I. Medication Description

Kevzara (sarilumab) binds to both soluble and membrane-bound interleukin-6 (IL-6) receptors (sIL-6R and mIL-6R), and has been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 is a pleiotropic pro-inflammatory cytokine produced by a variety of cell types including T-cells and B-cells, lymphocytes, monocytes, and fibroblasts. IL-6 has been shown to be involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.

II. Position Statement

Coverage is determined through a prior authorization with supporting clinical documentation for every request.

III. Policy

Coverage of Kevzara is provided for the treatment of rheumatoid arthritis (RA) when the following criteria are met:

- Prescribed by a rheumatologist AND
- Member has moderate to severe active disease AND
- Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) AND
- When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- Coverage will be provided when the member has tried at least TWO of the plan-preferred medications (Actemra, Enbrel, Humira, Xeljanz/XR) first OR when at least ONE of the following criteria have been met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the
medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

• Two 200 mg syringes/pens are covered per 28 days OR
• Two 150 mg syringes/pens are covered per 28 days when reduced dose is needed for management of neutropenia, thrombocytopenia, or elevated liver enzymes.

V. Coverage Duration

Coverage is provided for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed in up to 12 month intervals based upon the following criteria:

• Clinical response and remission of disease is maintained with continued use AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

• Available as:
  o Prefilled syringes (2 syringes per pack):
    ▪ 150 mg/1.14 mL single-dose solution
    ▪ 200 mg/1.14 mL single-dose solution
  o Pre-filled pens (2 pens per pack):
    ▪ 150 mg/1.14 mL single-dose solution
    ▪ 200 mg/1.14 mL single-dose solution

• Pertinent diagnosis:
  o Rheumatoid arthritis: M05.00, M05.30, M05.60, M06.1, M06.9

VIII. Summary of Policy Changes

• 7/1/17: new policy
• 1/1/18: no policy changes
• 6/22/18: updated available products
• 1/15/19: no policy changes
IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.