PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Kevzara Prior Authorization Policy
- Kevzara® (sarilumab subcutaneous injection – Regeneron/Sanofi-Aventis)

REVIEW DATE: 08/03/2022

OVERVIEW
Kevzara, an interleukin-6 receptor inhibitor, is indicated for the treatment of **rheumatoid arthritis** in adults with moderate to severe active disease who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).[1] Kevzara + conventional synthetic DMARD has demonstrated superior efficacy over placebo + conventional synthetic DMARD as assessed by American College of Rheumatology responses, physical function, and radiographic progression.

Guidelines
Guidelines for rheumatoid arthritis from the American College of Rheumatology (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.[2]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Kevzara. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kevzara as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Kevzara to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the approval duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

All reviews for use of Kevzara for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Kevzara is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Rheumatoid Arthritis.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
     - **i.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
       Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of

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biologics used for rheumatoid arthritis. A patient who has already tried a biologic is not required to "step back" and try a conventional synthetic DMARD.

ii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Kevzara. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kevzara is not recommended in the following situations:

1. **Ankylosing Spondylitis.** In a Phase II study, Kevzara did not demonstrate efficacy in patients with ankylosing spondylitis.[3]

2. **Concurrent Use with a Biologic or with a Targeted Synthetic DMARD.** Kevzara should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Kevzara.

3. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.[4-6]
Note: This includes requests for cytokine release syndrome associated with COVID-19.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kevzara® subcutaneous injection [prescribing information]. Bridgewater, NJ: Regeneron/Sanofi-Aventis; April 2018.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123.
3. Sieper J, Braun J, Kay J, et al. Sarilumab for the treatment of ankylosing spondylitis: results of a Phase II, randomised, double-blind, placebo-controlled study (ALIGN). *Ann Rheum Dis*. 2015;74(6):1051-1057.
4. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Updated May 31, 2022. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed August 8, 2022.
5. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2022 August 8]. Available from: https://clinicaltrials.gov/. Search terms: coronavirus, sarilumab.

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6. Rochwerg B, Siemieniuk R, Jacobs M, et al. Therapeutics and COVID-19: living guideline. Updated July 13, 2022. Available at: https://app.magicapp.org/#/guideline/nBkO1E. Accessed on August 8, 2022.

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/21/2021
Selected Revision	**Rheumatoid Arthritis:** Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.	12/01/2021
Annual Revision	No criteria changes.	08/03/2022

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APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.

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