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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	June 23, 2017
Subject:	Kevzara	**Page:**	1 of 10

Last Review Date: March 6, 2026

Kevzara

Description

Kevzara (sarilumab)

Background
Kevzara (sarilumab) is subcutaneous injectable treatment form that helps regulate inflammation by binding to a protein (interleukin IL-6) which is involved in inflammatory signaling. Kevzara binds to IL-6, prevents it from binding to its receptor, and inhibits its ability to trigger the inflammatory response (1).

Regulatory Status
FDA-approved indications: Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of (1):

- adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
- patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).

Evaluate patients for tuberculosis infection prior to initiating treatment with Kevzara. Do not administer Kevzara to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Kevzara. Consider anti-tuberculosis therapy prior to initiation of Kevzara in patients with a past history of latent or active tuberculosis in whom an adequate course of

treatment cannot be confirmed. Patients receiving Kevzara should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Kevzara affects the immune system, thus patients may have a greater risk of getting an infection. Serious allergic reactions have been reported with the use of Kevzara. Caution should be exercised when considering the use of Kevzara in patients with a chronic infection or history of recurrent infection, and in patients with active Crohn's Disease (1).

Patients treated with Kevzara should not receive live vaccines (1).

Safety and effectiveness of Kevzara in pediatric patients below the age of 18 with RA or PMR have not been established. Safety and effectiveness of Kevzara in pediatric patients below the age of 2 with pJIA have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kevzara may be considered **medically necessary** if the conditions indicated below are met.

Kevzara may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Moderate to severe active rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drug (DMARD) (see Appendix 2)

c. Inadequate treatment response, intolerance, or contraindication to at least **ONE** biologic or targeted synthetic (DMARD) (see Appendix 2) if adjudicated through the pharmacy benefit
d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Polymyalgia rheumatica (PMR)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to corticosteroids **OR** patient cannot tolerate corticosteroid taper

3. Active polyarticular juvenile idiopathic arthritis (pJIA)
   a. 2 years of age or older
   b. Weight ≥ 63 kg
   c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional (DMARD) (see Appendix 2)
   d. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:
   a. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
   b. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
   c. Absence of active infection (i.e., bacterial, fungal, TB)
   d. **NOT** given concurrently with live vaccines
   e. Documented ALT level less than 5 times upper limit of normal (ULN)
   f. Prescriber agrees to monitor neutrophil count and platelet count prior to initiation and 4 to 8 weeks after start of therapy and every 3 months as clinically indicated

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Polymyalgia rheumatica (PMR)
    a. 18 years of age or older

3. Polyarticular juvenile idiopathic arthritis (pJIA)
    a. 2 years of age or older
    b. Weight ≥ 63 kg
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

a. Condition has improved or stabilized with therapy
b. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
c. **NOT** given concurrently with live vaccines
d. Documented ALT level less than 5 times upper limit of normal (ULN)
e. Prescriber agrees to monitor neutrophil count and platelet count every 3 months as clinically indicated

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 syringes/pens per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 6 syringes/pens per 84 days

Duration 18 months

Rationale

Summary

Kevzara is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, polymyalgia rheumatica, and polyarticular juvenile idiopathic arthritis. Kevzara interacts with IL-6 to regulate inflammation signaling. It is administered as an injection under the skin. It should not be used in combination with other biological DMARDs or targeted synthetic DMARDs. Kevzara may inhibit the immune system and patients should be monitored for infections, including tuberculosis and should not receive live vaccines while on treatment. Safety and effectiveness of Kevzara in pediatric patients below the age of 18 with RA or PMR have not been established. Safety and effectiveness of Kevzara in pediatric patients below the age of 2 with pJIA have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Kevzara while maintaining optimal therapeutic outcomes.

References

1. Kevzara [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; September 2024.

Policy History

Date	Action
June 2017	New addition to PA Addition of ALT requirement
September 2017	Annual review
December 2017	Annual editorial review Addition of prescriber agreeing to monitor neutrophil count and platelet count prior to initiation and 4 to 8 weeks after start of therapy and every 3 months as clinically indicated Addition of the DMARD Appendix
March 2018	Annual editorial review Addition of age limit to renewal section
June 2018	Changed the inadequate response, intolerance, or contraindication to at least one conventional disease-modifying antirheumatic drugs (DMARDs) to inadequate response, intolerance, or contraindication to a 3-month trial of at least one conventional DMARDs Updated Appendix - List of DMARDS and added Appendix - Examples of Contraindications to Methotrexate
September 2018	Annual editorial review and reference update
March 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred product
March 2020	Annual review
December 2020	Annual review. Added Appendix 3 with a list of preferred medications based on diagnosis and plan. Changed initial approval duration to 12 months
April 2021	Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 2 updated.
June 2021	Annual review
June 2022	Annual review
September 2022	Annual review
March 2023	Per PI update, added indication polymyalgia rheumatica
June 2023	Annual review
March 2024	Annual review
June 2024	Per PI update, added pJIA as a non-preferred indication
September 2024	Annual review
March 2025	Annual review and reference update
December 2025	Annual review. Added documentation requirement. Revised Appendix 3
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.

Appendix 1 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix 2 - List of DMARDS

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
infliximab-dyyb	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla

baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 3 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists