



PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/08/2023

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Kevzara, an interleukin-6 receptor inhibitor, is indicated for the treatment of the following conditions:¹

- **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).
- **Polymyalgia rheumatica**, in adults who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

Guidelines

Kevzara is addressed in the following guidelines:

- **Rheumatoid Arthritis:** Guidelines from the American College of Rheumatology (ACR) [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
- **Polymyalgia Rheumatica:** Guidelines from the European League Against Rheumatism (EULAR)/ACR (2015) were published prior to approval of Kevzara of this condition.⁷ The minimum effective individualized duration of glucocorticosteroid therapy is strongly recommended.

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.

- **Kevzara® (sarilumab subcutaneous injection – Regeneron/Sanofi-Aventis)**
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 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.
- 2. Polymyalgia Rheumatica.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):
- i.** Patient has tried one systemic corticosteroid; AND
Note: An example of a systemic corticosteroid is prednisone.
 - 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)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Kevzara); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.
 - b)** Compared with baseline (prior to initiating Kevzara), patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness; improved range of motion; and/or decreased fatigue.

CONDITIONS NOT COVERED

- **Kevzara® (sarilumab subcutaneous injection – Regeneron/Sanofi-Aventis)** is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 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.

REFERENCES

1. Kevzara® subcutaneous injection [prescribing information]. Bridgewater, NJ: Regeneron/Sanofi-Aventis; February 2023.
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 January 26, 2023. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed March 7, 2023.
5. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 March 7]. Available from: <https://clinicaltrials.gov/>. Search terms: coronavirus, sarilumab.
6. Rochweg B, Siemieniuk R, Jacobs M, et al. Therapeutics and COVID-19: living guideline. Updated January 12, 2023. Available at: <https://app.magicapp.org/#/guideline/nBkO1E>. Accessed on March 7, 2023.
7. DeJaco C, Singh YP, Perel P, et al. 2015 Recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. *Ann Rheum Dis.* 2015;74(10):1799-807.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/03/2022
Early Annual Revision	Polymyalgia Rheumatica: This newly approved condition was added to the policy.	03/08/2023

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Silig™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* 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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