ALASKA MEDICAID
Prior Authorization Criteria

Kevzara™ (sarilumab)

FDA INDICATIONS AND USAGE[1]

Kevzara™ is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response 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.

APPROVAL CRITERIA[1,2,3,4]

Rheumatoid Arthritis

1. Patient is ≥ 18 years old **AND;**
2. Prescribed by or in consultation with a rheumatologist **AND;**
3. Diagnosis of moderate or severely active rheumatoid arthritis **AND;**
4. Patient has tried and failed at least one conventional DMARD (e.g. methotrexate, hydroxychloroquine, leflunomide, etc.) for at least 90 days **AND;**
5. Patient has tried and failed a TNF blocker (e.g. Humira) for at least 90 days

Polymyalgia Rheumatica

1. Patient is ≥ 18 years old **AND;**
2. Prescribed by or in consultation with a rheumatologist **AND;**
3. Patient has a diagnosis of polymyalgia rheumatica consistent with EULAR/ACR criteria **AND;**
4. Patient has a history of prednisone ≥ 20mg/day (or equivalent) for > 8 weeks **OR;**
5. Patient has experienced ≥ 1 flare while tapering off corticosteroids at a dose of ≥ 7.5mg prednisone/day (or equivalent) within the last 12 weeks

Note: Initial authorization request must include previous therapies trialed and the nature of the failure. Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample from the prescriber at no cost or any form of manufacturer sponsored assistance program shall be required to meet initial authorization criteria as a patient new to therapy.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Prescribed to treat any diagnosis other than RA or PMR. **OR;**
3. Current serious active infection **OR**;
4. Patient is or will be taking Kevzara in combination with another Biologic DMARD or JAK inhibitor **OR;**
5. Baseline Absolute Neutrophil Count (ANC) < 2000/mm3 **OR**;
6. Baseline AST or ALT > 1.5x ULN **OR;**
7. Baseline platelet count <150,000/mm^3

CAUTIONS[1]

- Patients treated with Kevzara are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving Kevzara. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- Patient should be evaluated for tuberculosis, HIV, Hepatitis B and Hepatitis C infection prior to initiating Kevzara treatment.
- Live vaccines should not be administered while patients are receiving Kevzara unless determined that the benefit outweighs the risk.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if:
    - RA: Documented evidence the patient has demonstrated a positive clinical response to treatment in at least one objective measure (e.g. CDAI, SDAI, PAS, etc)
    - PMR: Pt has shown improvement in adherence to corticosteroid taper and a decreased number of flares while on Kevzara

QUANTITY LIMIT

- 200mg (1.14ml) subcutaneously once every 14 days

REFERENCES / FOOTNOTES:

1. Kevzara [package insert]. Sandofi-Aventis U.S. LLC. Bridgewater, NJ February 2023
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2021 Jul;73(7):924-939. doi: 10.1002/acr.24596. Epub 2021 Jun 8. PMID: 34101387; PMCID: PMC9273041.
3. Lundberg IE, Sharma A, Turesson C, et al. An update on polymyalgia rheumatica. J Intern Med. 2022;292(5):717–732.
4. Cimmino MA, Camellino D; Steroid Schedules in PMR. Rheumatology, Volume 53, Issue suppl_2, July 2014, Pages i6–i7
5. Gonzalez-Gay MA, Matteson EL, Castaneda S. Polymyalgia rheumatica. Lancet. 2017;390(10103):1700–1712.