2025 Clinical Practice Guideline Update by the Infectious Diseases Society of America on the Treatment and Management of COVID-19: Baricitinib vs. Tocilizumab

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ABSTRACT. This article provides a focused update to the clinical practice guideline on the treatment and management of patients with COVID-19, developed by the Infectious Diseases Society of America. The guideline panel presents a new recommendation on the use of baricitinib vs. tocilizumab in hospitalized adults

with severe or critical COVID-19. The panel has previously issued recommendations on baricitinib vs. no baricitinib and tocilizumab vs. no tocilizumab, but this new recommendation compares baricitinib to tocilizumab when the decision has been made to give one or the other. The new recommendation does not address combinations of multiple immunomodulatory agents (i.e., baricitinib, tocilizumab, abatacept, infliximab). The recommendation is based on evidence derived from a systematic literature review and adheres to a standardized methodology for rating the certainty of evidence and strength of recommendation according to the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach.

Keywords. COVID-19; SARS-CoV-2; baricitinib; tocilizumab; guideline

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In patients hospitalized with severe or critical COVID-19 who require an additional immunomodulator in addition to systemic corticosteroids, which immunomodulator is more effective-- baricitinib or tocilizumab?

Recommendation: In hospitalized adults receiving systemic glucocorticoids who are experiencing rapidly progressing severe COVID-19* or critical COVID-19**, the IDSA guideline panel suggests the addition of *either* baricitinib or tocilizumab *(conditional recommendation, low certainty of evidence)*.

*Rapidly progressing severe COVID-19 is defined as patients with SpO_2 ≤94% on room air, including patients on supplemental oxygen who are worsening despite treatment with systemic glucocorticoids.

**Critical COVID-19 is defined as patients requiring high-flow nasal cannula oxygen/non-invasive ventilation or invasive mechanical ventilation or ECMO.

BACKGROUND

COVID-19–associated hypoxemic respiratory failure can be associated with heightened cytokine release, as indicated by elevated levels of IL-6 and other inflammatory cytokines. Thus, various immunomodulators have been considered as potential options for treating severe and critical COVID-19–related cytokine storm [1-3]. Specifically, baricitinib and tocilizumab are immunomodulatory agents used to mitigate the hyperinflammatory response in severe and critical COVID-19. Baricitinib is a Janus kinase (JAK) inhibitor that interferes with intracellular signaling pathways involved in immune activation and inflammation in COVID-19. Tocilizumab is an interleukin-6 (IL-6) receptor antagonist that reduces inflammation by blocking the activity of IL-6, a key driver of the inflammatory cascade in COVID-19.

The FDA granted approval for baricitinib in May 2022 and for tocilizumab in December 2022 for the treatment of COVID-19 in hospitalized adults who require supplemental oxygen, noninvasive ventilation (NIV), mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Baricitinib and tocilizumab are each authorized for treatment of COVID-19 in hospitalized pediatric patients 2 to <18 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. However, the focus of the panel's recommendation is use in adults.

METHODS

The panel's recommendation is based upon a systematic review of available evidence and adheres to a standardized methodology for rating the certainty of evidence and strength of recommendation according to the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach (Supplementary Figure 1) [4]. The recommendation has been endorsed by the Society of Infectious Diseases Pharmacists, and the Society of Critical Care Medicine.

Strong recommendations are made when the recommended course of action would apply to most people with few exceptions. Conditional recommendations are made when the suggested course of action would apply to the majority of people with many exceptions and shared decision making is important.

A literature search was conducted in February 2025 as part of a systematic review. Key eligibility criteria at both the topic and clinical question levels guided the selection of studies for inclusion. For this

clinical question, only hospitalized adults were included. The primary comparison of interest was baricitinib versus tocilizumab.

A critical appraisal of the evidence according to the GRADE approach, along with an assessment of the benefits and harms of care options, informed the recommendation(s) [4,5]. Details of the systematic review and guideline development processes are available in the Supplementary Material.

SUMMARY OF EVIDENCE

The literature search identified 1 RCT and 12 non-randomized studies (NRS) that evaluated hospitalized patients with severe or critical COVID-19 receiving systemic corticosteroids and treated with either baricitinib or tocilizumab (Supplementary Table 1) [6-18]. The RCT randomized 251 severe or critically ill patients to receive either baricitinib (4 mg/day orally or 2 mg/day for patients with renal impairment) or tocilizumab (8 mg/kg IV, with the potential for a second dose within 48 hours), along with other treatments such as dexamethasone and antivirals [7]. The RCT reported on the outcomes of 28-day mortality, need for mechanical ventilation, and adverse events (e.g., lobar consolidation, cardiac events, major bleeding, septic shock, thrombocytosis, increased creatine kinase, and elevated serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) values).

The search identified 12 cohort studies with sample sizes ranging from 98 to 10,000 comparing patients treated with baricitinib or tocilizumab for severe or critical COVID-19. Baricitinib was typically administered orally at 4 mg/day (adjusted for renal function) for up to 14 days, while tocilizumab was commonly given as a single IV dose of 8 mg/kg, with some studies allowing a second dose. These studies reported on the following outcomes: mortality, need for mechanical ventilation, need for ECMO, and severe adverse events (thrombotic events) (Table 1).

Table 1. GRADE Evidence Profile: In patients hospitalized with severe or critical COVID-19, in addition to systemic corticosteroids, would adding baricitinib vs. tocilizumab lead to better outcomes (e.g., serious adverse events, progression to non-invasive ventilation or invasive ventilation or ECMO, death)?

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Baricitinib	Tocilizumab	Relative (95% CI)	Absolute (95% CI)		
Mortality (RCT) (follow-up: 28 days)												
1[7]	randomized trials	not serious[a]	not serious	not serious	very serious[b,c]	none	40/125 (32.0%)	50/126 (39.7%)	**HR 0.73** (0.49 to 1.09)	**88 fewer per 1,000** (from 177 fewer to 27 more)	⊕⊕◯◯ Low	CRITICAL
Mortality (NRS)												
12[6,8-18]	non-randomized studies	serious[d]	not serious[e]	not serious	very serious[b]	none	1444/5297 (27.3%)	1312/4362 (30.1%)	**RR 0.97** (0.85 to 1.10)	**9 fewer per 1,000** (from 45 fewer to 30 more)	⊕◯◯◯ Very low	CRITICAL
Progression to mechanical ventilation (RCT) (follow-up: 28 days)												
1[7]	randomized trials	not serious	not serious	not serious	very serious[b,c]	none	47/125 (37.6%)	54/126 (42.9%)	**RR 0.88** (0.65 to 1.19)	**51 fewer per 1,000** (from 150 fewer to 81 more)	⊕⊕◯◯ Low	CRITICAL
Progression to mechanical ventilation (NRS)												
6[6,8,10,12,13,17]	non-randomized studies	very serious[d]	not serious[g]	not serious[h]	not serious	none	318/1389 (22.9%)	239/819 (29.2%)	**RR 0.72** (0.58 to 0.90)	**82 fewer per 1,000** (from 123 fewer to 29 fewer)	⊕⊕◯◯ Low	CRITICAL
Progression to ECMO (NRS)												

1[12]	non-randomized studies	serious[i]	not serious	serious[h]	very serious[b,c]	none	69/291 (23.7%)	71/291 (24.4%)	**RR 0.97** (0.73 to 1.30)	**7 fewer per 1,000** (from 66 fewer to 73 more)	⊕◯◯◯ Very low	CRITICAL

Serious adverse events (RCT) (follow-up: 28 days; assessed with: cardiac event, major bleed, septic shock, thrombocytosis, lobar consolidation)

1[7]	randomized trials	not serious[a]	not serious	not serious	very serious[b,c]	none	25/125 (20.0%)	33/126 (26.2%)	**RR 0.76** (0.48 to 1.21)	**63 fewer per 1,000** (from 136 fewer to 55 more)	⊕⊕◯◯ Low	CRITICAL

Serious adverse events (NRS) (assessed with: thrombotic events)

6[8,12-16]	non-randomized studies	serious[d]	not serious	not serious	serious[c,j]	none	111/1294 (8.6%)	147/1231 (11.9%)	**RR 0.73** (0.57 to 0.93)	**32 fewer per 1,000** (from 51 fewer to 8 fewer)	⊕⊕◯◯ Low	CRITICAL

CI: confidence interval; **HR:** hazard ratio; **NRS:** non-randomized studies; **RR:** risk ratio

Explanations

a. Open-label trial. Appropriate randomization process reported; therefore, likely not a serious concern for the outcomes of mortality or adverse events.
b. 95% CI cannot exclude the potential for both meaningful benefit or harm.
c. Few events suggest fragility of the estimate.
d. Majority of studies at Serious or Critical risk of bias due to uncontrolled confounders. However, consistent with studies at Low or Moderate risk of bias due to controlling for critical confounders.
e. Some heterogeneity introduced by Patanwala 2024 as subgroups for NIV and MV were entered separately into the analysis.
f. Critical risk of bias due to uncontrolled confounders.
g. In meta-analysis, I^2 quantifies the percentage of variation in study results due to heterogeneity. When including Peterson 2023 (combined outcome MV and ECMO) I^2=55%; when removed, I^2=15%
h. Peterson 2023 reports on a combined outcome of progression to MV or ECMO.
i. Moderate risk of bias due to uncontrolled confounders.
j. 95% CI cannot exclude no meaningful difference.

BENEFITS

Based on results from the RCT, baricitinib was associated with a lower point estimate of 28-day mortality compared to tocilizumab in hospitalized patients with severe or critical COVID-19 receiving systemic corticosteroids (RCT HR: 0.73, 95% CI: 0.49 to 1.09, low certainty of evidence). However, the confidence interval includes the possibility of no effect, and the certainty of evidence is low; therefore, one cannot determine with confidence whether one treatment is superior to the other. The pooled results from NRS suggest no meaningful difference on mortality between the two treatments; however, the evidence is very uncertain due to concerns with risk of bias and imprecision (NRS RR: 0.97, 95% CI: 0.85 to 1.10, very low certainty of evidence; Supplementary Figure 2).

Baricitinib may reduce the risk of progression to mechanical ventilation compared to tocilizumab among hospitalized patients with severe or critical COVID-19; however, this estimate cannot exclude the potential for no meaningful difference between treatments (RCT RR: 0.88, 95% CI: 0.65 to 1.19, low certainty of evidence; and NRS RR: 0.72, 95% CI: 0.58 to 0.90, low certainty of evidence; Supplementary Figure 3). The certainty of evidence was low due to concerns with imprecision in the single RCT, and risk of bias in the pooled NRS. Baricitinib may result in no difference in progression to ECMO compared to tocilizumab, but the evidence is very uncertain due to concerns with risk of bias, indirectness and imprecision (NRS RR: 0.97, 95% CI: 0.73 to 1.30, very low certainty of evidence).

HARMS

Patients receiving baricitinib may have a trend towards fewer serious adverse events (cardiac events, major bleeding, septic shock, thrombocytosis, lobar consolidation, and thrombotic events) compared to patients receiving tocilizumab (RCT RR: 0.76, 95% CI: 0.48 to 1.21, low certainty of evidence; and NRS RR: 0.73, 95% CI: 0.57 to 0.93, low certainty of evidence; Supplementary Figure 4).

OTHER CONSIDERATIONS

The panel agreed that the overall certainty of evidence comparing baricitinib and tocilizumab in hospitalized patients with severe or critical COVID-19 receiving systemic corticosteroids is low due to

concerns about risk of bias (Supplementary Tables 2a-d) and imprecision, specifically regarding estimates that crossed clinical thresholds and the occurrence of few events. Based on current evidence, the panel made a conditional recommendation for adding either baricitinib or tocilizumab to systemic corticosteroids in hospitalized patients with severe or critical COVID-19 who require an additional immunomodulator. Baricitinib is available as an oral tablet and tocilizumab is available as an IV infusion or subcutaneous injection. For patients unable to swallow pills, baricitinib can be dissolved in room temperature water and administered orally or via enteral tube. The recommended dosage for baricitinib in adults with an eGFR ≥60 mL/min is 4 mg orally once daily, with or without food, for 14 days or until hospital discharge, whichever occurs first. The recommended dosage for tocilizumab is 8 mg/kg (not to exceed 800 mg) as a single 60-minute IV infusion. If signs or symptoms worsen or do not improve after the first dose, an additional dose may be administered at least 8 hours after the initial dose. Further information on dosing and drug interactions is available in the package inserts, including for patients with renal or hepatic impairment [19,20]. Differences in the route of administration or treatment duration may influence treatment decisions (e.g., patients without enteral access may preferentially receive tocilizumab).

CONCLUSIONS AND RESEARCH NEEDS

The guideline panel suggests that either baricitinib or tocilizumab may be used in addition to systemic corticosteroids in hospitalized patients with severe or critical COVID-19 who require an additional immunomodulator.

Future well-designed RCTs directly comparing baricitinib and tocilizumab are needed to understand if there is a meaningful difference between these two treatments. In patients already receiving systemic corticosteroids, an important knowledge gap is whether a combination of two or more immunomodulatory agents (i.e., baricitinib, tocilizumab, abatacept, infliximab) offers additional mortality or recovery benefits.

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Drs. Adarsh Bhimraj and Rajesh T. Gandhi are chair and vice chair of the panel, respectively. The Hospitalized Patients subgroup, under the leadership of Dr. Nandita Nadig, led the development of the recommendation. Remaining panelists assisted with interpretation of data, as well as drafting, revising, and approving the recommendation and manuscript. Drs. Rebecca Morgan, lead methodologist, and Yngve Falck-Ytter, methodologist, were responsible for designing and performing the data analyses and leading the panel according to the GRADE process. Jennifer Loveless, methodologist, was responsible for project planning and management, including revisions to and final approval of the recommendation and manuscript.

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Additional Information: More detailed information on the analysis and development of the recommendation is available in the Supplementary Material.

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