COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Kevzara (sarilumab)**
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Kevzara, approved by the FDA in 2017, is an interleukin-6 (IL-6) receptor antagonist. IL-6 is a pleiotropic proinflammatory cytokine produced by a variety of cell types. Kevzara is 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). It may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs.
In 2023, Kevzara was also approved for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. Approval for this indication was based on the Phase 3 SAPHYR trial. PMR is an inflammatory rheumatic disease.
In 2024, Kevzara was also approved for patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).

Kevzara (sarilumab) will be considered for coverage when the following criteria are met:

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of methotrexate for at least 3 months;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be tried instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has a negative tuberculosis test within the past 12 months or will be tested prior to initiation.
6. **Dosage allowed/Quantity limit:** 200 mg once every two weeks given as a subcutaneous injection. (QL: 2 syringes/pens per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms such as fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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Polymyalgia Rheumatica (PMR)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of PMR; AND
4. Member has tried a corticosteroid for at least 8 weeks and had an inadequate response or could not tolerate corticosteroid taper; AND
5. Member has a negative tuberculosis test within the past 12 months or will be tested prior to initiation.
6. **Dosage allowed/Quantity limit:** 200 mg once every two weeks given as a subcutaneous injection, in combination with a tapering course of systemic corticosteroids.
   (QL: 2 syringes/pens per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of PMR such as resolved signs and symptoms or sustained reduction/discontinuation of corticosteroid, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:

1. Member must be 2 years of age or older and 63 kg or greater; AND
2. Medication is prescribed by or in consultation with a rheumatologist ; AND
3. Member has a documented diagnosis of pJIA; AND
4. Member has had an 8-week trial and failure of a conventional DMARD (ex. methotrexate, leflunomide, etc.); AND
5. Member has a negative tuberculosis test within the past 12 months or will be tested prior to initiation.
6. **Dosage allowed/Quantity limit:** 200 mg once every two weeks given as a subcutaneous injection. *Of note: the pre-filled pen is not recommended for use in pediatric patients*.
   (QL: 2 syringes per 28 days)

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling, decreased pain and improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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CareSource considers Kevzara (sarilumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/20/2017	New policy for Kevzara created.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria. Initial and reauthorization length placed for 12 months. ANC level requirement removed. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.
11/19/2020	Fixed quantity limit from 1 injection to 2 injections every 28 days. Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Removed repeated TB test in reauth. Replaced the list of excluded diagnoses with the generic statement. Updated references.
02/17/2022	Transferred to new template. Updated references. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1.
04/07/2023	Added new indication for PMR.
07/30/2024	Added new indication for pJIA. Updated/added references.

References:

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3. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
4. Genovese MC. Sarilumab Plus Methotrexate in Patients With Active Rheumatoid Arthritis and Inadequate Response to Methotrexate: Results of a Phase III Study. Arthritis Rheumatol. 2015 Jun;67(6):1424-37.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752
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7. Dejaco C, Singh YP, Perel P, et al. 2015 Recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. *Ann Rheum Dis*. 2015;74(10):1799-1807. doi:10.1136/annrheumdis-2015-207492
8. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guidelines for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res (Hoboken).* 2019 Jun;71(6):717-734.
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