



## 5.70.62

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<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	June 23, 2017
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**Last Review Date:** June 16, 2022

## Kevzara

### Description

#### Kevzara (sarilumab)

#### Background

Kevzara (sarilumab) is subcutaneous injectable treatment form that helps regulate inflammation in people with moderate to severe active rheumatoid arthritis (RA). Kevzara is an antibody that binds to a protein (interleukin IL-6) which is involved in inflammation. Kevzara binds to IL-6, prevents it from binding to its receptor, and inhibits its ability to trigger the inflammatory response that plays a role in the development of rheumatoid arthritis (1).

#### Regulatory Status

FDA-Approved indication: Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs) (1).

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

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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 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** in patients 18 years of age and older with active rheumatoid arthritis (RA) and if the conditions indicated below are met.

Kevzara may be considered **investigational** for patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Moderate to severe active Rheumatoid Arthritis (RA)

**AND ALL** of the following:

1. Inadequate response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 2)
2. Inadequate response, intolerance, or contraindication to at least **ONE** biologic or targeted synthetic disease-modifying antirheumatic drugs (DMARDs) (see Appendix 2) if adjudicated through the pharmacy benefit
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)

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4. 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
5. Absence of active infection (i.e., bacterial, fungal, TB)
6. **NOT** given concurrently with live vaccines
7. Documentation of ALT level less than 5 times upper limit of normal (ULN)
8. 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
9. 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)

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Rheumatoid Arthritis (RA)

**AND ALL** of the following:

1. Condition has improved or stabilized with therapy
2. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
3. **NOT** given concurrently with live vaccines
4. Documentation of ALT level less than 5 times upper limit of normal (ULN)
5. Prescriber agrees to monitor neutrophil count and platelet count every 3 months as clinically indicated
6. 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)

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## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity** 6 syringes per 84 days

**Duration** 12 months

## Prior – Approval *Renewal* Limits

**Quantity** 6 syringes per 84 days

**Duration** 18 months

## Rationale

### Summary

Kevzara is indicated for the treatments of adult patients (18 years or older) with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs). It is administered as an injection under the skin. It should not be used in combination with other biological DMARDs or targeted synthetic DMARDs (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]. Bridgewater, NJ: Sanofi-aventis U.S. LLC.; April 2018.

## Policy History

Date	Action
June 2017	New addition to PA Addition of ALT requirement
September 2017	Annual review

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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

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**

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## Appendix 1 – Examples of Contraindications to Methotrexate

<b>Contraindications to Methotrexate</b>
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

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## 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
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

### Targeted synthetic disease-modifying antirheumatic drugs (DMARDS)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

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## Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Rheumatoid Arthritis (RA)	<b>*must try TWO preferred products:</b> Actemra (SC) ( <b>must try Humira first</b> ) Enbrel Humira Rinvoq Xeljanz/XR	<b>*must try ONE preferred product:</b> Enbrel Humira