

Anakinra (KINERET) Emergency Use Authorization (EUA) Requirements: November 2022

VA Pharmacy Benefits Management Services

Anakinra (KINERET) (ANA) has been authorized by the FDA Emergency Use Authorization ([EUA](#)) to treat COVID-19 in hospitalized adults requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure and are likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). Use of product under the EUA must be consistent with and may not exceed terms of the Authorization (Section II), including scope of the Authorization and the Conditions of the Authorization (Section IV).

ANA may only be requested for patients when the following criteria and requirements are met:

The answer to ALL of the following questions should be YES for the patient to qualify for treatment with ANA

Q1. The patient has laboratory confirmed <u>COVID-19</u> diagnosis	YES NO
Q2. The patient is hospitalized for treatment of COVID-19 <u>AND</u> is requiring supplemental oxygen (low- or high-flow oxygen)	YES NO
Q3. The patient is at risk for progressing to severe respiratory failure and likely to have an elevated suPAR*	YES NO
Q4. The patient does not have a known hypersensitivity to ANA, <i>E.coli</i> derived proteins or any component of the product	YES NO
Q5. Counseling is provided and documented in the electronic health record as per EUA (This includes: that the provider has communicated with the patient/caregiver information consistent with the “Fact Sheet for Patients and Parents/Caregivers” prior to the patient receiving this EUA product; provider has documented in the medical record that the patient/caregiver has been given the Fact sheet; provider has informed that this product is an unapproved drug for the treatment of COVID-19 and authorized for use under EUA; provider has given information on alternatives and their risks and benefits, and the patient/caregiver has the right to refuse or accept)**	YES NO
Q6. The patient is not receiving TNF blocking agents	YES NO
Q7. The patient has been advised to notify the provider if any ADE occurs AND provider(S) are aware of requirement that ALL adverse events and medication errors (along with any intervention used to treat the event) MUST be recorded per local policy and ALSO placed in VA ADERS (with selection for MedWatch reporting) within 7 calendar days of notification of the event	

**Patients meeting at least 3 of 8 criteria are considered likely to have suPAR levels ≥ 6 ng/mL at baseline: age ≥ 75 years, severe pneumonia by WHO criteria, current/previous smoker, SOFA score ≥ 3 , neutrophil-to-lymphocyte ratio (NLR) ≥ 7 , hemoglobin ≤ 10.5 g/dL, history of ischemic stroke, blood urea ≥ 50 mg/dL and/or history of renal disease*

***If providing the information in the fact sheet for patients, parents and caregivers will delay administration of ANA to a degree that would endanger the life of a patient, the information must be provided to the caregiver as soon as feasible after ANA administration*

Dosing and Administration per the EUA

- Recommended dose of anakinra for COVID-19 in adults is
 - 100mg as a subcutaneous injection daily for 10 days
 - Consider reducing the dose to 100mg every other day in patients with severe renal insufficiency or end-stage renal disease (CrCl < 30 mL/min)

VHA Specific Request Process:

- ANA can be obtained via prime vendor orders. Facilities should order using normal procedures.
- In addition to local approval processes; to remain compliant with requirements from the FDA, facilities interested in treating patients with ANA for COVID-19 **must** submit a patient-specific request on the [PBM EUA portal](#):
 - Facilities that are eligible to provide EUA products must initiate a request that provides:
 - Patient name, last four of SSN and date of birth
 - Confirmation that patient is hospitalized with a positive SARS-CoV-2 viral test (date of test)
 - Confirmation that the patient was provided with the information in the [anakinra EUA Fact Sheet for Patients, parents and caregivers](#), was educated on alternative treatments, and was informed that ANA is not an FDA approved drug for COVID-19 but is authorized for use under an EUA, unless communication will delay administration of ANA to a degree which would endanger the life of the patient, in which case it should be provided to the caregiver as soon as is feasible after administration (which should be documented in the patient record)
- Requests that meet all specified criteria will be automatically approved. After approval is obtained, the site may initiate therapy.
 - Upon completion of therapy, the site must provide additional follow-up information including:
 - Which lots were administered
 - When the package arrived
 - Total number of doses given to the patient: For tracking purposes **one dose is 100mg as a SQ injection.**
 - If and adverse drug events occurred, and if they were documented appropriately
 - Certification that all information above was completed wholly and accurately (sites may choose to begin adding follow-up information before therapy is completed, and the information will not be considered final until certified).
 - ANY Adverse drug events that occur must be documented in accordance with local policy and ALSO placed in the VA ADERS program
 - PBM will assess weekly against other data sources to ensure requests are being documented in a timely manner. Sites that do not complete requests may become ineligible for future EUA allocations
 - Refer to [PBM EUA portal](#) for additional help and any updates or changes.
- Healthcare facilities and healthcare providers must ensure that appropriate storage is maintained until the authorized product is administered consistent with the terms of this letter

Additional information: [ANAKINRA Fact Sheet for Health Care Providers](#)