

## 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  $\geq 20\%$  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 ( $\geq 3\%$ ) 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  $\text{mm}^3$ , platelet count  $< 150,000$  per  $\text{mm}^3$ , 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.

- 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.



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