DRUG REVIEW:

KEVZARA

Review Date: 07/26/2017

Generic: sarilumab (FDA approved 5/22/2017)

Company: Sanofi and Regeneron

Agent for: rheumatoid arthritis (RA)

Mechanism of Action: Monoclonal antibody that binds to the IL-6 receptor to inhibit IL-6- mediated signaling

Indications: For patients with moderate to severe RA who have had an inadequate or intolerant response to disease-modifying anti-rheumatic drugs (DMARDs).

COMPARABLE DRUG: Targeted immune modulators (TIMs) including inhibitors of Tumor necrosis factor alpha (TNFα), T-cell, IL-6, Janus kinase (JAK), and the CD20-directed cytolytic B-cell antbody.

COST PER MONTH (WAC) FOR RHEUMATOID ARTHRITIS

ACTEMRA 162 MG = $1946
CIMZIA 400 MG = $3987
ENBREL 50 MG = $4812
HUMIRA 40 MG = $4811
INFLECTRA 100 MG = $1892
KEVZARA 200MG = $3250
ORENCIA 125 MG = $4,148
SIMPONI 50 MG = $4150
REMICADE 100 MG = $2336
RITUXAN 100 MG = $2,564
XELJANZ XR 11 MG = $3796

ADVANTAGES:

- May be used as a monotherapy or in combination with other DMARDs. (Kevzara has not been investigated in combination with JAK inhibitors or biological DMARDs).
- Modest evidence supports monotherapy may provide superior health benefit compared to Humira monotherapy
- Can be self administered; training videos are provided online by company.
- Dosage can be modified to decrease risk of adverse events.
- Less expensive than market leaders Humira and Enbrel, but more expensive than other IL-6 target Actemra.

DISADVANTAGES:

- Needs to sit at room temperature (77°F / 25°C) for 30 minutes prior to injection. Cannot be warmed in any other way.
- Patients with active infections should not use Kevzara. Patients need to be tested for TB prior to starting treatment and if positive, must be treated for TB before starting Kevzara.
- Lacks multiple FDA-approved indications

MOST IMPORTANT RISKS/ADVERSE EVENTS: Increased risk of developing serious infections that may lead to hospitalization or death. The most frequently observed infections in studies were pneumonia and cellulitis. Opportunistic infections were also reported.

MOST COMMON ADVERSE EVENTS: Common adverse reasons include a decrease in white blood cell count (neutropenia), elevated liver enzymes (increased ALT), redness near the injection site, upper respiratory infections and urinary tract infections.

USUAL DOSAGE: Recommended dosage is 200 mg once every two weeks. Dosage can be reduced to 150 mg once every two weeks to manage adverse events. It is administered as a subcutaneous injection. Injection sites should be rotated with each injection.

PRODUCT: Product is 150 mg or 200 mg / 1.14 mL sterile, clear to pale yellow solution in a single-dose pre-filled syringe. Should be stored at 36°F to 46°F (2°C to 8°C). Do not shake or freeze.

COMMENTS: Rheumatoid arthritis is an autoimmune disease that causes chronic inflammation in joints and other parts of the body. Symptoms can include joint pain, loss of range in movement, and joint deformity. The cause is unknown and there is no cure, but current treatments involve a combination of rest and exercises, joint protection, and occasionally surgery. Goals of treatment are to put the disease in remission by stopping inflammation, prevent joint damage, and to relieve symptoms. Elevated IL-6 protein levels are believed to be associated with RA by signaling cell receptors to send out signals that lead to inflammation. By

blocking these IL-6 receptors, inflammation signals are blocked, reducing the symptoms of RA. In two studies of adults, patients with inadequate responses to methotrexate or TNF- alpha antagonists were rescued by 200 mg of Kevzara every two weeks after 16 weeks and 12 weeks, respectively.