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Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	June 23, 2017
Subject:	Kevzara	**Page:**	1 of 9

Last Review Date: June 15, 2023

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 adult patients with (1):

- moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)
- polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper

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 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

Age 18 years of age or older

Diagnosis

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

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

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

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

Age 18 years of age or older

Diagnosis

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

1. Rheumatoid arthritis (RA)
    a. 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)

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 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 treatment of adult patients with moderately to severely active rheumatoid arthritis and polymyalgia rheumatica. 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. The safety and effectiveness of Kevzara in pediatric patients under 18 years of age 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]. Bridgewater, NJ: Sanofi-aventis U.S. LLC.; February 2023.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.

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
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
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
Rheumatoid Arthritis (RA)	*must try **TWO** preferred products: Actemra (SC) (**must try Humira first**) Enbrel Humira Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira