

## Immunomodulator Criteria for Use (Tocilizumab, Baricitinib, and Tofacitinib)

**COVID-19 Acute Respiratory Distress Syndrome (ARDS).** COVID-19 ARDS is associated with systemic inflammation and elevated inflammatory biomarkers (e.g., C-reactive protein [CRP], ferritin, D-dimer).

**Immunomodulation in COVID-19 ARDS.** In response to the mortality benefit demonstrated in the RECOVERY trial, glucocorticoid steroids are recommended for all hospitalized COVID-19 patients requiring supplemental oxygen. Given the available evidence, tocilizumab or baricitinib may potentially be used in addition to steroids in certain patients with COVID-19 ARDS. See [BWH covidprotocols](#) for a discussion of the RCT literature.

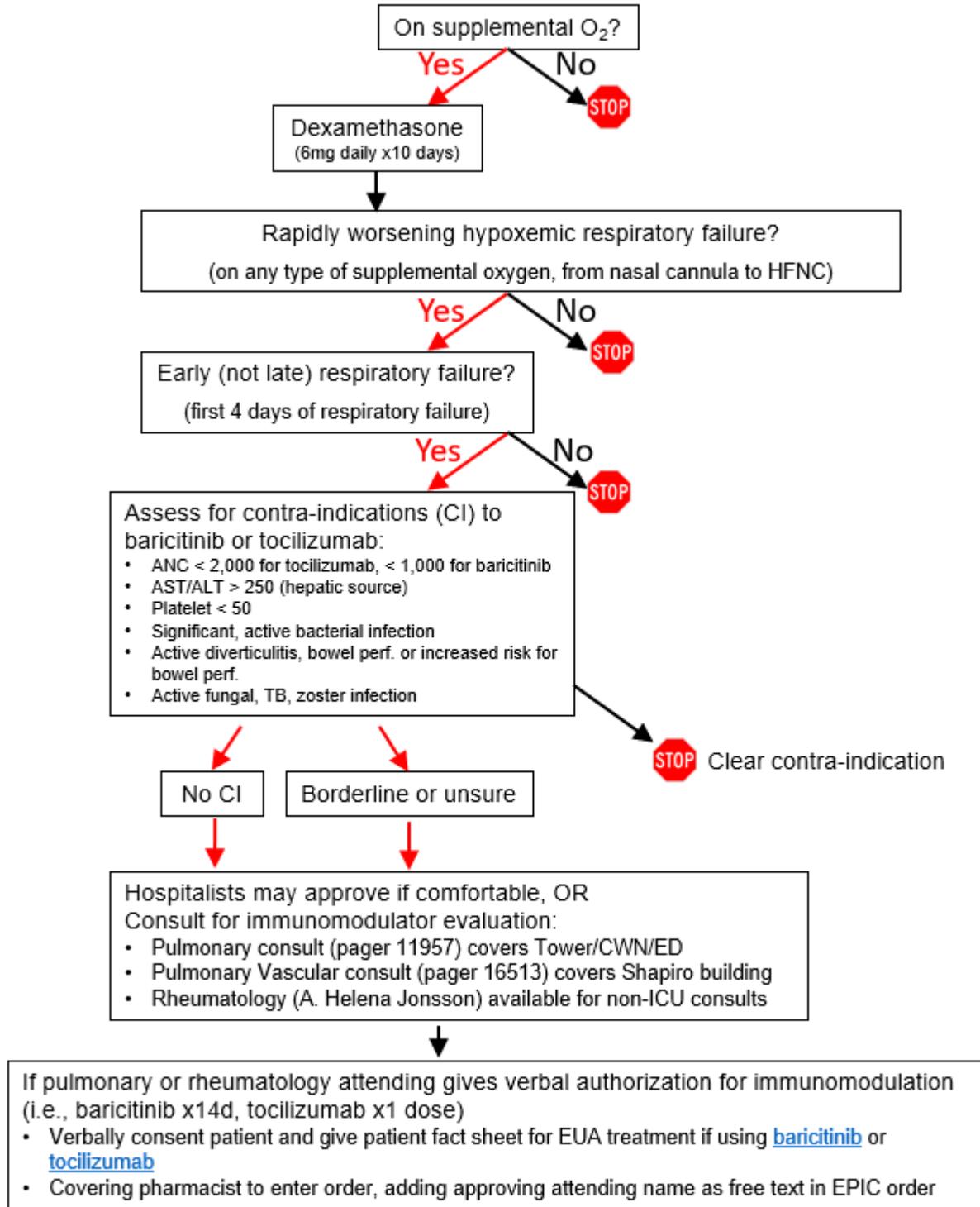
### **Tocilizumab or baricitinib (+ steroids) may be considered in select patients with multidisciplinary discussion**

\*if tocilizumab and baricitinib are unavailable, tofacitinib may be considered instead\*

- **Must meet ALL criteria and none of the absolute contraindications below:**

1. Approval by pulmonary, rheumatology, OR hospitalist attending
2. COVID-19: Confirmed SARS-CoV-2 infection
3. C-reactive protein (CRP) > 75 (tocilizumab only)
4. Early in acute hypoxemic respiratory failure due to COVID-19: Within 4 days of *initial* hospital admission for acute hypoxemic respiratory failure due to COVID-19; or within 4 days of developing acute hypoxemic respiratory failure if initially admitted for an unrelated diagnosis
  - a. Example of a patient who meets this criterion: A patient is admitted for a gastrointestinal hemorrhage and incidentally found to be SARS-CoV-2 positive. On hospital day 7 the patient develops acute hypoxemic respiratory failure attributed to COVID-19. While past hospital day 4, the patient is physiologically similar to patients early in their inpatient admission for respiratory failure due to COVID-19 and thus WOULD meet criterion for tocilizumab or baricitinib
  - b. Example of a patient who does **not** meet this criterion: A patient transferred to ICU from floor on hospital day 7 of an admission for acute respiratory failure due to COVID-19 would NOT meet this criterion. In addition, a patient with a recent admission for acute respiratory failure due to COVID-19 and now readmitted with worsening respiratory failure more than 4 days after their prior admission would NOT meet this criterion
  - c. This early administration is driven by RCT and observational data. Further, respiratory decompensation later in the hospital course has a higher likelihood of involving super-infection, thrombosis, or have other causes not directly relating to inflammation due to SARS-CoV-2
5. Critical or rapidly progressing hypoxemic respiratory failure (must meet 1 of 2 criteria below):
  - a. ICU admission specifically for ARDS
    - i. Patients would NOT meet this criterion if admitted to ICU for asthma exacerbation without severe hypoxemia or for non-respiratory issues (e.g., GI bleed or stroke)
  - b. Requirement for HFNC or NRB (regardless if patient is in ICU or on non-ICU floor).
    - i. The pulmonary or rheumatology attending can use their judgement and recommend tocilizumab or baricitinib for patients with rapidly progressing acute hypoxemic respiratory failure due to COVID-19 who are not yet on sustained HFNC or NRB
6. EUA fact sheet provided to patient or health care proxy & verbal consent obtained (tocilizumab & baricitinib only)

- **Absolute contraindications to tocilizumab and baricitinib**
  1. Neutropenia with ANC < 2,000 with tocilizumab, <1,000 with baricitinib
  2. Transaminitis with AST or ALT > 250 from presumed hepatic source
  3. Thrombocytopenia with platelet count < 50
  4. Significant active bacterial super-infection
  5. Active diverticulitis, bowel perforation, or at increased risk for bowel perforation
  6. Active fungal infection, active TB infection, or active zoster
- **Relative contraindications**
  1. Immunocompromised or on immunosuppressive agents (the consultative services [noted below](#) can help with determining whether the degree of immunocompromise or a particular immunosuppressive medication is a contraindication)
  2. Significant history of large intestinal disease, such as recent (<1 year) instance of severe diverticulitis, bowel perforation, major bowel surgery
  3. Patients with Crohn's disease can be considered for tocilizumab or baricitinib, but GI consultation and discussion is required prior to its administration



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