IL-6 Inhibitor COVID Treatment Allocation Plan

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11:30 AM

IL-6 inhibitors are indicated for the treatment of moderate to severe rheumatoid arthritis, giant cell arteritis, and an important off-label indication for the treatment of cytokine release syndrome in CAR-T patients. There is a growing body of evidence that IL-6 inhibitors likely provide a small mortality benefit in moderate to severely ill COVID patients. Currently we are experiencing a nationwide shortage of the IL-6 inhibitors tocilizumab and sarilumab. NM facilities have been unable to meet the increasing demand for these agents. In an attempt to ensure equitable access for patients who are most likely to benefit from IL-6 therapy, a subgroup of the NM Allocation Decision Making Team met to develop a protocol for access. The protocol for COVID patients is presented below:

IL-6 inhibitors for Rheumatology patients

- Doses for patients currently receiving tocilizumab for rheumatoid arthritis and giant cell arteritis will continue to be allocated
- A small supply will be maintained for newly identified giant cell arteritis patients to initiate tocilizumab treatment
- All other patients will be directed to SQ tocilizumab or alternative therapies as indicated

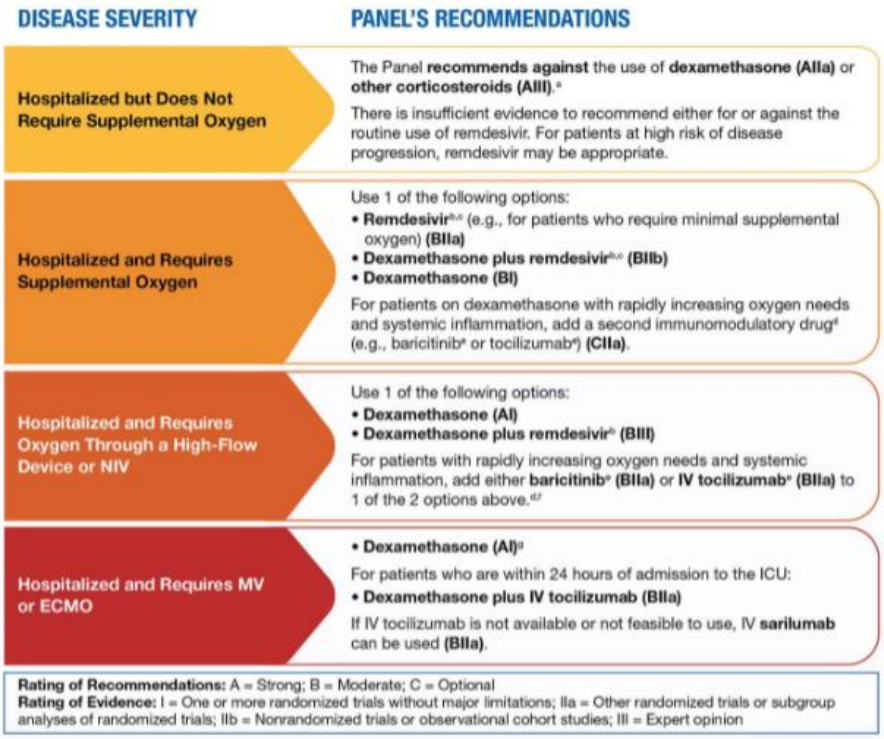
The use of IL-6 inhibitors for the treatment of COVID will be limited to the following patients:

- On mechanical ventilation
- Patient within 24 hours of admission to ICU
- Platelets > 50,000 (> 150,000 for sarilumab)
- AST/ALT < 10x ULN (< 1.5x ULN for sarilumab)
- ANC > 1000
- CRP >75

For patients on dexamethasone with rapidly increasing oxygen needs and systemic inflammation who are not on mechanical ventilation, baricitinib is available. The latest version of the NIH COVID Treatment guidelines state ***"There are no studies directly comparing baricitinib and tocilizumab and there is insufficient evidence to recommend one over the other. "***

See the updated NIH COVID Treatment Guidelines below:

Figure 2. Therapeutic Management of Hospitalized Adults With COVID-19 Based on Disease Severity



[a] Corticosteroids prescribed for an underlying condition should be continued.
[b] If the patient progresses to requiring high-flow oxygen, NIV, MV, or ECMO, complete the full course of remdesivir (refer to Table A).
[c] Evidence suggests that the benefit of remdesivir is greatest when the drug is given early in the course of COVID-19 (e.g., within 10 days of symptom onset). Clinical trials have not demonstrated a mortality benefit for remdesivir, but a large placebo-controlled trial showed that remdesivir reduced time to clinical recovery in hospitalized patients. See Rationale for the Use of Remdesivir below.
[d] Drugs are listed alphabetically. There are no studies directly comparing baricitinib and tocilizumab, and there is insufficient evidence to recommend 1 drug or 1 class of drug (i.e., JAK inhibitors, anti-IL-6 receptor mAbs) over the other. Treatment decisions should be based on local guidance, drug availability, and patient comorbidities.
[e] If baricitinib and IV tocilizumab are not available or not feasible to use, **tofacitinib** can be used instead of baricitinib **(BIIa)** and **IV sarilumab** can be used instead of IV tocilizumab **(BIIa)**.
[f] The Panel **recommends against** the use of **baricitinib** in combination with **tocilizumab** for the treatment of COVID-19, except in a clinical trial **(AIII)**. Because both baricitinib and tocilizumab are potent immunosuppressants, there is the potential for an additive risk of infection.
[g] The combination of **dexamethasone plus remdesivir** may be considered for patients who have recently been intubated **(CIII)**. The Panel **recommends against** the use of **remdesivir** monotherapy in these patients **(AIIa)**.

Key: ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IL = interleukin; IV = intravenous; JAK = Janus kinase; mAb = monoclonal antibody; MV = mechanical ventilation; NIV = noninvasive ventilation; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally

https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/