Humana.

CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Kevzara (sarilumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 200 mg for 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kevzara (sarilumab) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has at least 8 tender and 6 swollen joints at baseline; AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine (pregnancy category B), and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days.
6. **Dosage allowed:** 200 mg once every two weeks given as a subcutaneous injection.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kevzara (sarilumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Adult-onset Still disease
- Ankylosing spondylitis
- Crohn's disease
- Giant cell arteritis
- Neuromyelitis optica
- Polymyalgia rheumatica
- Psoriatic arthritis
- Relapsing polychondritis
- Systemic lupus erythematosus
- Systemic sclerosis-associated myopathy/polyarthritis
- Systemic vasculitis
- Takayasu arteritis
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Uveitis

DATE	ACTION/DESCRIPTION
06/20/2017	New policy for Kevzara created.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria. Initial and reauthorization length placed for 12 months. ANC level requirement removed. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.

References:

1. Kevzara [package insert]. Bridgewater, NJ: SANOFI-AVENTIS U.S. LLC; May 2017.
2. Genovese MC. Sarilumab Plus Methotrexate in Patients With Active Rheumatoid Arthritis and Inadequate Response to Methotrexate: Results of a Phase III Study. Arthritis Rheumatol. 2015 Jun;67(6):1424-37.
3. United States Food and Drug Administration. Kevzara (sarilumab) injection. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761037Orig1s000TOC.cfm. Accessed on 2/13/19.

Effective date: 04/01/2019
Revised date: 02/26/2019