U.S. FOOD & DRUG ADMINISTRATION

Frequently Asked Questions on the Emergency Use Authorization for Kineret (Anakinra) for Treatment of COVID-19

Q. What is an emergency use authorization (EUA)?

A. Under section 564 of the Federal Food, Drug & Cosmetic Act, after a declaration by the HHS Secretary based on one of four types of determinations, FDA may authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, FDA must determine, among other things, that based on the totality of scientific evidence available to the agency, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits of the product, when used to treat, diagnose or prevent such disease or condition, outweigh the known and potential risks of the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

Q. What does this EUA authorize?

A. This EUA authorizes the emergency use of Kineret injection for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR) (see the response to next question for criteria to identify these patients).

Q. Which patients with COVID-19 were studied?

A. A biomarker test for soluble urokinase plasminogen activator receptor (suPAR) levels was used to optimize the population enrolled in the study used to support authorization. All patients enrolled had a suPAR level ≥ 6 ng/mL at baseline. Since the suPAR test is not available for use in the United States, an alternative set of criteria were developed to identify patients who are likely to have a suPAR level ≥ 6 ng/mL at baseline. Patients who have at least three of the following eight criteria are considered likely to have suPAR ≥ 6 ng/mL at baseline:

- Age ≥ 75 years
- Severe pneumonia by WHO criteria
- Current/previous smoking status
- Sequential Organ Failure Assessment (SOFA) score ≥ 3
- Neutrophil-to-lymphocyte ratio (NLR) ≥ 7
- Hemoglobin ≤ 10.5 g/dL
- Medical history of ischemic stroke
- Blood urea ≥ 50 mg/dL and/or medical history or renal disease

Q: Is Kineret FDA-approved to prevent or treat COVID-19?

A. No, Kineret is not FDA approved to prevent or treat COVID-19. Kineret is FDA approved for treatment of rheumatoid arthritis (RA), cryopyrin-associated periodic syndromes (CAPS), and deficiency of IL-1 receptor antagonist (DIRA).

Q. Are there potential side effects of Kineret?

The most common adverse reactions (incidence ≥ 1%) with use of Kineret are elevated liver enzymes, neutropenia (an abnormally low count of a type of white blood cell), rash, and injection site reactions. Kineret has been associated with an increase of serious infections in patients with rheumatoid arthritis. Kineret is not recommended for use in combination with Tumor Necrosis Factor (TNF) blocking agents. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported. The impact of treatment with Kineret on the development of malignancies is not known. Patients should avoid live vaccines during treatment with Kineret. Neutropenia can occur with treatment with Kineret. Providers should assess neutrophil counts prior to initiating Kineret treatment.

The risk of toxic reactions to this drug may be greater in patients with impaired renal function.

For more information, see the Fact Sheet for Healthcare Providers.

Q. Are there data showing Kineret may provide benefit for treatment of COVID-19 in the authorized patient population?

According to clinical trial data, patients treated with Kineret had lower odds of more severe COVID-19 disease according to the World Health Organization Clinical Progression Scale at day 28 of treatment compared to placebo. Details on the clinical trial results can be found in Section 14 of the authorized Fact Sheet for Healthcare Providers.

Q. Are there certain patients who should not be administered Kineret?

A. Patients with known hypersensitivity to E. coli-derived proteins or any components of the product should not be given Kineret.

Q. Are there reporting requirements for health care facilities and providers as part of the EUA?

A. Yes. As part of the EUA, FDA requires health care providers who prescribe Kineret to report all medication errors and serious adverse events considered to be potentially related to Kineret through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's Fact Sheet for Health Care Providers. FDA MedWatch forms should also be provided to the EUA holder, Swedish Orphan Biovitrum AB (Sobi).

Q. Can health care providers share the patient/caregiver Fact Sheet electronically?

A. Under the authorization, the EUA holder, Sobi, must make available the authorized Fact Sheets on its website at: https://www.KineretRxHCP.com/EUA. Health care facilities and health care providers must

ensure that fact sheets are made available to patients, parents, and caregivers through “appropriate means” and electronic delivery of the Fact Sheet is an appropriate means.