Kevzara® (sarilumab) – New drug approval

- On May 22, 2017, Regeneron and Sanofi announced the approval and availability of Kevzara (sarilumab) for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

- RA is a chronic autoimmune disease. The immune system attacks the tissues of the joints, causing inflammation, pain, and eventually joint damage and disability. RA affects approximately 1.3 million Americans.

- Kevzara binds to both soluble and membrane-bound interleukin-6 (IL-6) receptors, thereby disrupting the IL-6 mediated inflammatory process.

- The safety and efficacy of Kevzara were based on placebo-controlled trials involving approximately 2,900 adults with moderate-to-severe RA who had an inadequate response to previous treatment regimens. The primary endpoint was the proportion of patients who achieved ≥ 20% improvement in RA signs and symptoms at week 24.

    — In both trials Kevzara plus background DMARDs demonstrated statistically significant, clinically meaningful improvements in RA signs and symptoms vs. placebo.

- Kevzara carries a boxed warning regarding the risk of serious infections.

- Other warnings and precautions of Kevzara include laboratory abnormalities, gastrointestinal perforation, immunosuppression, hypersensitivity reactions, active hepatic disease and hepatic impairment, and live vaccines.

- The most common adverse events (≥ 3%) with Kevzara use were neutropenia, increased alanine transaminase, injection site erythema, upper respiratory tract infections, and urinary tract infections.

- Kevzara may be used as monotherapy or in combination with methotrexate or other conventional DMARDs. The recommended dose of Kevzara is 200 mg by subcutaneous injection every 2 weeks.

    — Kevzara is not recommended in patients with an absolute neutrophil count < 2,000 per mm^3, platelet count < 150,000 per mm^3, or who have liver transaminases above 1.5 times the upper limit of normal.

- Regeneron and Sanofi have launched KevzaraConnect®, a comprehensive and specialized program to provide support services to patients, including assistance to eligible patients who are uninsured, lack coverage, or need assistance with their out-of-pocket copay costs. Additionally, KevzaraConnect offers support from nurses and other specialists, who are available 24/7.

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- Kevzara's wholesale acquisition cost is $39,000 per year.
- Kevzara is now available to U.S. patients. Kevzara is supplied as 150 mg/1.14 mL and 200 mg/1.14 mL solutions in single-dose prefilled syringes.