The Medical Letter®

on Drugs and Therapeutics

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COVID-19 Update

Tocilizumab *(Actemra)* FDA-Approved for Treatment of COVID-19

The interleukin-6 (IL-6) receptor antagonist tocilizumab (*Actemra* – Genentech) has been approved by the FDA for IV treatment of COVID-19 in hospitalized adults who are receiving a systemic corticosteroid and require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).[1] Tocilizumab was previously available for this indication under an Emergency Use Authorization (EUA); it remains available under an EUA for treatment of children 2-17 years old who are hospitalized with COVID-19 and require oxygen support.[2]

CLINICAL STUDIES – Issuance of the EUA for tocilizumab was based on the results of four randomized trials (three published; one summarized in the package insert) in a total of 5606 patients who were hospitalized with COVID-19 pneumonia.[3-6] Patients received either tocilizumab or placebo in addition to usual care. In a meta-analysis of these trials examining the subgroup of patients who were receiving corticosteroids at baseline (n=4295), the mortality rate at day 28 was significantly lower with tocilizumab than with placebo (absolute risk reduction 4.6% [95% CI 1.9%-7.3%]); NNT 21.7).[6]

DOSAGE AND ADMINISTRATION – *Actemra* is available in single-dose vials containing 80, 200, or 400 mg of tocilizumab. The recommended dose of tocilizumab for treatment of COVID-19 is 12 mg/kg in patients weighing <30 kg and 8 mg/kg in those weighing ≥30 kg (max dose 800 mg). Tocilizumab should be administered as a single IV infusion over 60 minutes. If clinical status does not improve, a second dose can be administered ≥8 hours after the first.[6] The wholesale acquisition cost of one dose of *Actemra* for a 70-kg patient is $3683.50.[7]

NIH GUIDELINES – The NIH recommends use of either tocilizumab or the oral Janus kinase inhibitor baricitinib *(Olumiant)* in adults hospitalized with COVID-19 who are receiving dexamethasone and have rapidly increasing conventional oxygen needs and systemic inflammation. Dexamethasone plus either tocilizumab or baricitinib is also recommended for those who require high-flow nasal cannula oxygen, ventilation, or ECMO.[8] ■

1. FDA News Release. FDA roundup: December 23, 2022. Available at: https://bit.ly/3CAn6X1. Accessed January 9, 2023.
2. An EUA for tocilizumab (Actemra) for COVID-19. Med Lett Drugs Ther 2021; 63:113.
3. RECOVERY Collaborative Group. Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. Lancet 2021; 397:1637.
4. C Salama et al. Tocilizumab in patients hospitalized with Covid-19 pneumonia. N Engl J Med 2021; 384:20.
5. IO Rosas et al. Tocilizumab in hospitalized patients with severe Covid-19 pneumonia. N Engl J Med 2021; 384:1503.
6. FDA. Fact sheet for health care providers: Emergency Use Authorization for Actemra (tocilizumab). December 21, 2022. Available at: https://bit.ly/360BR4Q. Accessed January 9, 2023.
7. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. January 5, 2023. Reprinted with permission by First Databank, Inc. All rights reserved. ©2023. www.fdbhealth.com/drug-pricing-policy.
8. NIH. COVID-19 treatment guidelines. Therapeutic management of hospitalized adults with COVID-19. August 8, 2022. Available at: https://bit.ly/3DfsFsJ. Accessed January 9, 2023.

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