Kevzara (sarilumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kevzara (sarilumab)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Kevzara (sarilumab) may be approved for the following:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated individual has had an inadequate response to pr is intolerant of conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

   AND
   E. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.:
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
         OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

   OR
   F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Kevzara (sarilumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      OR
   G. Documentation is provided that individual is unable to use the preferred agents due to demyelinating disease or heart failure with documented left ventricular dysfunction.

   *Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

II. Polymyalgia Rheumatica (PMR) when each of the following criteria are met:
   A. Individual is 18 years of age or older with PMR; **AND**
   B. Individual has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; **AND**
   C. Individual has had at least one episode of unequivocal PMR flare (unequivocal symptoms include shoulder and/or hip girdle pain associated with inflammatory stiffness) while on corticosteroid therapy (NCT03600818); **AND**
   D. Kevzara (sarilumab) is used in combination with a tapering course of corticosteroids; **OR**
   E. Kevzara (sarilumab) is used as a single agent following discontinuation of corticosteroids.

Continuation requests for Kevzara (sarilumab) may be approved if the following criteria are met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Kevzara. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Kevzara (sarilumab) may **not** be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. At initiation of therapy, absolute neutrophil count less than 2000/mm^3, platelet count less than 150,000/mm^3, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal ; **OR**
III. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating of therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention-recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Note:
Kevzara (sarilumab) has a black box warning for risk of serious infections. Individuals treated with Kevzara are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Kevzara should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before sarilumab use and during therapy. Treatment for

latent TB should be initiated prior to use. Risks and benefits of treatment with sarilumab should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection.

Key References:

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 4, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed on: October 13, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023, Updated periodically.
7. Raghu G, Remy-Jardin M, Richeldi, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults. Am J Respir Crit Care Med. 2022;205(9):e18-e47.
8. Ringold S, Angeles-Han ST, Beukelman T, et al. 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 Rheum. 2019; 71(6):846-863.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.