Kevzara® (sarilumab) – New indication

- On June 11, 2024, Regeneron and Sanofi announced the FDA approval of Kevzara (sarilumab), for treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients who weigh 63 kg or greater.

- Kevzara is also approved for the treatment of adults 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).
    — Polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

- Use of Kevzara in pediatric patients with pJIA is supported by evidence from adequate and well-controlled studies of Kevzara in adults with RA, pharmacokinetic data from adult patients with RA, and pharmacokinetic comparability from study 4. Study 4 was an open-label, two-phase study in patients aged 2 to 17 years of age with pJIA who had an inadequate response to current therapy.

- Kevzara carries a boxed warning for risk of serious infections.

- The most common adverse reactions with Kevzara use for pJIA were nasopharyngitis, neutropenia, upper respiratory tract infection and injection site erythema.

- The recommended dose of Kevzara for the treatment of pJIA is 200 mg once every two weeks given as a subcutaneous injection (maximum dose 200 mg). Dosage in this patient population can be achieved by administering the 200 mg/1.14 mL pre-filled syringe.

    — The pre-filled pen is not intended for use in pediatric patients.
    — Kevzara is not approved in pediatric patients weighing less than 63 kg because of the lack of an appropriate dosage form.

- Refer to the Kevzara drug label for dosing for its other indications.