



Louisiana

sarilumab (Kevzara™)

Policy # 00589

Original Effective Date: 01/01/2018

Current Effective Date: 01/01/2018

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.*

Based on review of available data, the Company may consider sarilumab (Kevzara®)‡ for the treatment of adult 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 to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs); 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 failed treatment with TWO of the following after at least TWO months of therapy with EACH product: tocilizumab (Actemra®)‡, etanercept (Enbrel), adalimumab (Humira), or tofacitinib (Xeljanz/XR) 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 criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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: tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), or tofacitinib (Xeljanz/XR) to be **not medically necessary****:

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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 DMARDs. Kevzara is supplied as 150 mg or 200 mg single dose prefilled syringes. The recommended dosage is 200 mg given subcutaneously once every 2 weeks. The dosage should be reduced to 150 mg once every two weeks for the management of neutropenia, thrombocytopenia and elevated liver enzymes.

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 DMARDs are used to treat this condition. An example of a DMARD would include methotrexate.

Disease-Modifying Anti-Rheumatic Drugs (DMARDs)

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

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 DMARDs.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield

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Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Kevzara 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%).

References

1. Tremfya [package insert]. Sanofi-Aventis. Bridgewater, New Jersey. Updated 2017.

Policy History

Original Effective Date: 01/01/2018

Current Effective Date: 01/01/2018

12/07/2017 Medical Policy Committee review

12/20/2017 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 12/2018

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

**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.

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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.

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