

Introducing

KEVZARA® (sarilumab) for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroid or who cannot tolerate corticosteroid taper



Intended for use with payers, formulary committees, or other similar entities for purposes of population-based drug selection, coverage and/or reimbursement decision making, pursuant to FD&C Act Section 502(a).

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INDICATION

KEVZARA® (sarilumab) is indicated for treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with KEVZARA are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving KEVZARA. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of KEVZARA in patients with an active infection.

Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before KEVZARA use and during therapy. Treatment for latent infection should be initiated prior to KEVZARA use.
- Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
- Bacterial, viral and other infections due to opportunistic pathogens.

Closely monitor patients for signs and symptoms of infection during treatment with KEVZARA. If a serious infection develops, interrupt KEVZARA until the infection is controlled.

Consider the risks and benefits of treatment with KEVZARA prior to initiating therapy in patients with chronic or recurrent infection.

IMPORTANT SAFETY INFORMATION (cont)

CONTRAINDICATION

Do not use KEVZARA in patients with known hypersensitivity to sarilumab or any of the inactive ingredients.

WARNINGS AND PRECAUTIONS

- **Infections.** Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents including KEVZARA. The most frequently observed serious infections with KEVZARA included pneumonia and cellulitis. Among opportunistic infections, TB, candidiasis, and pneumocystis were reported with KEVZARA.
 - Hold treatment with KEVZARA if a patient develops a serious infection or an opportunistic infection.
 - Patients with latent TB should be treated with standard antimycobacterial therapy before initiating KEVZARA. Consider anti-TB therapy prior to initiation of KEVZARA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but having risk factors for TB infection.
 - Consider the risks and benefits of treatment prior to initiating KEVZARA in patients who have: chronic or recurrent infection, a history of serious or opportunistic infections, underlying conditions that may predispose them to infection, been exposed to TB, or lived in or traveled to areas of endemic TB or endemic mycoses.
 - Viral reactivation has been reported with immunosuppressive biologic therapies. Cases of herpes zoster were observed in clinical studies with KEVZARA.
- **Laboratory Abnormalities.** Treatment with KEVZARA was associated with decreases in absolute neutrophil counts (including neutropenia), and platelet counts; and increases in transaminase levels and lipid parameters (LDL, HDL cholesterol, and/or triglycerides). Increased frequency and magnitude of these elevations were observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination with KEVZARA. Assess neutrophil count, platelet count, and ALT/AST levels prior to initiation with KEVZARA. Monitor these parameters 4 to 8 weeks after start of therapy and every 3 months thereafter. Assess lipid parameters 4 to 8 weeks after start of therapy, then at 6 month intervals.

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IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

- **Gastrointestinal Perforation.** GI perforation risk may be increased with concurrent diverticulitis or concomitant use of NSAIDs or corticosteroids. Gastrointestinal perforations have been reported in clinical studies, primarily as complications of diverticulitis. Promptly evaluate patients presenting with new onset abdominal symptoms.
- **Immunosuppression.** Treatment with immunosuppressants may result in an increased risk of malignancies. The impact of treatment with KEVZARA on the development of malignancies is not known but malignancies have been reported in clinical studies.
- **Hypersensitivity Reactions.** Hypersensitivity reactions have been reported in association with KEVZARA. Hypersensitivity reactions that required treatment discontinuation were reported in 0.3% of patients in controlled RA trials. Injection site rash, rash, and urticaria were the most frequent hypersensitivity reactions. Advise patients to seek immediate medical attention if they experience any symptoms of a hypersensitivity reaction. If anaphylaxis or other hypersensitivity reaction occurs, stop administration of KEVZARA immediately. Do not administer KEVZARA to patients with known hypersensitivity to sarilumab.
- **Active Hepatic Disease and Hepatic Impairment.** Treatment with KEVZARA is not recommended in patients with active hepatic disease or hepatic impairment, as treatment with KEVZARA was associated with transaminase elevations.
- **Live Vaccines.** Avoid concurrent use of live vaccines during treatment with KEVZARA due to potentially increased risk of infections. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving KEVZARA.

ADVERSE REACTIONS

- **For Polymyalgia Rheumatica:** Serious adverse reactions of neutropenia occurred in 2 patients (3.4%) in the KEVZARA group compared to none in the placebo group. The proportion of patients with serious infections was similar in the KEVZARA group (5.1%) compared to the placebo group (5.2%). The common adverse reactions occurring in $\geq 5\%$ of patients treated with KEVZARA were neutropenia, leukopenia, constipation, rash pruritic, myalgia, fatigue, and injection site pruritus.

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IMPORTANT SAFETY INFORMATION (cont)

DRUG INTERACTIONS

- Exercise caution when KEVZARA is co-administered with CYP substrates with a narrow therapeutic index (e.g. warfarin or theophylline), or with CYP3A4 substrates (e.g. oral contraceptives or statins) as there may be a reduction in exposure which may reduce the activity of the CYP3A4 substrate.
- Elevated interleukin-6 (IL-6) concentration may down-regulate CYP activity such as in patients with RA and hence increase drug levels compared to subjects without RA. Blockade of IL-6 signaling by IL-6R α antagonists such as KEVZARA might reverse the inhibitory effect of IL-6 and restore CYP activity, leading to altered drug concentrations.

USE IN SPECIFIC POPULATIONS

- KEVZARA should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Because monoclonal antibodies could be excreted in small amounts in human milk, the benefits of breastfeeding and the potential adverse effects on the breastfed child should be considered along with the mother's clinical need for KEVZARA.
- Use caution when treating the elderly.

Advise patients to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

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Overview of PMR

PMR is the second-most common inflammatory rheumatic disease after RA^{1,2}



Disease presentation

- PMR is typically characterized by aching, symmetrical pain, and morning stiffness in the neck, shoulders, and pelvic girdle^{1,3}
- Limited range of motion and unilateral shoulder bursitis occurs in >95% of patients^{4,5}
- Pain is worse in the morning and after prolonged inactivity²



Epidemiology

- As of 2020, the estimated prevalence in the United States was ~800,000 cases^{6,7}
- PMR affects adults >50 years and incidence increases with advancing age¹
- Women are affected 2-3 times more than men⁸
- Incidence is highest in people of Northern European ancestry, although PMR can occur in any ethnic group⁶
- Peak incidence is among patients 70-80 years of age⁸



Diagnosis

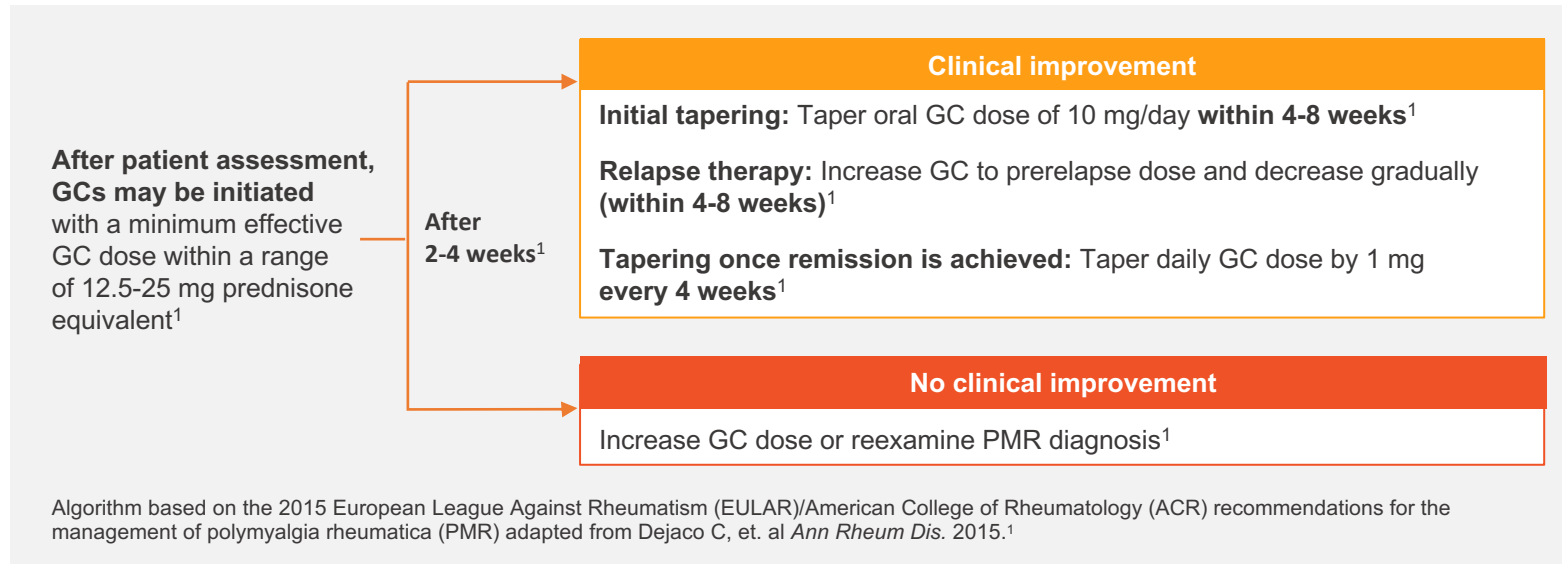
- There is no specific diagnostic test for PMR⁹
 - Clinicians often use the clinical response to GC as a “test of treatment” to establish the diagnosis⁸
 - Diagnosis is made through a process of exclusion^{4,9}
- Elevated inflammatory markers (ie, CRP and ESR), while not needed for PMR diagnosis, are characteristic features found in ~96% of patients with PMR^{1,4}

CRP=C-reactive protein; ESR=erythrocyte sedimentation rate; GC=glucocorticoid.

References: 1. González-Gay MA, et al. *Lancet*. 2017;390:1700-1712. 2. Acharya S, Musa R. *Polymyalgia Rheumatica*. [Updated 2021 Jun 26]. In: StatPearls [Internet]. StatPearls Publishing; 2022 Jan. 3. Mackie SL. *Clin Med (Lond)*. 2013;13(4):398-400. 4. Dasgupta B, et al. *Arthritis Rheum*. 2012;64(4):943-954. 5. Ruta S, et al. *Clin Rheum* 2012;31:1383-1387. 6. Crowson CS, et al. *Semin Arthritis Rheum*. 2017;47(2):253-256. 7. United States Census Bureau. American Community Survey, Age and Sex. 2020. Accessed June 7, 2022 . <https://data.census.gov/cedsci/table?t=Age%20and%20Sex&g=0100000US&y=2020&tid=ACST5Y2020.S0101> 8. Raheel S, et al. *Arthritis Care Res*. 2017;69:1282–1285. 9. Kermani TA, Warrington KJ. *Ther Adv Musculoskelet Dis*.2014;6(1):8-19.

GCs are currently the standard of care in the treatment of PMR¹

EULAR/ACR guidelines suggest that patients demonstrate clinical improvement before tapering begins



EULAR/ACR Recommendations¹

- ✓ *Strongly recommend:*
GC use over NSAID therapy
- *Conditionally recommend:*
Early introduction of MTX with GCs
- ✗ *Recommend against:*
Anti-TNFα agents and Chinese herbal preparations

Some patients may not achieve adequate management of symptoms with GCs and thus limit their treatment options.²

MTX=methotrexate; NSAID=non-steroidal anti-inflammatory drug.

References: 1. Dejaco C, et al. *Ann Rheum Dis.* 2015;74(10):1799-1807. 2. Buttgeriet F, et al. *JAMA.* 2016;315(22):2442-2458.

Challenges remain with GC use in some patients with PMR¹

Frequent relapses require additional GC therapy, which may lead to a longer cumulative exposure and subsequent adverse reactions¹



Relapse rates

It is estimated that up to 43% of patients taking GCs relapse within 1 year²



Duration of therapy

GCs are typically used for ≥ 12 months^{1,3}

As time on therapy increases, so does the cumulative GC dose⁴



Comorbidities

Comorbidities associated with GC use in older patients include⁴:

- Cardiovascular disease
- Osteoporosis
- Fragility fractures
- Diabetes mellitus
- Cataracts
- Glaucoma

To determine the appropriateness of GC use, EULAR/ACR recommends assessing comorbidities, other relevant medications, and risk factors for GC-related adverse events.¹

GENERAL DEFINITIONS:
REMISSION AND FLARE

IL-6 is implicated in the pathogenesis of PMR¹

IL-6 plays an important role in PMR^{1,2}:

- Under normal physiologic conditions, IL-6 performs many functions, but it is also responsible for responding to infection or injury¹
- Persistently-elevated IL-6 levels cause inflammation observed in autoimmune and chronic inflammatory conditions²⁻⁴
- In PMR, IL-6 is a major driver of acute-phase response and systemic inflammation^{2,4}
- Elevated IL-6 is associated with relapse and a need for higher GC doses in patients with PMR⁴⁻⁶
- IL-6 levels correlate with PMR disease activity⁷
- Elevated serum soluble IL-6 concentrations were identified as a potential prognostic marker for PMR relapses^{7,8}

IL-6R=interleukin-6 receptor.

References: 1. Tanaka T, Kishimoto T. *Int J Biol.* 2012;8(9):1227-1236. 2. González-Gay MA, et al. *Lancet.* 2017;390:1700-1712. 3. Jiemy WF, et al. *Ann Rheum Dis.* 2022;0:1-2.

4. Salvarani C, et al. *Arthritis & Rheumatism.* 2005;53(1):33-38. 5. Pulsatelli L, et al. *Arthritis Rheum.* 2008;59(8):1147-1154. 6. Martinez-Taboada VM, et al. *Cytokine* 2008;44:207-220. 7. Roche NE, Fulbright JW, Wagner AD, et al. Correlation of interleukin-6 production and disease activity in polymyalgia rheumatica and giant cell arteritis. *Arthritis & Rheumatism.* 1993;36(9):1286-1294. 8. Mori S, Koga Y. Glucocorticoid-resistant polymyalgia rheumatica: pretreatment characteristics and tocilizumab therapy. *Clin Rheumatol.* 2016;35:1367-1375.

KEVZARA for the Treatment of PMR

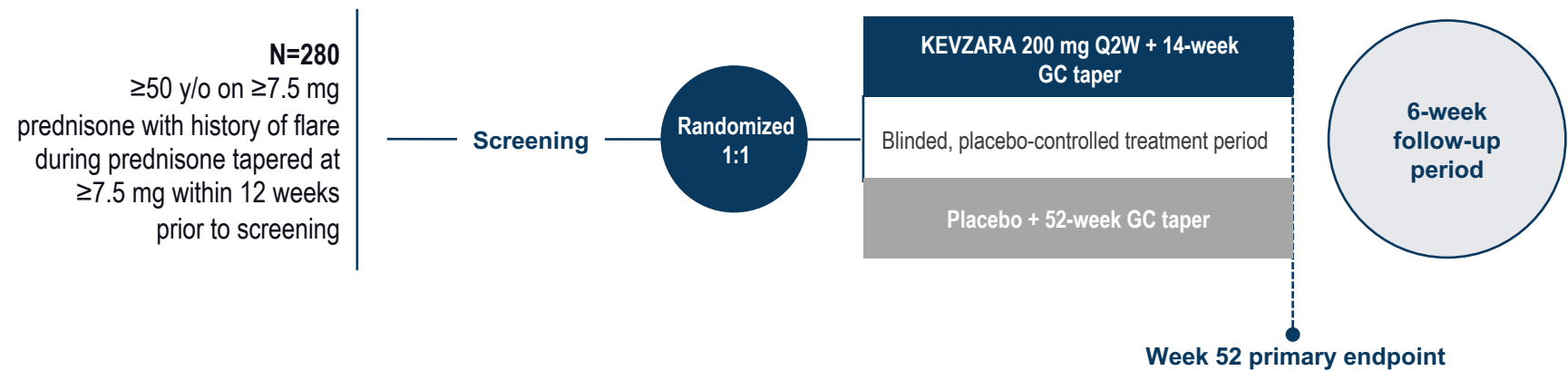
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KEVZARA[®]
(sarilumab)

The logo graphic for KEVZARA, featuring a stylized, abstract shape that resembles a lowercase 'k' or a wing, positioned to the right of the text.

KEVZARA is an IL-6Ri approved for the treatment of PMR^{1,2}

The SAPHYR trial was designed to evaluate the efficacy and safety of KEVZARA in patients with PMR^{1,3}



Primary endpoint ^{1,3}	Select secondary endpoints ^{1,3}
Percentage of patients achieving sustained remission at week 52	<ul style="list-style-type: none">Components of sustained remission (4 criteria) at week 52*Cumulative equivalent prednisone dose over 52 weeksSafety

- INCLUSION CRITERIA ▶
- EXCLUSION CRITERIA ▶
- EULAR/ACR CLASSIFICATION CRITERIA FOR PMR ▶
- ENROLLMENT IMPACT ▶

*Disease remission achieved by week 12; absence of disease flare from week 12 to week 52; normalization of CRP (<10 mg/L) from week 12 to week 52; adherence to prednisone taper from week 12 to week 52.

IL-6Ri=interleukin-6 receptor inhibitor; Q2W=every 2 weeks; R=randomization; y/o=years old.

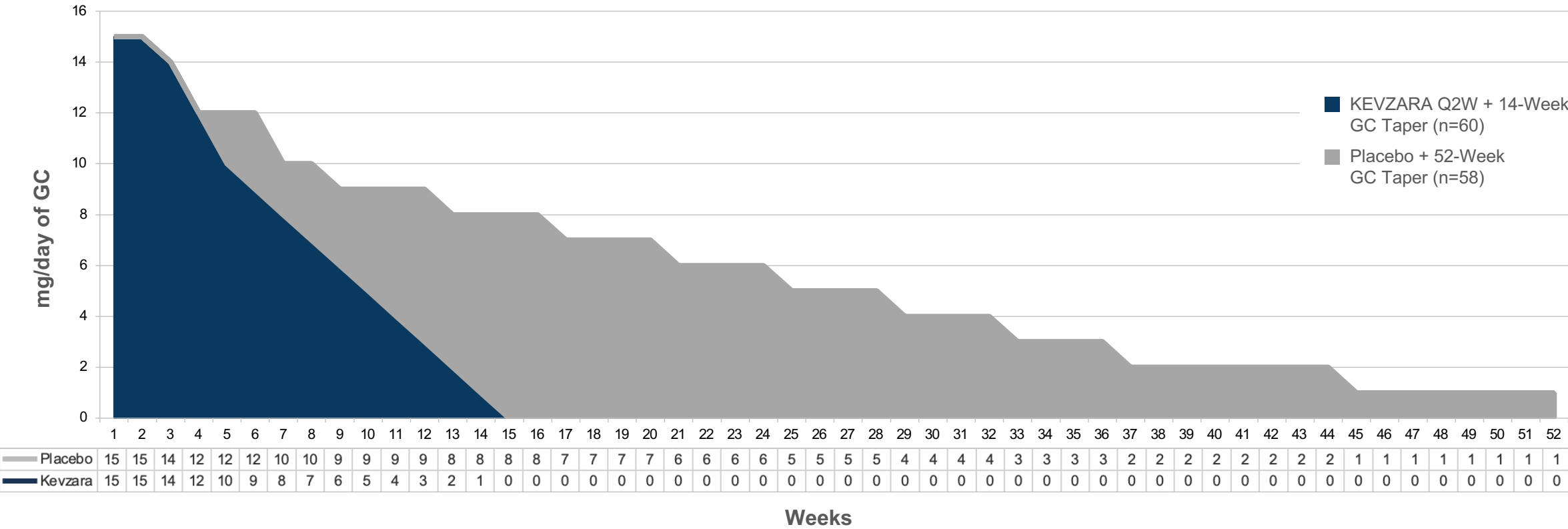
References: 1. Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p18-19,21 2. Data on file, Sarilumab SAPHYR Phase 3 Key Results, Medical Q & A, 2022. 3. ClinicalTrials.gov. Evaluation of the Efficacy and Safety of Sarilumab in Patients With Polymyalgia Rheumatica. Updated June 10, 2022. Accessed July 7, 2022. <https://clinicaltrials.gov/ct2/show/NCT0360081>

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In SAPHYR, the KEVZARA cohort employed a more rapid GC tapering regimen

The initial dose of GCs for both groups was 15 mg/day for the first 2 weeks after randomization. Participants then followed different tapering regimens per assigned groups



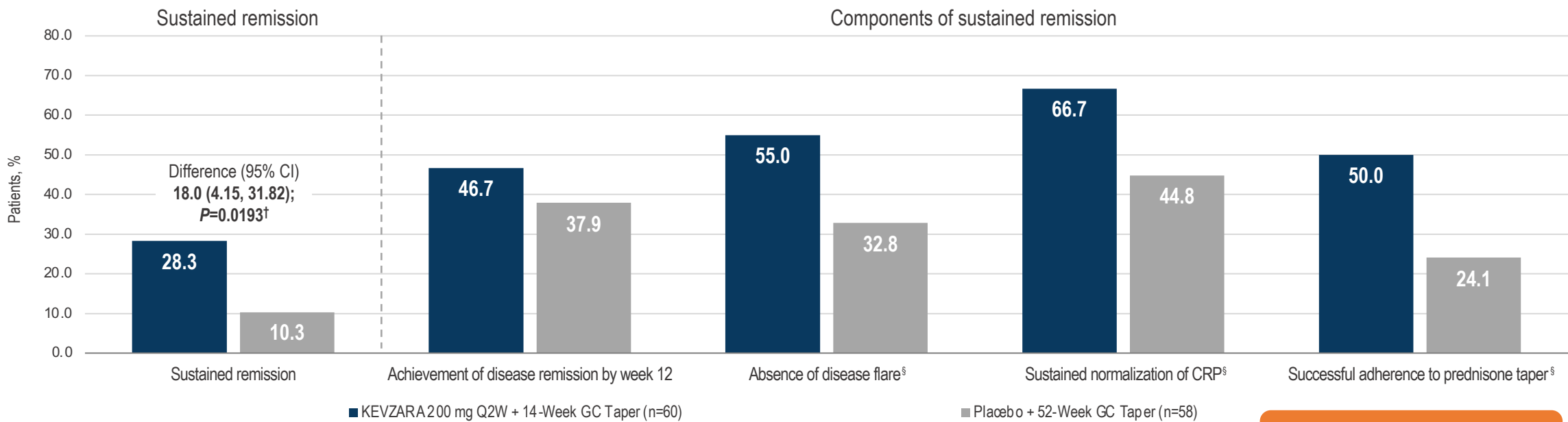
Reference: Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p18

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Nearly 3 times as many patients taking KEVZARA achieved sustained remission

Proportion of patients in sustained remission* at week 52



SAPHYR DEFINITION:
SUSTAINED REMISSION

CI=confidence interval.
*Sustained remission was defined as having met all the following parameters: disease remission achieved by week 12, absence of disease flare from week 12 to week 52, normalization of CRP from week 12 to week 52, and adherence to prednisone taper week 12 to week 52.
[†]P value from Fisher's exact test.
[‡]P value is nominal section mark.
[§]From weeks 12 to 52.
Reference: KEVZARA [package insert]. Bridgewater, NJ: Sanofi/Regeneron Pharmaceuticals, Inc; 2023.

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Patient Safety Information

Safety studied in one Phase 3 study in 117 PMR patients of whom 59 received subcutaneous KEVZARA 200 mg*

- Common adverse reactions occurring in $\geq 5\%$ of patients treated with KEVZARA:
 - neutropenia (15.3%)
 - leukopenia (6.8%)
 - constipation (6.8%)
 - rash pruritic (5.1%)
 - myalgia (6.8%)
 - fatigue (5.1%)
 - injection site pruritus (5.1%)
- Serious adverse reactions of neutropenia occurred in 2 patients (3.4%) in the KEVZARA group compared to none in the placebo group
- The proportion of patients with serious infections was similar in the KEVZARA group (5.1%) compared to the placebo group (5.2%)

The most common adverse reactions that resulted in permanent discontinuation of therapy with KEVZARA were neutropenia in 3 patients (5.1%) and infection in 3 separate patients (5.1%), including COVID-19 (n=1), intervertebral discitis (n=1), and pneumonia (n=1).

*Of these, 45 patients received KEVZARA for at least 24 weeks, 44 patients for at least 40 weeks, and 10 patients for at least 52 weeks.

Reference: KEVZARA [package insert]. Bridgewater, NJ: Sanofi/Regeneron Pharmaceuticals, Inc; 2023.

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Summary

Consider KEVZARA for your formulary

PMR is a debilitating condition and the second-most common inflammatory rheumatic disease after RA¹

EULAR/ACR guidelines strongly recommended GCs as initial treatment for PMR²

GCs are the mainstay of treatment for patients with PMR; however, they may present a challenge for some patients^{1,2}

IL-6 is implicated in the pathogenesis of PMR³

KEVZARA is an IL-6 inhibitor approved for the treatment of PMR

Nearly a third of patients taking KEVZARA achieved sustained remission^{4*}

Patient safety findings were generally consistent with the known safety profile of sarilumab⁴

*Sustained remission was defined as having met all the following parameters: disease remission achieved by week 12, and absence of disease flare from week 12 to week 52, normalization of CRP from week 12 to week 52 and adherence to prednisone taper week 12 to week 52.

References: 1. González-Gay MA, et al. *Lancet*. 2020;(17):31825. 2. Dejaco C, et al. *Ann Rheum Dis*. 2015;74(10):1799-1807. 3. Guggino G, et al. *Reumatismo*. 2018;70(1):10-17. 4. Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p56,114

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Appendix

2012 EULAR/ACR classification criteria for patients with PMR

- Age ≥ 50 years
- Elevated acute-phase reactants
- Bilateral shoulder pain

Scoring Criteria	Score Without Ultrasound	Score With Ultrasound
Duration of morning stiffness >45 minutes	2	2
Hip pain or limited range of motion	1	1
Seronegative for RF and anti-CCP	2	2
Absence of other joint involvement	1	1
≥ 1 shoulder with subdeltoid bursitis and/or biceps tenosynovitis and/or glenohumeral synovitis (either posterior or axillary) and ≥ 1 hip with synovitis and/or trochanteric bursitis	N/A	1
Both shoulders with subdeltoid bursitis, biceps tenosynovitis, or glenohumeral synovitis	N/A	1

A score of ≥ 4 is categorized as PMR in the algorithm without ultrasound, and a score of ≥ 5 is categorized as PMR in the algorithm with ultrasound.

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CCP=cyclic citrullinated peptides; RF=rheumatoid factor.

Reference: Dasgupta B, et al. *Arthritis Rheum.* 2012;64(4):943-954.

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SAPHYR inclusion criteria

- ✓ Diagnosis of PMR according to EULAR/ACR classification criteria
- ✓ Participants must be on prednisone of at least 7.5 mg/day (or equivalent) and not exceeding 20 mg/day at screening and during the screening period
- ✓ Participants were willing and able to take prednisone of 15 mg/day at randomization
- ✓ Participants had a history of being treated for at least 8 weeks with prednisone ≥ 10 mg/day or equivalent
- ✓ Participants must have had at least 1 episode of unequivocal PMR flare while attempting to taper prednisone at a dose that was ≥ 7.5 mg/day or equivalent within the past 12 weeks prior to screening
 - Unequivocal symptoms of PMR flare included shoulder and/or hip girdle pain associated with inflammatory stiffness
- ✓ Participants had ESR ≥ 30 mm/hr and/or CRP ≥ 10 mg/L associated with PMR disease activity within 12 weeks prior to screening

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Reference: ClinicalTrials.gov. Evaluation of the efficacy and safety of sarilumab in patients With polymyalgia rheumatica. Updated June 10, 2022. Accessed July 19, 2022. <https://clinicaltrials.gov/ct2/show/NCT03600818>

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SAPHYR exclusion criteria

- X Diagnosis of giant cell arteritis (eg, persistent or recurrent localized headache, temporal artery or scalp tenderness, jaw claudication, extremity claudication, blurry or loss of vision, symptoms of stroke)
- X Diagnosis of active fibromyalgia
- X Concurrent RA or other inflammatory arthritis or other connective tissue diseases, such as but not limited to systemic lupus erythematosus, systemic sclerosis, vasculitis, myositis, mixed connective tissue disease, and ankylosing spondylitis
- X Concurrent diagnosis of rhabdomyolysis or neuropathic muscular diseases
- X Inadequately treated hypothyroidism
- X Organ transplant recipient
- X Therapeutic failure, including inadequate response or intolerance or contraindication to biological IL-6 antagonist
- X Any prior (within the defined period below) or concurrent use of immunosuppressive therapies but not limited to any of the following:
 - Janus kinase inhibitor within 4 weeks of baseline
 - Alkylating agents including cyclophosphamide within 6 months of baseline
 - Cell-depletion agents (eg, anti CD20) without evidence of recovery of B cells to baseline level
 - TNF inhibitors within 2-8 weeks (etanercept within 2 weeks, infliximab, certolizumab, golimumab, or adalimumab within 8 weeks), or after at least 5 half-lives have elapsed, whichever was longer
 - Abatacept within 8 weeks of baseline
 - Anakinra within 1 week of baseline
 - Cyclosporine, azathioprine or mycophenolate mofetil or leflunomide within 4 weeks of baseline
- X Unstable MTX dose and/or MTX dose >15 mg/week within 3 months of baseline
- X Concurrent use of systemic CS for conditions other than PMR
- X Pregnant or breastfeeding woman
- X Participants with active or untreated latent tuberculosis
- X Participants with history of invasive opportunistic infections
- X Participants with fever associated with infection or chronic, persistent, or recurring infections requiring active treatment
- X Participants with uncontrolled diabetes mellitus
- X Participants with non-healed or healing skin ulcers
- X Participants who received any live, attenuated vaccine within 3 months of baseline
- X Participants who were positive for hepatitis B, hepatitis C, and/or human immunodeficiency virus
- X Participants with a history of active or recurrent herpes zoster
- X Participants with a history of or prior articular or prosthetic joint infection
- X Prior or current history of malignancy
- X Participants who have had surgery within 4 weeks of screening or planned surgery during study
- X Participants with a history of inflammatory bowel disease or severe diverticulitis or previous gastrointestinal perforation

◀ BACK

CS=corticosteroids; RA=rheumatoid arthritis.

Reference: ClinicalTrials.gov. Evaluation of the efficacy and safety of sarilumab in patients With polymyalgia rheumatica. Updated June 10, 2022. Accessed July 19, 2022. <https://clinicaltrials.gov/ct2/show/NCT03600818>

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Sustained remission in the SAPHYR clinical trial was defined as meeting the following 4 criteria¹

1. Disease remission achieved by week 12

Defined as resolution of signs and symptoms of PMR, and normalization of CRP (<10 mg/L)

2. Absence of disease flare from week 12 to week 52

Flare defined as either recurrence of signs and symptoms attributable to active PMR plus an increase in GC dose due to PMR, or elevation of ESR attributable to active PMR plus an increase in GC dose due to PMR

- Increase in GC dose—any dose increases during protocol-defined steroid taper or reinitiation of GC after protocol-defined taper has been completed

3. Normalization of CRP from week 12 to week 52

CRP <10 mg/L, with absence of successive elevations to ≥10 mg/L

4. Adherence to prednisone taper from week 12 to week 52

Given there are no standardized endpoints for PMR, in consultation with the Food and Drug Administration, the primary endpoint, sustained remission, was based on a similar definition used in the GiACTA study.²

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References: 1. Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p58 2. Stone JH, et al. *N Engl J Med*. 2017;377(4):317-328.

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These are the recommended definitions of remission and flare



Remission

Resolution of signs and symptoms of PMR



Flare

Recurrence of signs and symptoms attributable to active PMR plus an increase in corticosteroid dose due to PMR

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Reference: Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p58

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KEVZARA[®]
(sarilumab)

KEVZARA is an IL-6Ri approved for the treatment of PMR^{1,2}

The SAPHYR trial was designed to evaluate the efficacy and safety of KEVZARA in patients with PMR^{1,3}

Enrollment Impact

- SAPHYR enrollment terminated by sponsor in July 2020 due to a combination of protracted recruitment timelines and COVID-19 impact¹
- Enrolled patients were allowed to complete the full study Study enrolled 118 (117 treated) of the intended 280 participants¹
- Protocol amendment changed alpha significance level from <0.01 to <0.05¹

 CLOSE

*Disease remission achieved by week 12; absence of disease flare from week 12 to week 52; normalization of CRP (<10 mg/L) from week 12 to week 52; adherence to prednisone taper from week 12 to week 52.

IL-6Ri=interleukin-6 receptor inhibitor; Q2W=every 2 weeks; R=randomization; y/o=years old.

References: 1. Data on file, Sanofi/Regeneron. SAPHYR CSR. 2022. p18-19,21 2. Data on file, Sarilumab SAPHYR Phase 3 Key Results, Medical Q & A, 2022. 3. ClinicalTrials.gov. Evaluation of the Efficacy and Safety of Sarilumab in Patients With Polymyalgia Rheumatica. Updated June 10, 2022. Accessed July 7, 2022. <https://clinicaltrials.gov/ct2/show/NCT0360081>

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