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| **Section:** | Prescription Drugs | **Effective Date:** | April 1, 2025 |
| **Subsection:** | Analgesics and Anesthetics | **Original Policy Date:** | June 23, 2017 |
| **Subject:** | Kevzara | **Page:** | 1 of 9 |

***Last Review Date:*** March 7, 2025

# 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:

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

## Prior – Approval *Renewal* Requirements

**Diagnoses**

Patient must have **ONE** of the following:

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

## 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<br>Addition of ALT requirement |
| September 2017 | Annual review |
| December 2017 | Annual editorial review<br>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<br>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<br>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 |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**

**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 |
| 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

| Diagnosis | Standard Option/Basic Option Preferred Products | Blue Focus Preferred Products |
|---|---|---|
| Polyarticular Juvenile Idiopathic Arthritis (PJIA) | *must try **TWO** preferred products:<br>Actemra SC<br>Enbrel<br>Humira**<br>Rinvoq<br>Xeljanz | *must try **ONE** preferred product:<br>Enbrel<br>Humira** |
| Rheumatoid Arthritis (RA) | *must try **TWO** preferred products:<br>Actemra (SC)<br>Enbrel<br>Humira**<br>Rinvoq<br>Xeljanz/XR | *must try **ONE** preferred product:<br>Enbrel<br>Humira** |

**Including all preferred biosimilars (see reference product criteria)