Original Effective Date: 08/01/2018
Current Effective Date: 12/29/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
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, Polyarticular Juvenile Idiopathic Arthritis

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. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label

AND

2. 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
3. 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 serious side effects 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

C. ACTIVE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA):

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) in a pediatric member
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. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide
AND
4. Member weighs 63kg or more

AND

5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. RHEUMATOID ARTHRITIS, POLYMYALGIA RHEUMATICA, AND POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS:

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. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

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:

RHEUMATOID ARTHRITIS AND POLYMYALGIA RHEUMATICA: 18 years of age and older
JUVENILE IDIOPATHIC ARTHRITIS: 2 years of age and older

QUANTITY:

Maximum of 200 mg once every 2 weeks.
Reduce dose to 150 mg once every two weeks or hold or discontinue per labeled recommendations for neutropenia, thrombocytopenia, and elevated liver enzymes (see Background).
Use only the pre-filled syringe for pediatric patients.

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:

Subcutaneous injection

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; and indicated in patients who weight 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).

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.

Use of Kevzara in pediatric patients with pJIA is supported by evidence from adequate and well-controlled studies of Kevzara in adults with RA, pharmacokinetic data from adult patients with RA, and pharmacokinetic (PK) comparability from Study 4. Supportive efficacy and safety data were provided from Study 4, which was a multicenter, open-label, two-phase study in patients aged 2 to 17 years of age with polyarticular juvenile idiopathic arthritis (pJIA) diagnosed according to American College Rheumatology (ACR) classification criteria who had an inadequate response to current therapy. Kevzara is not approved in pediatric patients weighing less than 63 kg because of the lack of an appropriate dosage form. Dosage in this patient population can be achieved by administering the 200 mg/1.14 mL pre-filled syringe. The pre-filled pen is not intended for use in pediatric patients.

<u>Dosing and Laboratory Monitoring</u>
Discontinue Kevzara in patients with PMR who develop the following laboratory abnormalities: neutropenia (ANC below 1,000 per mm3 at the end of the dosing interval), thrombocytopenia (platelet count below 100,000 per mm3), AST or ALT elevations 3 times above the ULN. Dosage modifications have not been studied in patients with PMR with these conditions.
Dose reduction of Kevzara has not been studied in the pJIA population. Discontinue Kevzara if ALT >5

ULN, platelet count ≤50,000 cells/mm3, neutrophil count 3 to ≤5 ULN, platelet count >50,000 to ≤100,000 cells/mm3, and neutrophil count ≥500 to <1000 cells/mm3, and until the clinical condition has been evaluated. The decision to discontinue Kevzara should be based upon the medical assessment of the individual patient. If appropriate, the dose of concomitant methotrexate and/or other medications should be modified or discontinued.

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, avoid use during an active infection, avoid use with live vaccines.

OTHER SPECIAL CONSIDERATIONS:

Kevzara (sarilumab) has a black boxed warning for risk of serious infections.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

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

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6. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., & Becker, M. et al. (2019). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care & Research, 71(6), 717-734. doi: 10.1002/acr.23870

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update	Q4 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Background References	Q3 2024
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