ARCALYST has **redefined the treatment landscape** for recurrent pericarditis

2025 ACC Concise Clinical Guidance affirms the standard for management of recurrent pericarditis.[1]

ACC, American College of Cardiology.

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.

Arcalyst® (rilonacept) For Injection

Recurrent pericarditis **may be more common and serious** than clinicians realize

There are an estimated 160,000 individuals with pericarditis in the United States[2]

Up to

1 in 3

individuals with an initial episode of pericarditis may experience a recurrence within 18 months[3]*

Approximately

~40,000

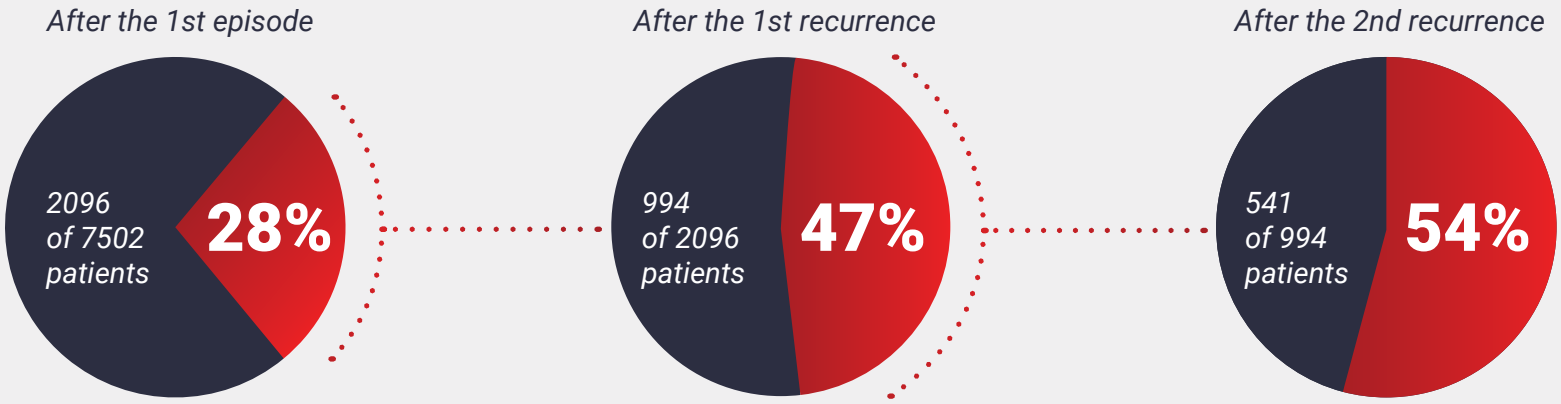
individuals seek care for recurrent pericarditis annually[3]*

An estimated

~14,000

have ≥2 recurrences[4]

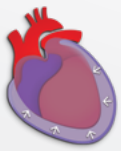
With each recurrence of pericarditis, the risk of additional episodes increases[3]



With multiple events, risk of recurrence increases while time to recurrence decreases.[3]

Patients with recurrent pericarditis have heightened risk of serious complications vs the overall pericarditis population[3]*

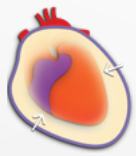
Pericardial effusion:



3x greater

(49% vs 18.1%)

Cardiac tamponade:



2x greater

(8.9% vs 5.1%)

Constrictive pericarditis:

2x greater

(3.9% vs 1.7%)

*Klein A, et al. *JAHA* 2021. Data from the PharMetrics Plus database, collected between January 1, 2013, and March 31, 2018, were used for this retrospective analysis (N=7502 patients with pericarditis, 2096 of whom experienced ≥1 recurrence).

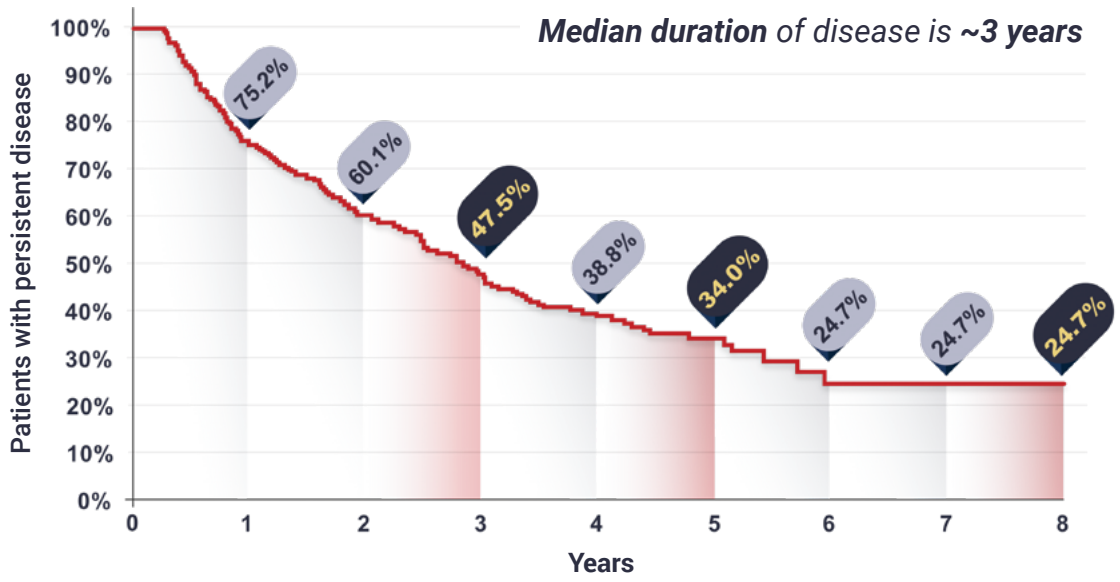
Recurrent pericarditis is a **chronic, interleukin-1 (IL-1)-driven autoinflammatory disease**[5,6]

Recurrent pericarditis often lasts for years[5]

- Observational study of 375 patients with ≥2 recurrences of recurrent pericarditis

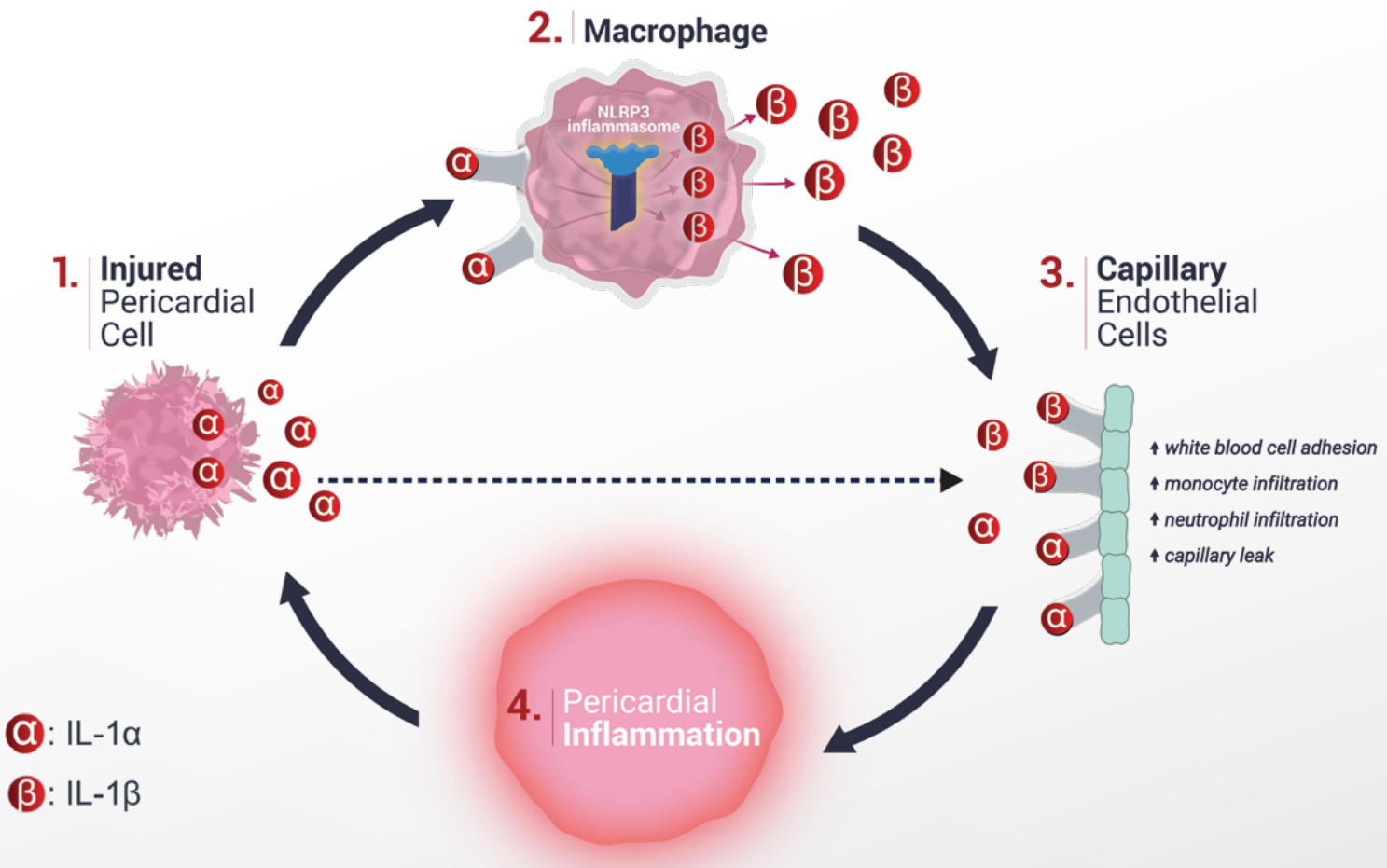
- Approximately one-third of patients were still suffering at **5 years**
- Approximately one-quarter of patients were suffering at **8 years**

Data from Optum Health Care Solutions, Inc., collected from January 1, 2007, through March 31, 2017, were analyzed.



The distinct pathophysiology of recurrent pericarditis[6]

Recurrences and disease duration are driven by a self-perpetuating cycle of IL-1-driven autoinflammation.



The distinct pathophysiology of recurrent pericarditis requires a distinct approach.[6,7]

Patients often suffer in silence and may wait years for an accurate diagnosis

In a Harris Poll survey of 125 patients with recurrent pericarditis[4]*:

74% **had withdrawn from many aspects of life** due to fear or anxiety about having another flare.

80% agreed that they **had not fully regained their prior quality of life** since experiencing recurrent pericarditis.

~3 **episodes before receiving a recurrent pericarditis diagnosis.**

96% **were diagnosed with other conditions before receiving an accurate diagnosis.**

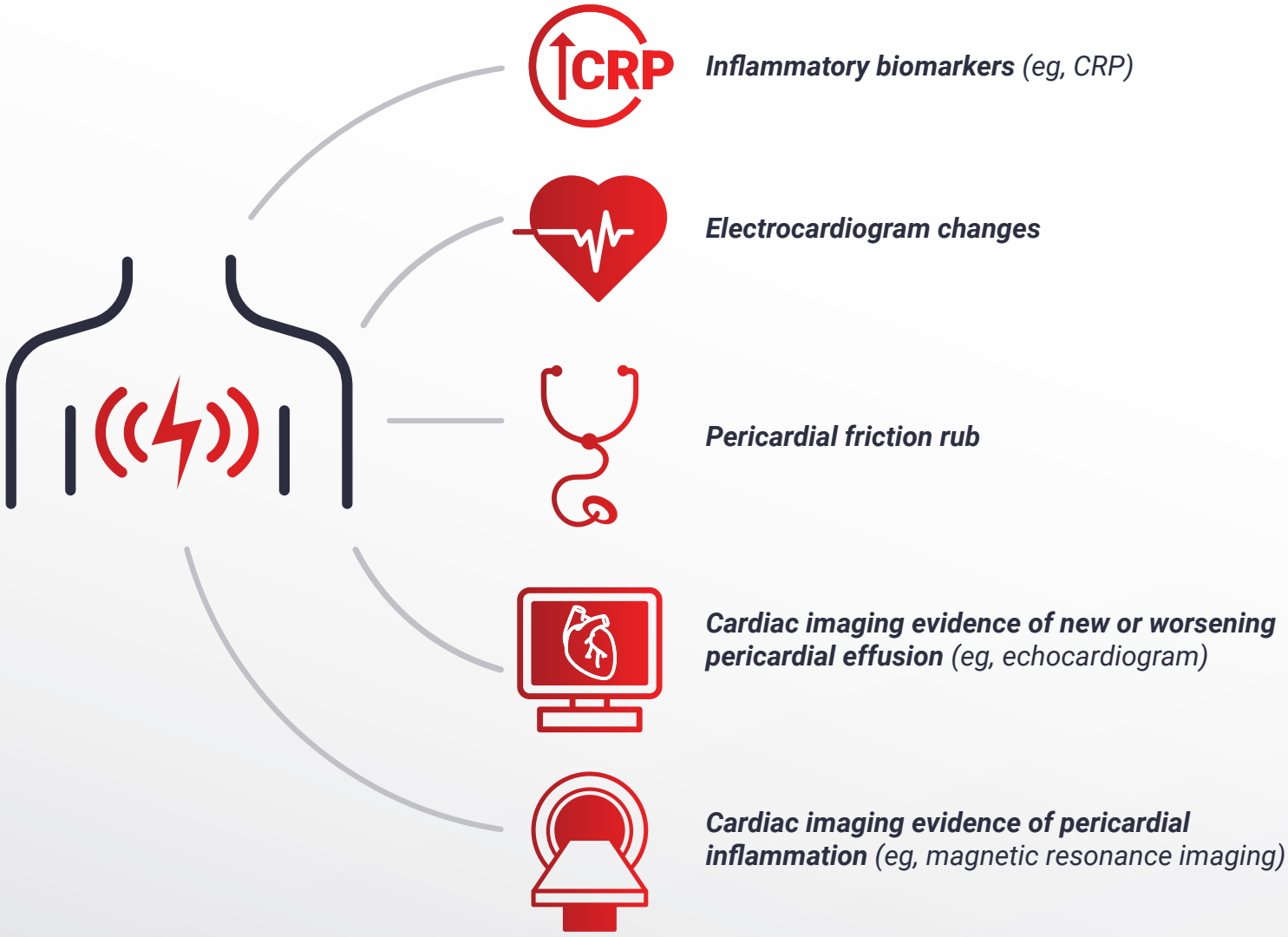
A diagnosis of recurrent pericarditis follows the same criteria as first-episode pericarditis, plus a symptom-free interval of at least 4 to 6 weeks[1]

Must be present: pleuritic chest pain (or equivalent suggestive presentation)†

+

1 more finding (possible diagnosis)

2 or more (definite diagnosis)



CRP, C-reactive protein.

*This survey was conducted online within the United States by The Harris Poll on behalf of Kiniksa Pharmaceuticals from May 4–June 1, 2023, among 125 US adults ages 18+ who have been diagnosed with recurrent pericarditis and are not currently pregnant or breastfeeding and have never used/are not currently using an IL-1 antagonist. The sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data are accurate to within +/– 8.7 percentage points using a 95% confidence level.

†If there are no other findings, recurrent pericarditis is unlikely but cannot be ruled out.

Patients are counting on you to accurately identify and treat their disease

In a Harris Poll survey of 125 patients with recurrent pericarditis[4]*:

88%

want their healthcare provider to ask more questions about their symptoms and/or flares.

Patients saw an average of 3 healthcare providers before receiving an accurate diagnosis.

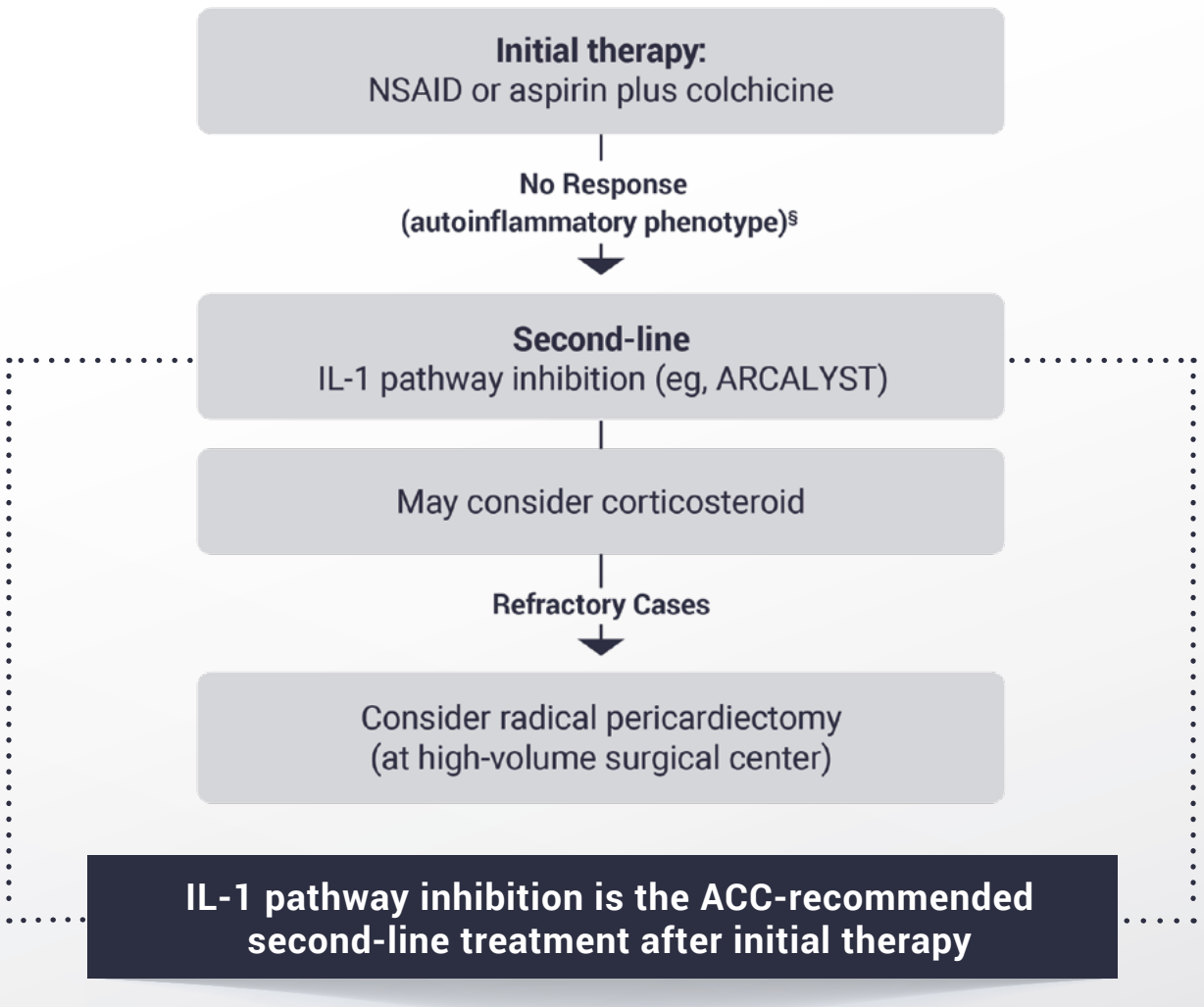
Tips for proactively identifying patients with recurrent pericarditis:

- ✓ When a new patient presents with a flare, determine if it's the first or a recurrence
- ✓ Ask patients to immediately report any new symptoms after the first flare resolves
- ✓ Have staff flag patients who request refills of NSAIDs or colchicine
- ✓ Perform a search in your EHR with the following criteria:
  - —*ICD-10* codes‡: I30.0 / I30.8 / I30.9 / I31.9
  - —Prescription refill history: NSAIDs, colchicine, and/or corticosteroids

EHR, electronic health record; *ICD-10, International Statistical Classification of Diseases, Tenth Revision*; NSAIDs, nonsteroidal anti-inflammatory drugs.

‡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.

2025 ACC Concise Clinical Guidance affirms key role of IL-1 pathway inhibition in the treatment of recurrent pericarditis[1]



Adapted from Wang TKM, et al. *J Am Coll Cardiol*. 2025.

§Autoinflammatory phenotype is defined as patients having fever and/or elevation of CRP and/or cardiac magnetic resonance (CMR) imaging evidence of pericardial inflammation.

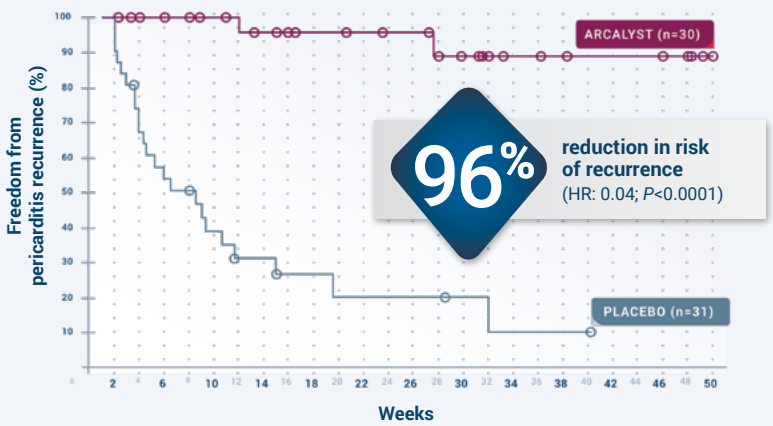
In clinical trials

ARCALYST prevented recurrences for **up to 3 years** while on therapy

ARCALYST blocks IL-1 signaling, breaking the cycle of IL-1-mediated autoinflammation that drives recurrent pericarditis.[8]

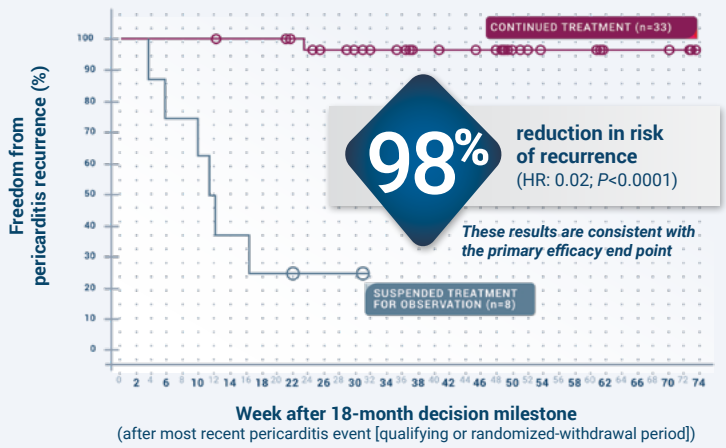
- Traditional therapies such as **corticosteroids do not directly target** the underlying disease[1]

RHAPSODY randomized-withdrawal period (primary end point)[8,9]



Recurrence-free rate was 93% (28 of 30) for ARCALYST and 26% for placebo (8 of 31) at the time that the event-driven, randomized-withdrawal period was closed

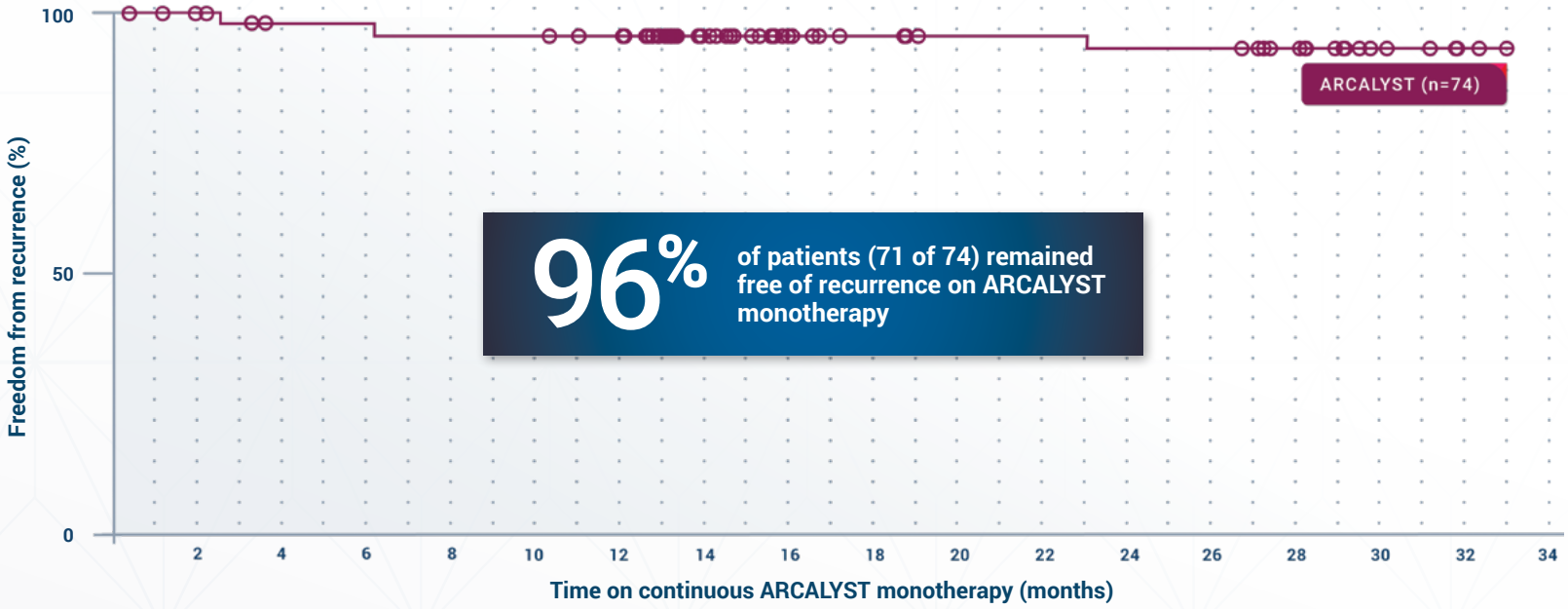
RHAPSODY long-term extension past the 18-month decision milestone[10]



Recurrence-free rate was 97% (32 of 33) for ARCALYST and 25% (2 of 8) for those who suspended therapy

ARCALYST monotherapy over the full 3-year RHAPSODY trial[11]

(pooled data from the randomized-withdrawal period and long-term extension)



- **Recurrence rate observed in pooled data is consistent with the rate observed in the randomized-withdrawal period**[8,11]
- All recurrences in the patients treated with ARCALYST occurred during temporary treatment interruptions[10,11]

CI, confidence interval; HR, hazard ratio, NE, not estimable.
*Primary efficacy end point was time to first adjudicated recurrence.

IMPORTANT SAFETY INFORMATION (continued)

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 at ARCALYST.com/PI.

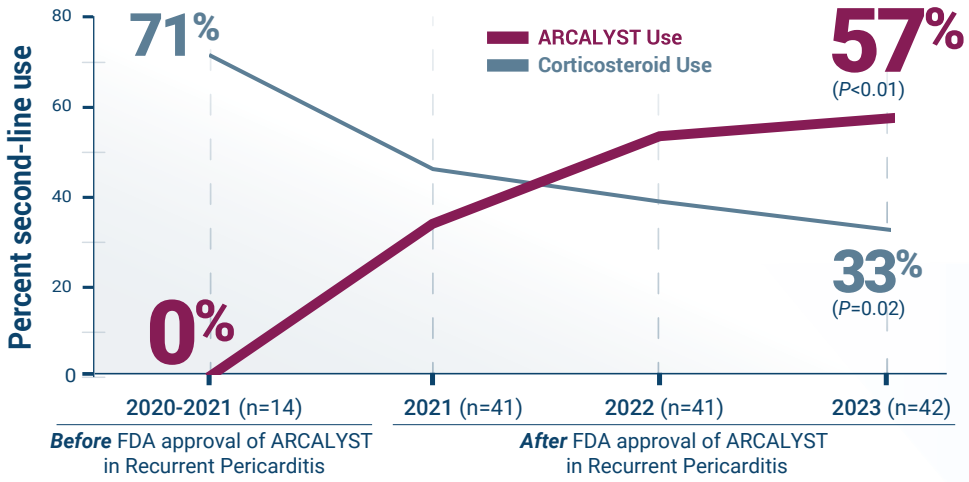
Arcalyst® (rilonacept) For Injection

ARCALYST contributes to a **shift away from corticosteroid therapy** in recurrent pericarditis

Data from RESONANCE, the largest real-world registry of patients with recurrent pericarditis[12]

- Data drawn from 313 patients with recurrent pericarditis from 29 sites

Second-line use in patients with recurrent pericarditis failing NSAIDs/aspirin/colchicine



ARCALYST has increasingly replaced corticosteroids in second-line use

Interval data analysis March 1, 2020, to December 31, 2023.

These data are retrospective and observational in nature and should be interpreted within that context. Predictive value is therefore limited. Results are possibly subject to bias due to site experience; generalizability to centers with different experience levels may be affected.

TEAEs occurring in the run-in and randomized-withdrawal periods of the RHAPSODY study in ≥5% of patients with recurrent pericarditis[4]

TEAE	ARCALYST or Placebo, n (%) (N=86)
Patients with any TEAE	74 (86.0)
Injection-site reactions†	29 (33.7)
Upper respiratory infections‡	19 (22.1)
Arthralgia	10 (11.6)
Myalgia	10 (11.6)
Headache	7 (8.1)
Musculoskeletal chest pain	7 (8.1)
Back pain	6 (7.0)
Cough	6 (7.0)
Diarrhea	5 (5.8)
Fatigue	5 (5.8)

During the run-in and randomized-withdrawal periods (n=86):

- No AEs led to death
- Four AEs led to treatment discontinuation
- Five serious AEs (SAEs) occurred:
  1 during the run-in period (stroke due to carotid artery dissection), 1 in the ARCALYST treatment arm (squamous cell carcinoma), 1 in the placebo arm (cardiac flutter), and 2 in the placebo arm following ARCALYST bailout (pyrexia and ileus)

AEs reported in RHAPSODY were generally consistent with previously approved indications.

AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

†Injection-site reactions include events occurring at the injection site, other events anatomically distant from the injection site may have been assessed as injection-site reactions.

‡Pooled terms, patients counted only once within a preferred term or system organ class.

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.
- 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.

Arcalyst® (rilonacept) For Injection

Starting your patients on ARCALYST

Initiating treatment

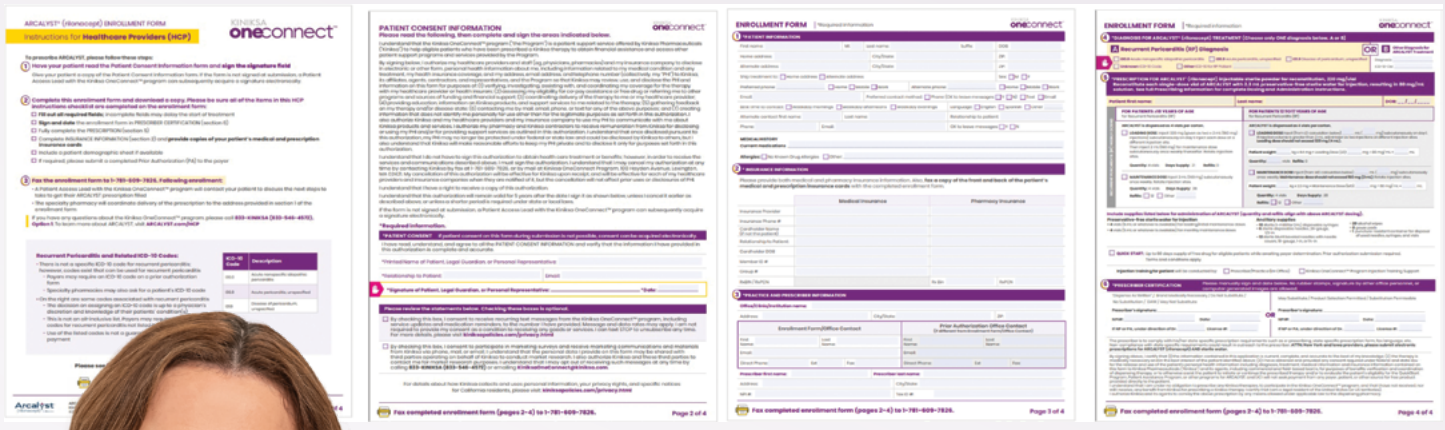
- ARCALYST should not be initiated in patients with an active or chronic infection
- Ensure your patient's vaccination history is up-to-date, including pneumonia and flu vaccines
- Refer to current practice guidelines for evaluation and treatment of possible latent tuberculosis infections before initiating ARCALYST

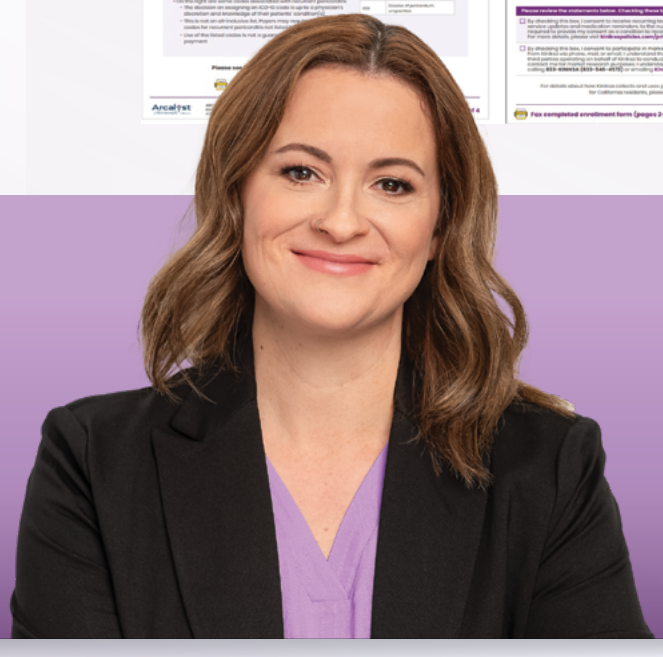
Enrollment completion

- By completing an Enrollment Form, your patient may be eligible to receive benefits of the Kiniksa OneConnect™ program, such as financial assistance and injection training. The Enrollment Form also serves as a prescription for ARCALYST

ARCALYST Enrollment Form

Download an ARCALYST Enrollment Form with this QR code *or* at ARCALYST.com/enrollment





Comprehensive support throughout the treatment journey

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

Once you have enrolled your patient in the program, a dedicated Patient Access Lead (PAL) will be the point of contact for both you and your patient throughout their treatment journey.

KINIKSA oneconnect™

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.

Arcalyst® (rilonacept) For Injection

Market access for ARCALYST is **highly favorable**

LOW *out-of-pocket* **COST** **$0**

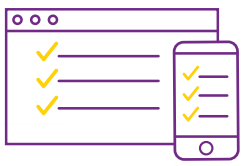
Eligible, commercially insured patients pay as little as **$0 per month** for ARCALYST treatment with the copay assistance program*

High *commercial* **access** **97%** **PA approval**

A significant majority of PA requests for ARCALYST have been approved*†

PA, prior authorization.
*Based on final coverage approval.
†From approval in March 2021 to September 1, 2025.

Reimbursement support



Insurance coverage and benefits

After verifying benefits with the insurer, the PAL will provide both you and your patient a summary of benefits, including the patient's copay responsibility.

PA support

We'll inform your office if a PA is required, including documentation required and how to submit.

Appeals support

If you receive notification that coverage has been denied, your PAL can provide a guide with sample letter template for submitting a Letter of Appeal to the insurer.

Financial Assistance Programs

Commercial Copay Assistance Program*

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

Quick Start Program†

Supports eligible patients with limited or no coverage for treatment.

- Program offered at no cost for up to 60 days while awaiting PA

Patient Assistance Program‡

Supports eligible patients with limited or no coverage for treatment.

- Qualified patients can receive treatment at no cost for up to 12 months

Eligibility requirements, terms and conditions, and restrictions apply.

*To be eligible for the Kiniksa Copay Assistance Program, your patients must have commercial insurance, must not have Medicare, Medicaid, or other government insurance, and must meet other eligibility criteria. Your patient also must agree to the rules set forth in the terms and conditions for the program. Please visit kiniksapolicies.com/copay to review additional eligibility criteria.
†Program offered for up to 60 days. To be eligible for the Kiniksa Quick Start Program, your patient must meet certain financial eligibility requirements. Please visit kiniksapolicies.com/qstart to review additional eligibility criteria.
‡Program offered for up to 12 months. Please visit kiniksapolicies.com/pap to review additional eligibility criteria.

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 at ARCALYST.com/PI.

Arcalyst® (rilonacept) For Injection

Backed by the latest clinical data, choose ARCALYST for 3 years for your appropriate patients with recurrent pericarditis.

IMPORTANT SAFETY INFORMATION (continued)

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

References: 1. Wang TKM, Klein AL, Cremer PC, et al. 2025 concise clinical guidance: an ACC expert consensus statement on the diagnosis and management of pericarditis: a report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2025. doi:10.1016/j.jacc.2025.05.023 **2.** Luis SA, LeWinter MM, Magestro M, et al. Estimating the US pericarditis prevalence using national health encounter surveillance databases. *Curr Med Res Opin*. 2022;38(8):1385-1389. **3.** Klein A, Cremer P, Kontzias A, et al. US database study of clinical burden and unmet need in recurrent pericarditis. *J Am Heart Assoc*. 2021;10:e018950. doi:10.1161/JAHA.120.018950 **4.** Data on file. Kiniksa Pharmaceuticals. **5.** Lin D, Laliberté F, Majeski C, et al. Disease and economic burden associated with recurrent pericarditis in a privately insured United States population. *Adv Ther.* 2021;38(10):5127-5143. doi:10.1007/s12325-021-01868-7 **6.** Dinarello CA, Simon A, van der Meer JWM. Treating inflammation by blocking IL-1 in a broad spectrum of diseases. *Nat Rev Drug Discov*. 2012;11(8):633-652. doi:10.1038/nrd3800 **7.** Imazio M, Mardigyan V, Andreis A, Franchin L, De Biasio M, Collini V. New developments in the management of recurrent pericarditis. *Can J Cardiol*. 2023;39(8):1103-1110. doi:10.1016/j.cjca.2023.04.008 **8.** ARCALYST. Package insert. Kiniksa Pharmaceuticals; 2021. **9.** Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. *N Engl J Med*. 2021;384(1):31-41. **10.** Imazio M, Klein AL, Brucato A, et al. Sustained pericarditis recurrence risk reduction with long-term rilonacept. *J Am Heart Assoc*. 2024:e032516. doi:10.1161/JAHA.123.032516 **11.** Lotan D, Imazio M, Klein AL, et al; for the RHAPSODY Investigators. Rilonacept as monotherapy for long-term recurrent pericarditis management: sustained disease control over three years. Presented at: European Society of Cardiology Congress; August 29, 2025-September 1, 2025; Madrid, Spain. **12.** Cremer PC, Luis SA, Garshick MS, et al. IL-1 pathway inhibition in recurrent pericarditis management: real-world adoption of corticosteroid sparing in RESONANCE. *JACC Adv*. 2025;4(9):102050. doi:10.1016/j.jacadv.2025.102050

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