Actemra®
Covered Medication

 Tocilizumab injectable (Actemra®)

What it does and how it is used

 Actemra® is an interleukin-6 (IL-6) receptor inhibitor. IL-6 is a proinflammatory cytokine produced by synovial and endothelial cells in joints affected by inflammatory processes like rheumatoid arthritis.

 Actemra is indicated in

  o Adults with moderate to severe RA, for use as monotherapy or in combination with methotrexate or nonbiologic DMARDs, in patients who have had an inadequate response to or have been intolerant to treatment with at least one biological or TNF-antagonist (e.g., Orencia, Rituxan, Remicade, Enbrel, Humira, Kineret, Cimzia, and Simponi).

  o Children > 2 years of age who have been diagnosed with Systemic Idiopathic Juvenile Arthritis (SJIA).

 Rheumatoid arthritis (RA) is a chronic, inflammatory, autoimmune disease that is characterized by progressive destruction of the synovial joints, including loss of cartilage and bone. Cytokines are implicated in each phase of the pathophysiology of RA, from promoting autoimmunity to the initiation of the disease to playing a role in maintaining chronic inflammation and driving tissue destruction of joints.

 Systemic juvenile idiopathic arthritis is a heterogeneous condition which occurs in children. Up to 30% of patients are predicted to still have active disease after 10 years and morbidity within this group is high.

 Actemra is used alone or in combination with methotrexate. Actemra® is not recommended in combination with biological agents (such as TNF antagonists) because of the possibility of increased immunosuppression and increased risk of infection.

 Patients should be closely monitored for the development of signs and symptoms of infection (e.g., tuberculosis, bacterial, invasive fungal, viral, and other opportunistic infections) during and after treatment with Actemra. This includes the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

 The recommended starting dose for rheumatoid arthritis is 4mg/kg infusion every 4 weeks. It can be titrated to clinical response to 8mg/kg (max of 800mg per infusion). Dose modifications are necessary for elevated liver enzymes, neutropenia and thrombocytopenia.

 The recommended starting dose for systemic juvenile idiopathic arthritis (SJIA) is weight based – 12 mg/kg in patients less than 30 kg weight and 8 mg/kg in patients 30 kg of weight or more, every 2 weeks. Dose modifications are recommended for liver enzyme abnormalities, low neutrophil counts, and low platelet counts.

Rationale for coverage authorization

To reduce exposure to cost associated with use when adequate response or tolerance to methotrexate or non-biologic DMARDS, and TNF inhibitors has not been assessed or for conditions in which the effectiveness of Actemra® is not known, or when used in combination with another biologic DMARD agent.

Benefit design

 Coverage is determined through prior authorization for every claim

Coverage authorization criteria

Coverage for Actemra is provided in accord with the following criteria:

1. Coverage is NOT provided for use in COMBINATION with other biological agents or TNF antagonists (e.g., Remicade, Enbrel®, Humira®, Kineret®, Cimzia®, etc)

   AND

2. The prescriber has considered and screened for the presence of latent TB infection

   AND

3. Coverage is provided for the treatment of the following:

    Patient is 16 years of age or older with a diagnosis of moderate to severe rheumatoid arthritis

   AND

    Patient is receiving methotrexate or had a failure, intolerance, or unable to receive methotrexate

   OR

    Patient had a failure, intolerance, or is unable to receive at least 2 nonbiologic DMARDs (eg. hydroxychloroquine, leflunomide, minocycline, or sulfasalazine)

   AND
- Patients had an inadequate response to, is intolerant to, or is unable to receive treatment with at least a two month trial with one TNF-alpha inhibitor (e.g., Remicade®, Enbrel®, Humira®, etc)

OR

4. Patient is 2 years of age or older with a diagnosis of systemic juvenile idiopathic arthritis (SJIA)

Coverage duration: 24 months; coverage may be renewed.

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