

ALL INDIA INSITITUTE OF MEDICAL SCIENCES RISHIKESH

Patient name: UHID: Admitted location:

Hospital Treatment Policy – "Tocilizumab" Information Sheet

(10.04.21 onwards)

Method of how to get the drug

While choosing any experimental therapy (CP, IFN, Tocilizumab, Remdesivir, etc) for any patient as per shared guidance flow chart, once treating faculty/SR decides the drug to be indented from sub-pharmacy/blood bank at own area, treating faculty/SR has to print this page, tick on the indication, cross on contra-indications, tick on each side effects/warnings after explaining to patient/relatives, write name of patient with UHID no and patient admitted location, sign this page, take another sign from one witness person (NO/doctor not treating this pt), sign on behalf of relative after telephonically consent obtained, then submit a copy at sub-pharmacy store/blood bank to obtain the drug for total doses and keep one copy with patient e-hospital file.

Indications in COVID-19:

Presence of 1 or more of following selection criteria: 1-4

- Deteriorating severe pneumonia after 48hrs of steroid intake, defined as at least one of the following:
 - Presence of a respiratory rate of 30 or more breaths per minute
 - Peripheral blood oxygen saturation (SaO2) of less than 93% in room air
 - PaO2/FiO2 ratio <300 mmHg
 - Lung infiltrates of >50% within 24–48h
 - Rapid worsening of respiratory gas exchange with or without availability of noninvasive or invasive ventilation
- IL-6 levels >40 pg/mL (if not available, see hs-CRP >75 or D-dimer levels >2500 ng/mL or ferritin >500)
- Symptom onset > 7days Or CT suggestive of majority GGO

Contraindications:

- Coexistent infection other than COVID-19
- o Chronic glucocorticoid use
- History of severe allergic reactions to monoclonal antibodies
- O Less than 500 per μL neutrophils or less than 50×10^9 platelets
- Active diverticulitis, inflammatory bowel disease, or another symptomatic gastrointestinal tract condition that might predispose patients to bowel perforation
- o Severe haematological, kidney, or liver function impairment

Sign of treating faculty/SR *Sign of Patient care taker (consented)* Sign of Witness @Dr. P. K. Panda (Nodal officer, Covid-19 Task Force, AIIMS Rishikesh, 9868999488)



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Infants <1 year of age

Dose schedule & Administration:

- Intravenous: 8mg/kg (Maximum dose 800mg per dose) single dose
- Administration: Tocilizumab should be diluted in 0.9% 100ml NS IV bag made up of PVC, polyethylene, and polypropylene. Diluted solution should be allowed to reach the room temperature prior to administration; infuse over 60minutes using a dedicated IV line. Do not administer IV push or IV bolus. Do not use if opaque particle or discoloration are visible.

Special situation:

 Currently the safety and efficacy of Tocilizumab in pregnancy or breastfeeding women is not been established.

Monitoring parameters:

- All patients should be screened and ruled out for latent TB infection with QuantiFERON TB GOLD /TST prior to therapy
- Neutrophils, platelets, ALT/AST, alkaline phosphatase, total bilirubin should be done prior to therapy and at second dose administration
- Lipid profile, especially Cholesterol (prior to therapy and 4 to 8 weeks following initiation of therapy)
- Monitor for signs/symptoms of infections and CNS demyelinating disorders

References:

- Nicastri E, Petrosillo N, Bartoli TA, Lepore L, Mondi A, Palmieri F, D'Offizi G, Marchioni L, Murachelli S, Ippolito G, Antinori A. National institute for the infectious diseases "L. Spallanzani", IRCCS. Recommendations for COVID-19 clinical management. Infectious Disease Reports. 2020 Feb 25;12(1).
- Guaraldi, G., Meschiari, M., Cozzi-Lepri, A., Milic, J., Tonelli, R., Menozzi, M., et al., 2020. Tocilizumab in patients with severe COVID-19: a retrospective cohort study. The Lancet Rheumatology, [online] Available at: https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30173-9/fulltext#.
- 3. https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/
- COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines.
 National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov

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