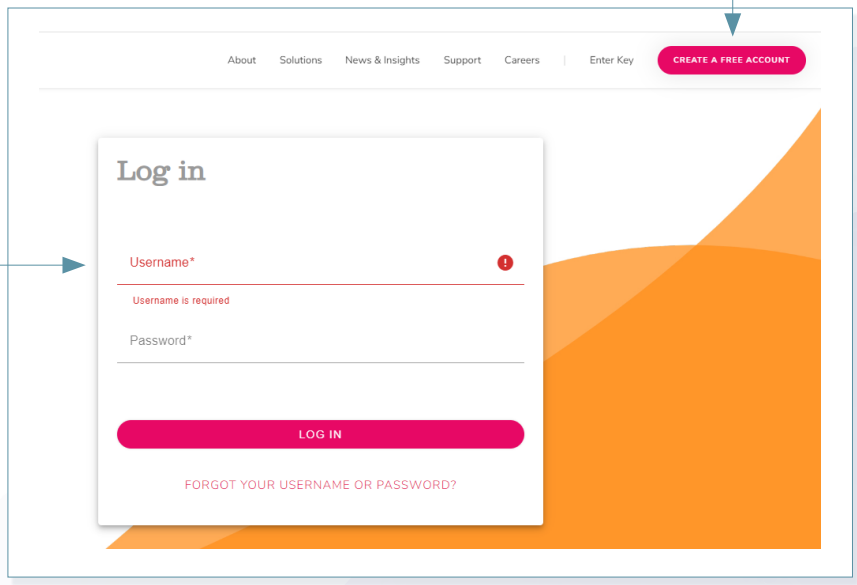
Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Table of *Contents*

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

Getting *Started*

- Go to www.CoverMyMeds.com
- Either log in or create a new account



IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

· Discontinue ARCALYST if a patient develops a serious infection.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

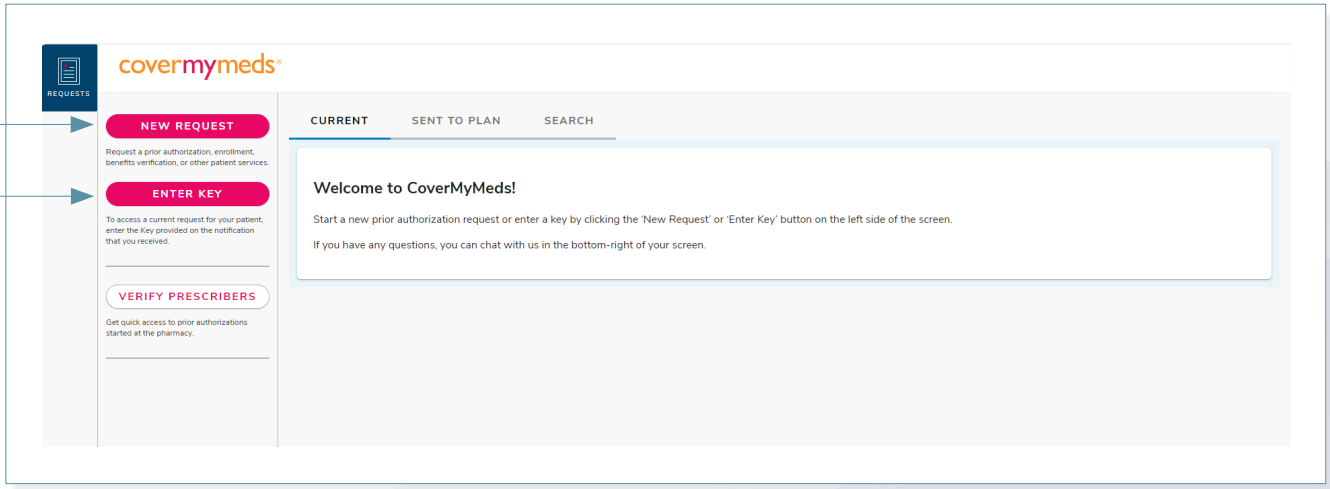
ARCALYST® (rilonacept) May Require 2 *PA Submissions*

- **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)

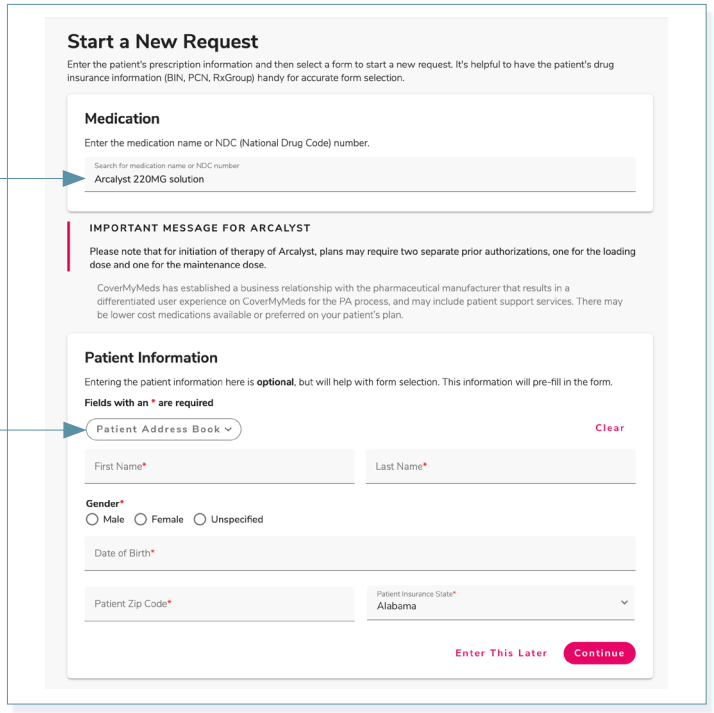
Warnings and Precautions (continued)

- 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 at ARCALYST.com/PI.

Prior Authorization *Assistance*

As you enter ARCALYST, the name will appear.



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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 **full Prescribing Information at ARCALYST.com/PI**.

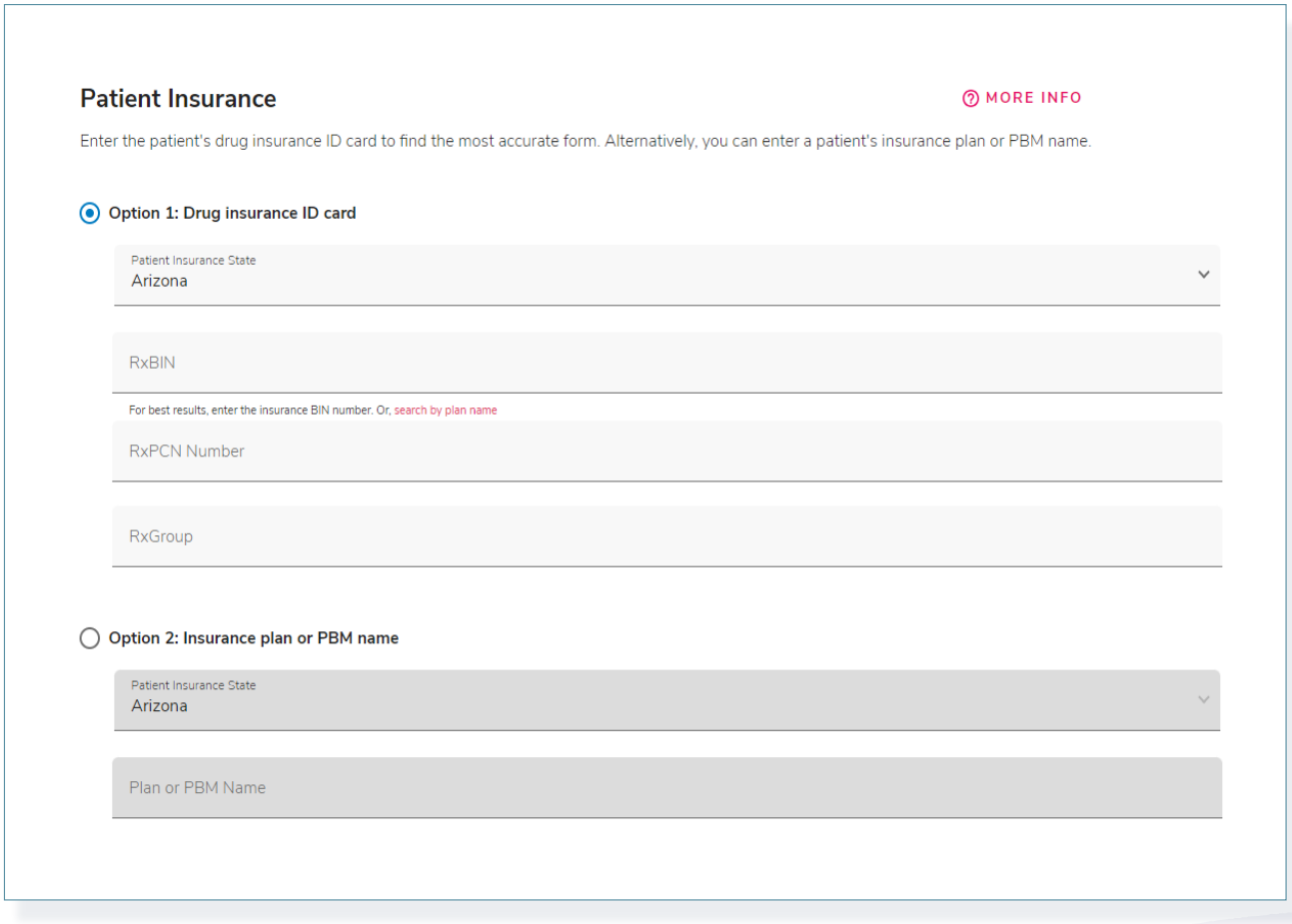
IMPORTANT SAFETY INFORMATION (continued)

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 at ARCALYST.com/PI.

Enter *Insurance* Information



Sample depiction only

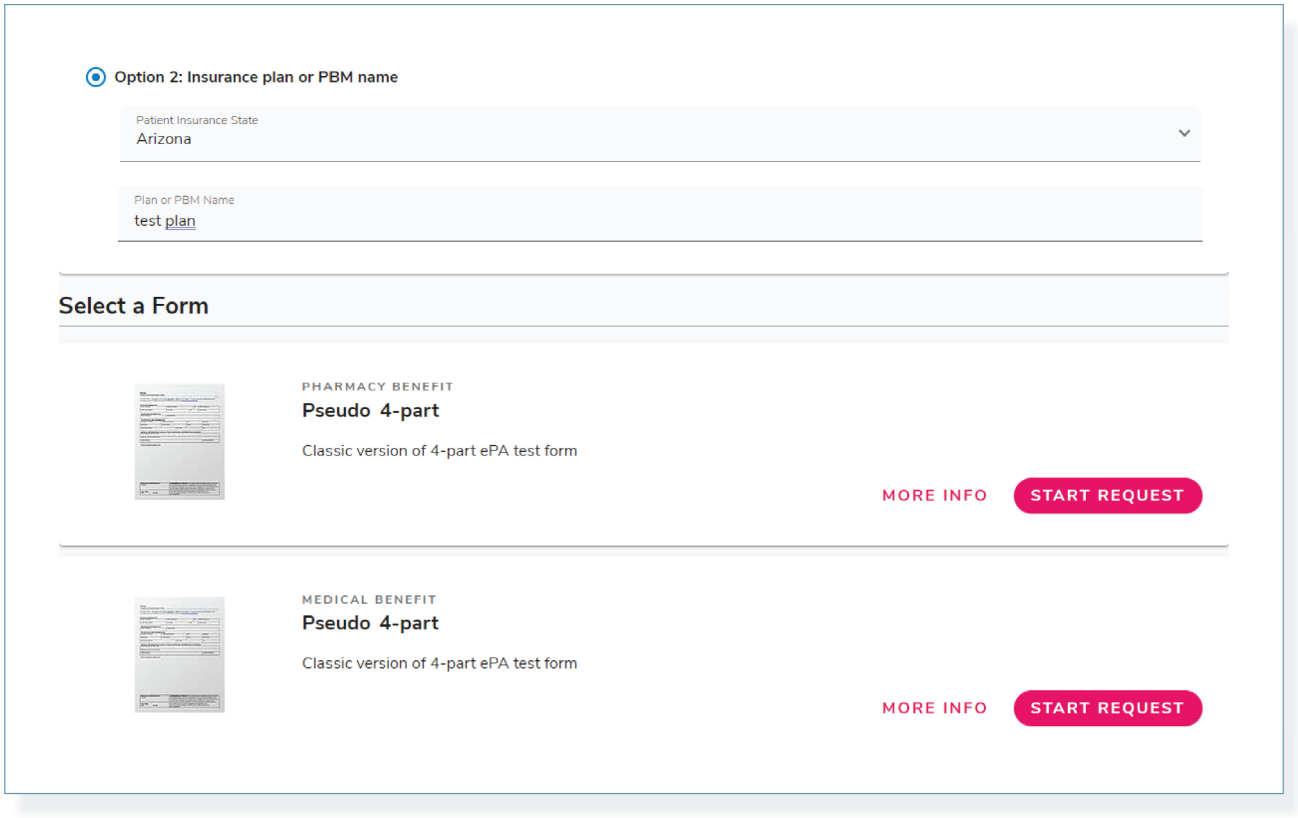
Choose the Patient Insurance State in the drop-down list under Option 2. Then type in Plan or PBM Name.

- 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



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.

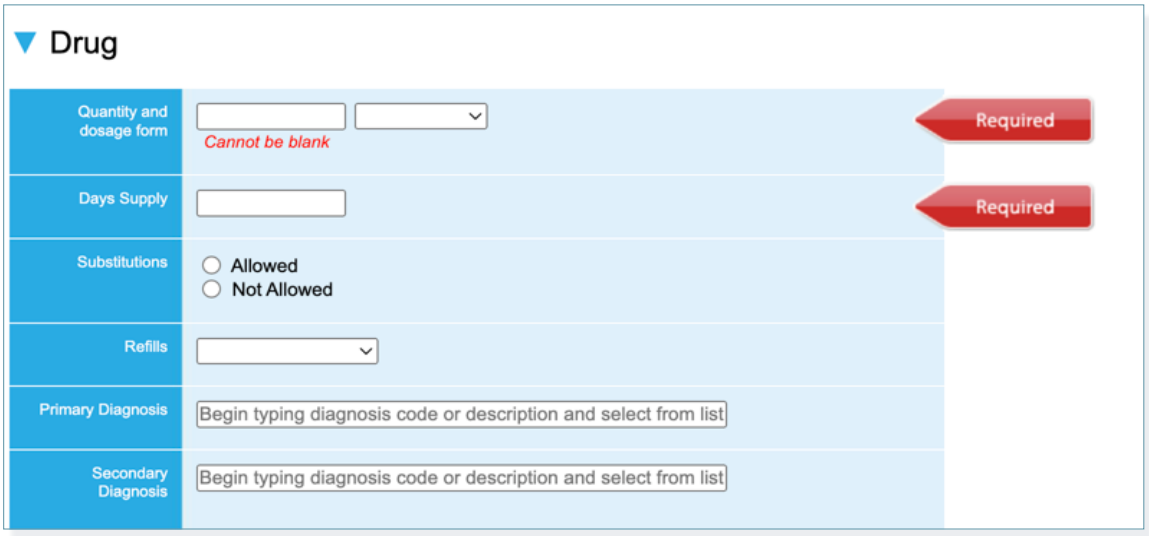
For ARCALYST® (rilonacept) *Loading Dose* PA Requests

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 **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.

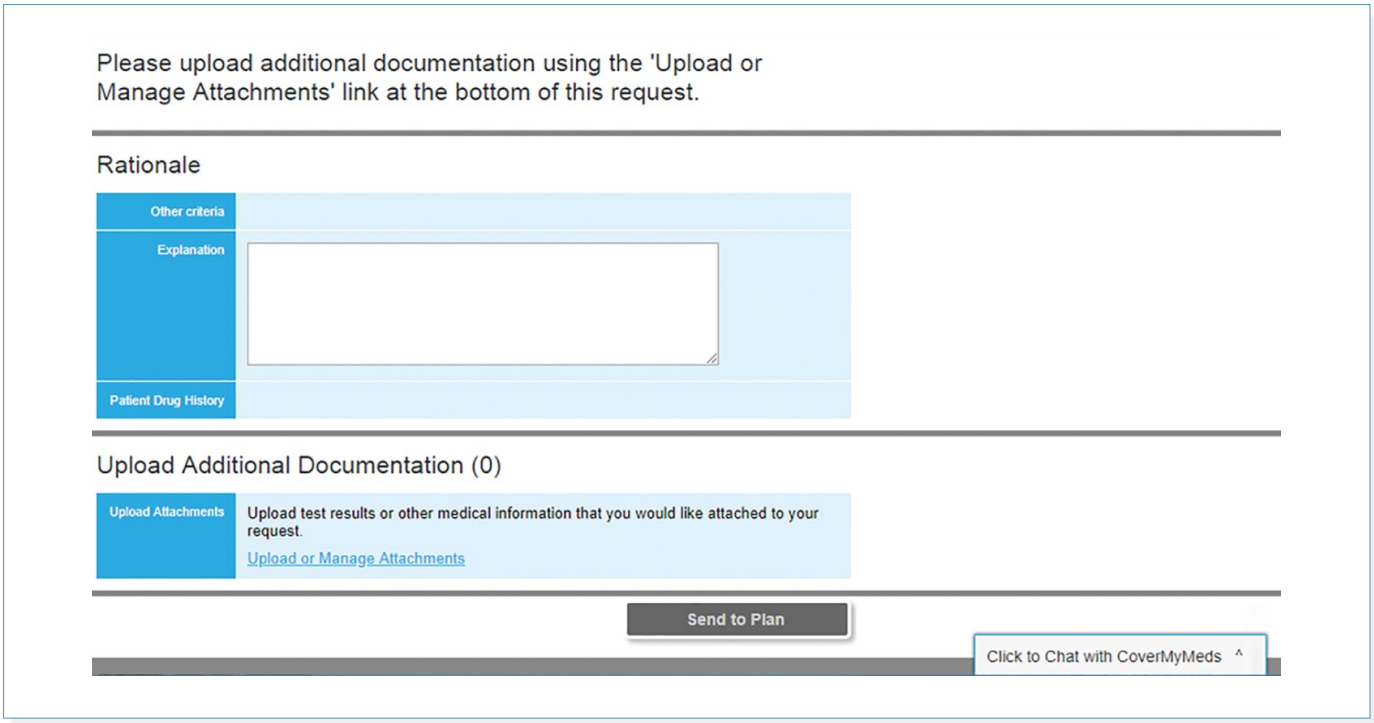
IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

· 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 at ARCALYST.com/PI.

Attaching Documentation: *Helpful Tips*



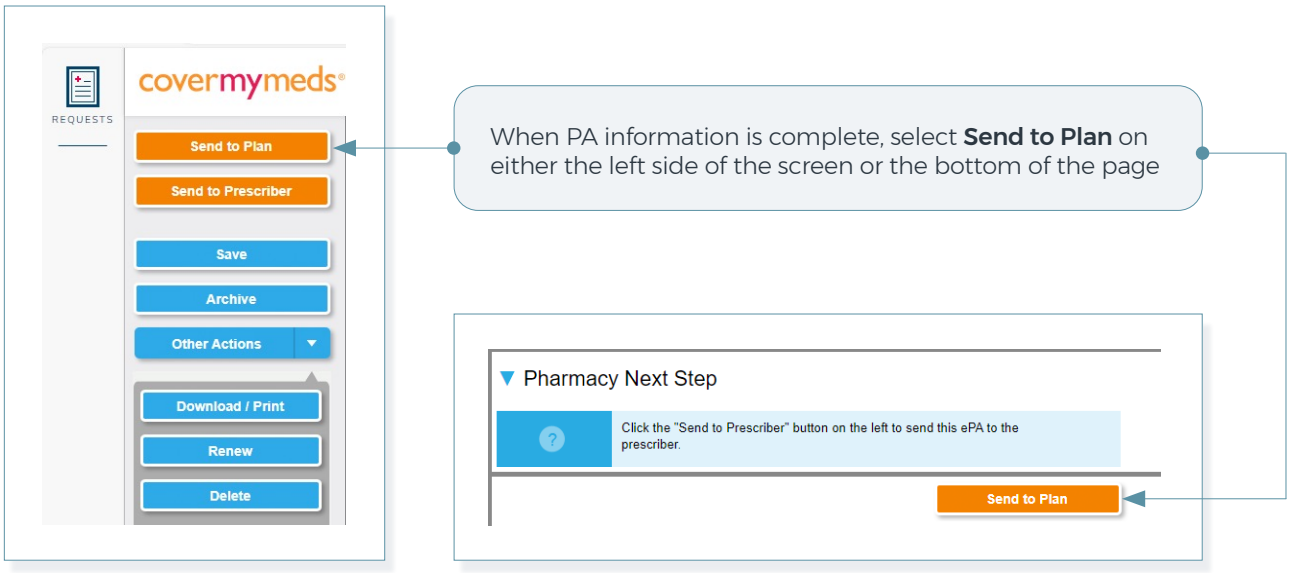
Sample depiction only

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*

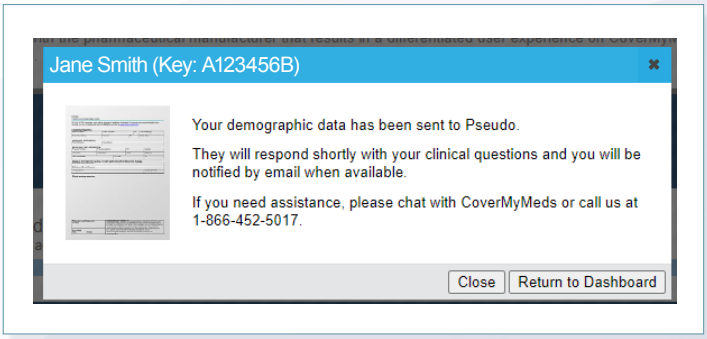


Sample depiction only

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

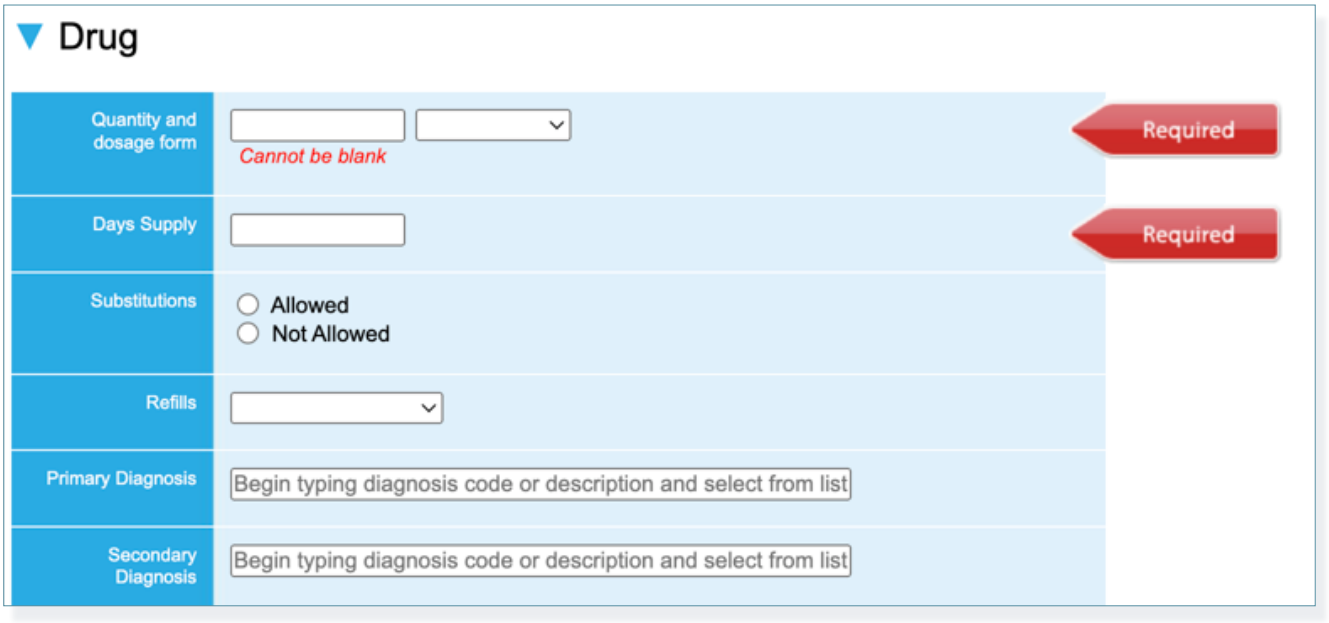
For ARCALYST® (rilonacept) *Maintenance Dose* PA Requests

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 **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.

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

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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 at ARCALYST.com/PI.

Examples of *PA Denial Reasons*

Why Are ARCALYST® (rilonacept) *PAs Being Denied?*

Top PA Denial Reasons

Data obtained July 2023 to December 2023

- Tuberculosis test needs to be completed before initiating therapy (within 6 months)
- Additional documentation needed
- Off-label use
- Quantity/Days supply limitation (approved)
- Must try and fail formulary alternatives

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.

Tuberculosis (TB) test *Requirement*

Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy?

- (●) Yes
- ( ) No

Some major payers mandate that a TB test be administered to patients prior to the use of ARCALYST® (rilonacept). If you patient has had a TB test, it is important that you document or indicate testing has been performed.

Sample payer policy on TB test needed to obtain ARCALYST:*
*Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)** within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.*

Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.
**If the screening testing for TB is positive, there must be further testing to confirm there is no active disease.

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 at ARCALYST.com/PI.

Must Try and Fail *Formulary Alternatives*

Has the member previously tried and failed other medications for their diagnosis?
If yes, please list the medication(s) previously tried for this diagnosis AND the outcome(s).

- (●) Yes
- ( ) No

If an HCP selects "No," the claim may be denied.

Sample payer policy on formulary alternatives needed to obtain ARCALYST® (rilonacept):*

Member has failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids).

Most payers require trial of NSAIDs, colchicine and, at times, corticosteroids prior to the use of ARCALYST. If the patient has been on these medications, this should be indicated in the PA request.

If the patient has an intolerance to the therapies above, this should be noted as able in the PA request.

*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.

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.

Diagnosis *not covered*

What is the indication or diagnosis?

- ○ Cryopyrin-associated periodic syndrome (CAPS)
- ○ Deficiency of interleukin-1 receptor antagonist
- ◉ Recurrent pericarditis
- ○ All other diagnoses

Document the patient's diagnosis or indication.

Recurrent pericarditis

Indications

ARCALYST (rilonacept) is an interleukin-1 blocker indicated for:

- Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older
- Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more
- Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older

If an HCP selects an indication that is not on the ARCALYST label, the claim may be denied. Below is an example of payer policy language on appropriate indications for coverage.

Sample payer policy on diagnosis requirements to obtain ARCALYST:*

FDA-Approved Indications

A. Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years of age and older.

B. Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kilograms (kg).

C. Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.

All other indications are considered experimental/investigational and not medically necessary.

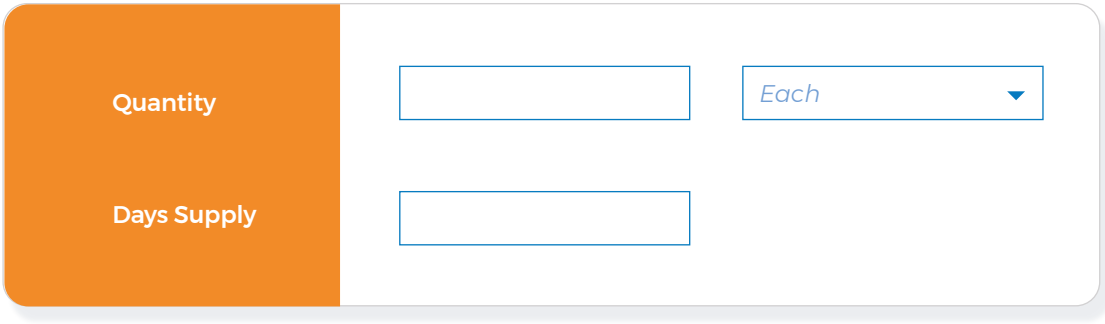
*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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.

Quantity *limitation*



If an HCP selects a quantity that is not covered by the plan's allowable limit, the claim may be denied

Sample payer policy on ARCALYST® (rilonacept) Quantity Limits:*

Dosing for RP and CAPS

Adults

- ***Loading dose:*** *320 mg, delivered as two 160 mg (2 mL) injections.*
- ***Maintenance dose:*** *160 mg (2 mL) injection once weekly.*

Pediatric patients 12 years to 17 years

- ***Loading dose:*** *4.4 mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 injections (not to exceed 2 mL/injection).*
- ***Maintenance dose:*** *2.2 mg/kg, up to a maximum of 160 mg (2 mL) injection, once weekly.*

Quantity limit of 4 vials/28 days

- *A one-time override of 5 vials per 28 days will be allowed for diagnosis of CAPS, FCAS, MWS and RP to accommodate for the loading dose.*

*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

· Discontinue ARCALYST if a patient develops a serious infection.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

Patient has had at Least Two Episodes of *Recurrent Pericarditis*

Has the patient had at least two episodes of recurrent pericarditis?

- (●) Yes
- ( ) No

Some payers mandate that a patient have at least 2 episodes of recurrent pericarditis to approve ARCALYST® (rilonacept) use.

Sample payer policy on number of recurrent pericarditis episodes experienced by the patient needed to obtain ARCALYST:*

Recurrent pericarditis for members 12 years or older for the treatment of recurrent pericarditis when both of the following criteria are met:

1. Member has had at least two episodes of recurrent pericarditis;

2. Member has failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids).

*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.

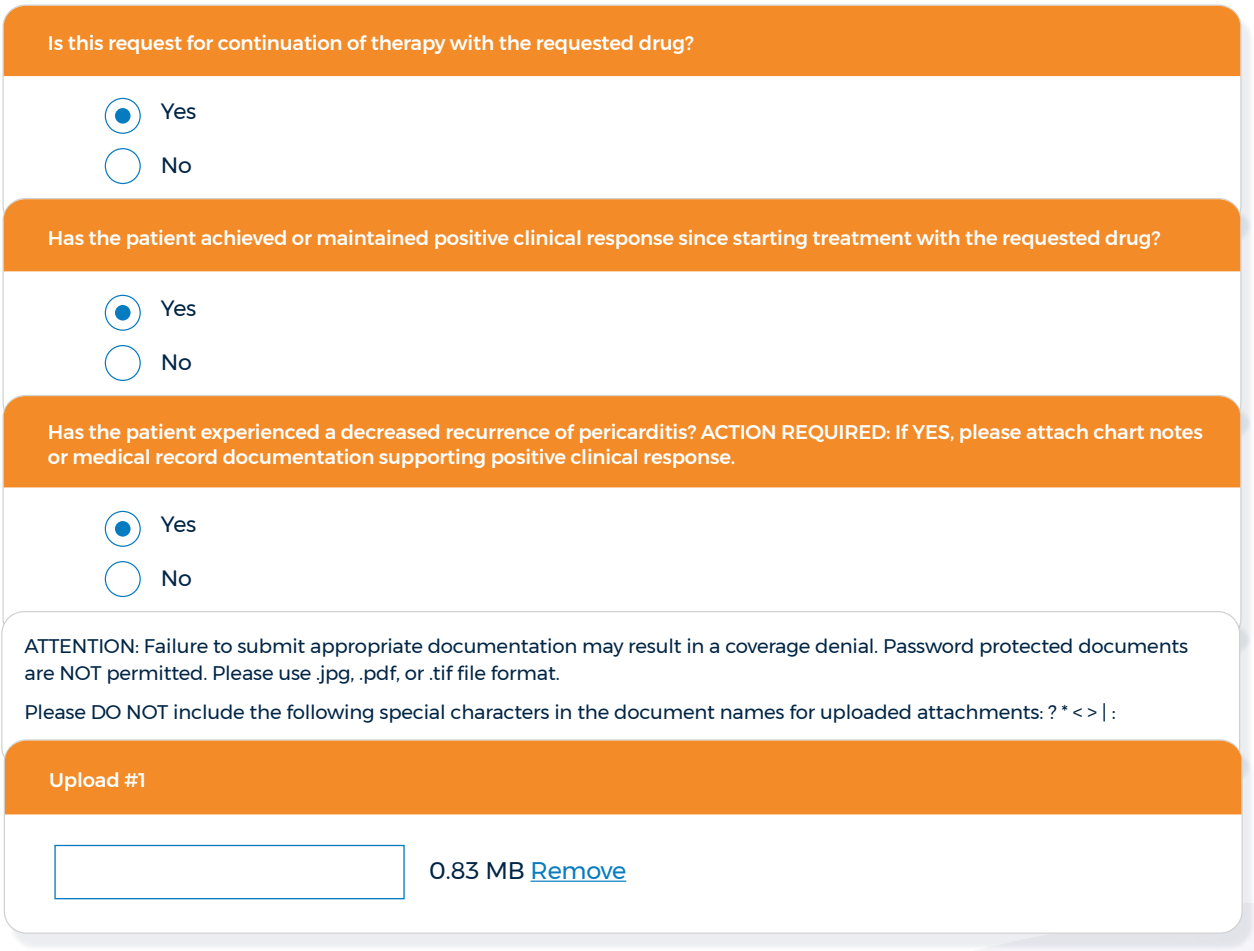
IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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 at ARCALYST.com/PI.

Must Have a Positive Clinical Response to Therapy *for Continuation*



If documentation does not note improvement in the patient's status with use of ARCALYST® (rilonacept), the claim may be denied.

Always remember to submit appropriate documentation for PA renewals as requested from the payer. Information that may be requested:

- Documentation that confirms tolerance and symptom improvement while on medication
- Lab results if taken
- Affirmation of diagnosis
- Confirmation of number of pericarditis attacks prior to the start of ARCALYST
- Confirmation that other biologics are not being used

Sample payer policy on positive clinical response for continued therapy:*
Disease response as indicated by improvement in patient's symptoms (e.g., pericarditis pain, etc.), inflammatory markers (e.g., CRP, etc.), and/or decreased rate of recurrence of disease compared to baseline

*This is an example of one payer policy. Coverage for ARCALYST will vary by specific payer plan.

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 at ARCALYST.com/PI.

Frequently Asked Questions

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

Frequently Asked Questions

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.

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.

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 at ARCALYST.com/PI.

CoverMyMeds is *Here to Help*

covermymeds®

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