Original Effective Date: 08/01/2018
Current Effective Date: 12/09/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C14653-A

Kevzara (sarilumab)

PRODUCTS AFFECTED

Kevzara (sarilumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid Arthritis, Polymyalgia rheumatica

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests

*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
3. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
5. Prescriber attests that member does NOT have an ANC less than 2000/mm3, platelets less than 150,000/mm3 or liver transaminases above 1.5 times ULN

A. RHEUMATOID ARTHRITIS:

1. Documentation of moderate to severe rheumatoid arthritis diagnosis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
OR
(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months, [this includes patients who have tried other biologic DMARDs for at least 3 months
(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3- month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD)
AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

B. POLYMYALGIA RHEUMATICA:

1. Documented diagnosis of polymyalgia rheumatica (PMR)
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND

3. (a) Documented inadequate treatment response to corticosteroids (e.g., prednisone) after at least 8 weeks of treatment
   OR
   (b) Documentation member is unable to tolerate a corticosteroid taper as evidenced by at least 1 flare while tapering in the previous 12 weeks

CONTINUATION OF THERAPY:

A. RHEUMATOID ARTHRITIS AND POLYMYALGIA RHEUMATICA:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified rheumatologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Maximum of 200 mg once every 2 weeks. Reduce dose to 150 mg once every two weeks for neutropenia, thrombocytopenia, and elevated liver enzymes.

Maximum Quantity Limits – 200 mg every 2 weeks (2.28mL/28 days)

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

DRUG CLASS:
Interleukin-6 Receptor Inhibitors

FDA-APPROVED USES:
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); and indicated for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Kevzara (sarilumab) is an interleukin-6 receptor (IL-6) 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 ant rheumatic drugs.

Kevzara is also approved in polymyalgia rheumatica (PMR) in patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. The efficacy and safety of Kevzara in PMR were assessed in a randomized, double-blind, placebo-controlled, 52-week, multicenter study (Study 3) (NCT03600818) in adults with PMR. Patients had at least one episode of unequivocal PMR flare while attempting to taper corticosteroids. Patients with active PMR were randomized to receive Kevzara 200 mg every two weeks with a pre-defined 14-week taper of prednisone (n= 60) or placebo every two weeks with a pre-defined 52-week taper of prednisone (n=58). Patients experiencing a disease flare or unable to adhere to the assigned prednisone tapering schedule could receive corticosteroids as rescue therapy. The primary endpoint was the proportion of patients with sustained remission at Week 52. An additional endpoint was total cumulative corticosteroid dose over 52 weeks. The proportion of participants achieving sustained remission at Week 52 was higher in the Kevzara arm compared to the placebo arm; this difference was statistically significant. At 52 weeks, a higher proportion of patients in the Kevzara arm achieved each component of the sustained remission endpoint compared to the placebo. The total actual cumulative prednisone equivalent corticosteroid dose was lower in the Kevzara arm (mean [SD] 1039.5 [612.2] mg and median 777 mg) relative to the placebo arm (mean [SD] 2235.8 [839.4] mg and median 2044 mg). American College of Rheumatology 2015 recommendations for the management of polymyalgia rheumatica describe corticosteroids as the mainstay of therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Kevzara (sarilumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Do not initiate if ANC is <2,000/mm3, platelets are <150,000/mm3 or if ALT or AST are >1.5 times ULN. Not to be used in combination with other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitors. Contraindications to Kevzara (sarilumab) include: patients with known hypersensitivity to sarilumab or any of the inactive ingredients, use during an active infection, use with live vaccines.

OTHER SPECIAL CONSIDERATIONS:
Kevzara (sarilumab) has a black boxed warning for risk of serious infections.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Kevzara SOAJ 150MG/1.14ML single-dose prefilled pen
Kevzara SOAJ 200MG/1.14ML single-dose prefilled pen
Kevzara SOSY 150MG/1.14ML single-dose prefilled syringe
Kevzara SOSY 200MG/1.14ML single-dose prefilled syringe

REFERENCES

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-aventis, U.S. LLC/Regeneron Pharmaceuticals, Inc.; 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. June 2015;67(6):1424-37.
3. Strand V, Reaney M, Chen C, et al. Sarilumab improves patient-reported outcomes in rheumatoid arthritis patients with inadequate response/intolerance to tumour necrosis factor inhibitors. RMD Open. 2017; 3:e000416. doi: 10.1136/rmdopen-2016-000416.
4. Fraenkel, L., Bathon, J., England, B., St. Clair, E., Arayssi, T., & Carandang, K. et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 73(7), 924-939. doi: 10.1002/acr.24596
5. Dejaco, C., Singh, Y. P., Perel, P., Hutchings, A., Camellino, D., Mackie, S., . . . Dasgupta, B. (2015). 2015 recommendations for the management of Polymyalgia Rheumatica: A European League against Rheumatism/American College of Rheumatology Collaborative initiative. Arthritis & Rheumatology, 67(10), 2569-2580. doi:10.1002/art.39333

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q2 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file