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PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Kineret (anakinra)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz for RA QUANTITY LIMIT— 28 syringes per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kineret (anakinra) is a **non-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.

CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS)

For **initial** authorization:

1. Member must be diagnosed with Neonatal-Onset Multisystem Inflammatory Disease (NOMID); AND
2. Prescriber has submitted laboratory evidence of a genetic mutation in the Cold-Induced Auto-Inflammatory Syndrome 1 (CIAS1—sometimes referred to as the NLRP3); AND
3. Medication must be prescribed by a rheumatologist or under recommendation of a rheumatologist or CAPS specialist; AND
4. 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.
5. **Dosage allowed:** Initial dose: Inject 1-2 mg/kg subcutaneously once daily in 1 or 2 divided doses; adjust dose in 0.5-1 mg/kg increments as needed. Usual maintenance dose: 3-4 mg/kg once daily (maximum of 8 mg/kg per day).

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.

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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 must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine 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; AND
5. Member has tried and failed treatment with at least **two** of the following: Actemra, Enbrel, Cimzia and Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 30 days of therapy with each drug.
6. **Dosage allowed:** Inject 100 mg subcutaneously once daily.

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 Kineret (anakinra) 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:

- Ankylosing Spondylitis
- Anterior cruciate ligament injury
- Diabetes mellitus (type 1 and type 2)
- Familial Mediterranean fever
- Fatigue associated with Sjogren's syndrome
- Gout
- Heart failure (prevention of heart failure after acute MI)
- Inflammatory bowel disease
- Kawasaki disease
- Lupus arthritis
- Myopathy/myositis
- Non-neuropathic hereditary familial amyloidosis
- Osteoarthritis
- Pyoderma gangraenosum
- Reactive arthritis

- Systemic lupus erythematosus

DATE	ACTION/DESCRIPTION
05/15/2017	New policy for Kineret created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira was removed from criteria; Actemra, Cimzia, Kevzara, Olumiant and Xeljanz for RA added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Referenced added.

References:

1. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; May, 2016.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications Vol. 65, No. 10, October 2013, pp 2499–2512.
4. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. Clin Exp Dermatol. 2008;33(1):1-9.
5. Scott IC, et al. A randomised trial evaluating anakinra in early active rheumatoid arthritis. Clin Exp Rheumatol. 2016 Jan-Feb;34(1):88-93.
6. Fleischmann RM, et al. Safety of extended treatment with anakinra in patients with rheumatoid arthritis. Ann Rheum Dis. 2006;65(8):1006-12.
7. Galloway JB, et al. The risk of serious infections in patients receiving anakinra for rheumatoid arthritis: results from the British Society for Rheumatology Biologics Register. Rheumatology (Oxford). 2011 Jul;50(7):1341-2.

Effective date: 04/01/2019
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