

Tocilizumab (ACTEMRA) Emergency Use Authorization (EUA)

Requirements: July 2021

VA Pharmacy Benefits Management Services

Tocilizumab (ACTEMRA) (TOCI) has been authorized by the FDA Emergency Use Authorization ([EUA](#)) to treat COVID-19 in hospitalized adults and children who are receiving systemic corticosteroids and require supplemental oxygen non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Tocilizumab is NOT FDA approved for treatment of COVID-19. 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).

TOCI 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 TOCI

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 receiving systemic corticosteroids <u>AND</u> requires supplemental oxygen, non-invasive or invasive mechanical ventilation or ECMO	YES NO
Q3. The patient does not have a known hypersensitivity to TOCI	YES NO
Q4. The dose of tocilizumab to be used is ≤ 800 mg (maximum dose per EUA)	YES NO
Q5. Information consistent with the TOCI fact sheet for patients, parents and caregivers has been communicated to the patient and/or caregivers prior to TOCI administration and it is documented this in the medical record that such communication occurred *	YES NO
Q6. The patient does not have an ongoing, active infection other than COVID-19	YES NO
Q7. The most recent absolute neutrophil count (ANC) is $> 1000/\text{mm}^3$, most recent platelet count is $> 50,000/\text{mm}^3$, most recent AST and ALT are < 10 x the upper limit of normal, and the patient is without active hepatic disease or impairment	YES NO

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

Dosing and Administration per the EUA

- Recommended dose of tocilizumab for COVID-19 in adults is
 - 8 mg/kg as a single intravenous infusion over 60 minutes (maximum dose 800 mg)
 - One additional dose may be administered at least 8 hours after the initial dose if symptoms worsen or do not improve with the first dose

VHA Specific Request Process:

- TOCI can be obtained via prime vendor orders. There is not a unique McKesson item number for this product in the prime vendor catalog, so 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 TOCI 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
 - Confirmation that the patient was provided with the information in the [tocilizumab EUA Fact Sheet for Patients, parents and caregivers](#), was educated on alternative treatments, and was informed that TOCI is not an FDA approved drug for COVID-19 but is authorized for use under an EUA, unless communication will delay administration of TOCI 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
 - Date/time therapy initiated and completed
 - 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
- Once administration has occurred, the following will be tracked by the site
 - Number of doses administered to the patient
 - Date and time of infusion(s), including date and time of a second dose if given
 - Other drugs administered for COVID-19, such as corticosteroids and remdesivir
 - Any adverse events noted (if any occur, these must also be documented in VA ADERS and per local policy)

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