

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

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Article

IN THIS ISSUE

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

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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).<sup>1</sup> 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.<sup>2</sup>

**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.<sup>3-6</sup> 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).<sup>6</sup>

**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.<sup>6</sup> The wholesale acquisition cost of one dose of *Actemra* for a 70-kg patient is \$3683.50.<sup>7</sup>

**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.<sup>8</sup> ■

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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](http://www.fdbhealth.com/drug-pricing-policy).
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