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. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. If methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. 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 agents [Current preferred agents include –preferred adalimumab (Reference product Humira), Enbrel (etanercept), or Simponi (golimumab)]*. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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 is currently on Kevzara (sarilumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR
   G. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:

1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Kevzara (sarilumab); **OR**
2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Kevzara (sarilumab);

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor.

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;

OR

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older weighing at least 63 kg with moderate to severe PJIA; **AND**
   B. Individual has had an inadequate response to, or is intolerant of conventional therapy [nonbiologic DMARDS (such as methotrexate)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate;

   AND

   D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred agents include: preferred adalimumab (Reference product Humira), Enbrel (etanercept)]. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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

   E. Documentation is provided that individual is currently on Kevzara (sarilumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
   OR

F. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
    1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Kevzara (sarilumab); **OR**
    2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Kevzara (sarilumab);

OR

IV. Immunotherapy-related toxicities when each of the following criteria are met (NCCN 2A):
    A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**
    B. Individual is using for one of the following toxicities related immune checkpoint inhibitor therapy:
        1. Giant cell arteritis; **OR**
        2. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs; **OR**
        3. Steroid-refractory polymyalgia rheumatica.

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 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. If initiating therapy, an 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 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.

Key References:

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 12, 2024.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed on: September 23, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024, Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 23, 2024.
    a. Acute Lymphoblastic Leukemia. V2.2024. Revised July 19, 2024.
    b. Castleman Disease. V1.2024. Revised January 18, 2024.
    c. Management of Immunotherapy-related Toxicities. V1.2024. Revised December 7, 2023.
    d. Hematopoietic Cell Transplantation. V2.2024. Revised August 30, 2024.
7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569.
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 policies may take precedence over the application of this clinical criteria.

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