sarilumab (Kevzara®)

Policy # 00589
Original Effective Date: 01/01/2018
Current Effective Date: 11/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Company may consider sarilumab (Kevzara®)‡ for the treatment of patients with moderately to severely active rheumatoid arthritis to be **eligible for coverage.****

Patient Selection Criteria

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

- Patient has a diagnosis of moderately to severely active rheumatoid arthritis; AND
- Patient is 18 years of age or older; AND
- Patient has a negative tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has failed treatment with one or more traditional disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
- Kevzara is NOT given concomitantly with biologic disease modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira®, biosimilars)‡ or etanercept (Enbrel®)‡, or other drugs such as apremilast (Otezla®)‡ or tofacitinib (Xeljanz/XR®)‡; AND

- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, biosimilars), tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq™)‡, or subcutaneous tocilizumab (Actemra®, biosimilar)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

Polymyalgia Rheumatica

Based on review of available data, the Company may consider sarilumab (Kevzara) for the treatment of patients with polymyalgia rheumatica to be **eligible for coverage.****

Patient Selection Criteria

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

Initial

- Patient has a diagnosis of polymyalgia rheumatica; AND
- Patient is 18 years of age or older; AND
- Patient has a negative tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has had an inadequate response to corticosteroids or is unable to tolerate a corticosteroid taper; AND
- Kevzara is NOT given concomitantly with biologic disease modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel), or other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND

Continuation

- Patient has received an initial authorization; AND
- Kevzara is NOT given concomitantly with biologic disease modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) or etanercept (Enbrel), or other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has had a beneficial clinical response to therapy such as stabilization or improvement in clinical signs and symptoms.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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Polyarticular Juvenile Idiopathic Arthritis

Based on review of available data, the Company may consider sarilumab (Kevzara) for the treatment of patients with polyarticular juvenile idiopathic arthritis to be **eligible for coverage.****

Patient Selection Criteria

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

- Patient has a diagnosis of active polyarticular juvenile idiopathic arthritis; AND
- Patient weighs 63 kg or more; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira, biosimilars), etanercept (Enbrel), tofacitinib (Xeljanz), upadacitinib (Rinvoq), or SubQ tocilizumab (Actemra, biosimilar) unless there is clinical evidence or patient history that suggests that these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Requested drug is NOT given concomitantly with biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel), or other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of sarilumab (Kevzara) when the patient has not failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, biosimilars), tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq), or subcutaneous tocilizumab (Actemra, biosimilar) to be **not medically necessary.****

Based on review of available data, the Company considers the continued use of sarilumab (Kevzara) when the patient has not experienced a beneficial clinical response to Kevzara to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of sarilumab (Kevzara) when patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more traditional DMARDs. It is also indicated in adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper and for patients who weigh 63 kg or greater with polyarticular juvenile idiopathic arthritis (pJIA). Kevzara is supplied as 150 mg or 200 mg single dose prefilled syringes/pens. The recommended dosage is 200 mg given subcutaneously once every 2 weeks. For patients with polyarticular juvenile arthritis, only the 200 mg/1.14 ml prefilled syringe is recommended for administration. The prefilled pen is not intended for use in pediatric patients. The dosage should be reduced to 150 mg once every two weeks for the management of neutropenia, thrombocytopenia and elevated liver enzymes in patients with rheumatoid arthritis. Dosage modifications have not been studied in patients with PMR.

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Rheumatoid Arthritis
Rheumatoid Arthritis is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Traditional Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
Traditional DMARDS are typically used for the treatment of rheumatoid arthritis. These drugs slow the disease process by modifying the immune system. Examples include:

- methotrexate
- cyclosporine
- sulfasalazine
- mercaptopurine
- gold compounds

Polymyalgia Rheumatica
Polymyalgia rheumatica (PMR) is an inflammatory rheumatic condition that is often characterized by shoulder, hip girdle, neck, and torso aching and stiffness and can often be associated with giant cell arteritis. It is most common in adults over the age of 50. Glucocorticoids are first line treatment for PMR.

Juvenile Idiopathic Arthritis
Polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis are types of juvenile idiopathic arthritis, a chronic form of arthritis in children. Polyarticular juvenile idiopathic is characterized by inflammation in five or more joints within the first six months of the disease, while in systemic juvenile idiopathic arthritis, many of the signs and symptoms (such as rash and fever) affect the whole body, and not just the joints. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more traditional DMARDs. In February of 2023, Kevzara's indications expanded to include the treatment of polymyalgia rheumatica in adult patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. In June of 2024, Kevzara was approved for patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Kevzara in RA was established in two pivotal studies in patients with active rheumatoid arthritis. In MOBILITY, Kevzara 200 mg every 2 weeks plus methotrexate was significantly better than placebo plus methotrexate as measured by the ACR (American College of Rheumatology) 20 at week 24 (66% vs. 33%). TARGET enrolled adults who had an inadequate response to one or more tumor necrosis factor (TNF) inhibitors. Kevzara every 2 weeks fared better than placebo in ACR 20/50/70 responses (61%/41%/16% vs. 34%/18%/7%).

The efficacy and safety of Kevzara in PMR were assessed in a randomized, double-blind, placebo-controlled, 52-week, multicenter study in adults with PMR diagnosed according to American College of Rheumatology/European Union League against Rheumatism (ACR/EULAR) classification criteria. Patients had at least one episode of unequivocal PMR flare while attempting to taper corticosteroids. In SAPHYR, Kevzara 200 mg every two weeks with a pre defined 14 week taper of prednisone was significantly better than placebo every two weeks with a pre defined 52 week taper of prednisone (28.3% vs. 10.3%).

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Supportive efficacy and safety data of Kevzara in pJIA were provided from 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. This study was divided into a dose range finding portion and a confirmatory portion. 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 the two phase study.

References

1. Kevzara [package insert]. Sanofi-Aventis. Bridgewater, New Jersey. Updated June 2024.
2. Salvarani, Carlo. Murator, Francesco. Clinical manifestations and diagnosis of polymyalgia rheumatica. UpToDate. Accessed October 2023.

Policy History

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12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. New policy.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added Rinvoq as a preferred option for rheumatoid arthritis.
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. Removed Actemra SubQ as a choice prior to Kevzara.
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Added subcutaneous Actemra to the list of products than can be tried and failed prior to use of Kevzara.

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01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. No change to coverage.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Added coverage criteria for new indication, polymyalgia rheumatica. Updated relevant sections.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Added new indication, polyarticular juvenile idiopathic arthritis, to policy with criteria. Updated relevant sections.

Next Scheduled Review Date: 10/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.