MEDICAL MUTUAL®

Drug Policy

Policy:	**201724**	**Initial Effective Date: 06/22/2017**
Code(s):	**HCPCS J3490, J3590**	**Annual Review Date: 03/16/2023**
SUBJECT:	**Kevzara™ (sarilumab)**	**Last Revised Date: 03/16/2023**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

OVERVIEW

Kevzara for subcutaneous (SC) injection is a recombinant humanized interleukin-6 (IL-6) receptor inhibitor.[1] IL-6 is a pro-inflammatory cytokine that is involved in various physiologic processes. Kevzara has demonstrated efficacy and is indicated for the treatment of rheumatoid arthritis (RA) in adults with moderate to severe active RA who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs).[1-2] Kevzara + conventional synthetic (cs)DMARD has demonstrated superior efficacy over placebo + csDMARD as assessed by American College of Rheumatology (ACR) responses, physical function, and radiographic progression.

POLICY STATEMENT

This policy involves the use of Kevzara. Prior authorization is recommended for pharmacy benefit coverage of Kevzara Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. Kevzara may be subject to step therapy in the Inflammatory Conditions Care Value program.

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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.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Rheumatoid Arthritis (RA), Initial Therapy**
   Criteria. Approve if the following criteria is met (A and B):
   A) Kevzara is prescribed by or in consultation with a rheumatologist; AND
   B) The patient meets one of the following (i or ii):
      i. The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine); OR
      ii. The patient has tried ONE biologic disease-modifying antirheumatic drug (DMARD) for at least 3 months (Refer to Appendix A for examples); OR

2. **Polymyalgia Rheumatica, Initial Therapy**
   Criteria. Approve if the following criteria are met (A and B):
   A) Kevzara is prescribed by or in consultation with a rheumatologist; AND
   B) The patient meets one of the following (i or ii):
      i. The patient has tried and/or failed ONE systemic corticosteroid; OR
      ii. The patient is not a candidate for corticosteroid therapy; OR

3. **Patients Currently Receiving Kevzara.** Approve if the patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kevzara.

   Initial Approval/ Extended Approval.
   A) *Initial Approval:* 6 months
   B) *Extended Approval:* 1 year

Dosing in Rheumatoid Arthritis. *Dosing must meet the following (medical benefit only):*

- The recommended dosage of Kevzara is 200 mg subcutaneously, once every 2 weeks.
  - For RA, Kevzara maybe used as monotherapy or in combination with methotrexate.

Dosing in Rheumatoid Arthritis. *Dosing must meet the following (medical benefit only):*

- The recommended dosage of Kevzara is 200 mg subcutaneously, once every 2 weeks in combination with a tapering course of corticosteroids.
  - Kevzara can be used as monotherapy following the discontinuation of corticosteroids.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Kevzara has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Ankylosing Spondylitis (AS).** In a Phase II study, Kevzara did not demonstrate efficacy in patients with AS.[5]

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 A 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.[6-7] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Actemra IV.

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

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Kevzara™ injection [prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC: February 2023
2. Genovese MC, Fleischmann R, Kivitz AJ, et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a Phase III study. *Arthritis Rheumatol*. 2015;67(6):1424-1437.
3. Fleischmann R, van Adelsberg J, Lin Y, et al. Sarilumab and nonbiologic disease-modifying antirheumatic drugs in patients with active rheumatoid arthritis and inadequate response or intolerance to tumor necrosis factor inhibitors. *Arthritis Rheumatol*. 2017;69(2):277-290.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.

5. 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.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.

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
Siliq™ (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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