

GOVERNMENT OF ODISHA
HEALTH & FAMILY WELFARE DEPARTMENT

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From

Sri P. K. Mohapatra, IAS
Additional Chief Secretary to Government

To

All Collectors/All Municipal Commissioners
All CDM & PHOs
Director, AIIMS, Bhubaneswar
Director, AHPGIC, Cuttack
Director, Capital Hospital
Director, IGH, Rourkela
All Dean & Principals & Superintendent of Govt. & Pvt. M.C of the State
Superintendent SVPPGIP
Medical Superintendent / CMOs of all Pvt. Health care Institution in the State

Sub: Revised Guidelines for use and issue of Tocilizumab and other New drugs in COVID 19.

Madam/Sir,

This has the reference to this Department Letter No-13134, dated-30.04.2021 and Letter No-13561, dated-06.05.2021 regarding the constitution of an Expert Committee for taking the decision on the use of Tocilizumab and other new drugs for Covid patients in Covid treatment facilities and the SOP for requisition of Tocilizumab & other new Drugs

In this context, I am to say that the AIIMS/ ICMR-COVID-19 National Task Force/ Joint Monitoring Group (Dte.GHS) Ministry of Health & Family Welfare, Government of India Clinical Guidance For Management of Adult Covid-19 Patients, Dtd.17.05.2021 recommends that Tocilizumab (**Off-label**) may be considered when all of the below criteria are met:

- Presence of severe disease (preferably within 24 to 48 hours of onset of severe disease/ICU admission).
- Significantly raised inflammatory markers (CRP &/or IL-6).
- Not improving despite the use of steroids.
- No active bacterial/fungal/tubercular infection.

❖ Recommended single dose: 4 to 6 mg/kg (400 mg in 60kg adult) in 100 ml NS over 1 hour.

In India, the drug controller general of India (DCGI) is the regulatory authority for granting approval for new drugs but, unfortunately, there is no clear-cut guideline on the off-label use of drugs.

It is also dangerous to suggest that doctors should be free to decide about off-label use based on their experience and knowledge. (BMJ, 2004 Apr 24; 328(7446): 974)

The off-label drug use also carries some risks for the patients in case inappropriately utilized. When there is no surety about the scientific validity of off-label use, then it might expose the patient to unrestricted experimentation, unknown health risks, or ineffective medicine.

As such the availability of Tocilizumab is limited in India and indiscriminate prescription for COVID 19 patients may have a compounding effect on its availability and may lead to public discontentment.

The Government of Odisha had issued a guideline on 30.04.2021 to ensure availability of the Tocilizumab from the Govt. stock through an expert committee and also to avoid its use when that is not indicated or when there is a contraindication. But several complaints have been received regarding the delay in supply on the grounds of non-compliance with the required documents; resulting in a delay in the initiation of the treatment. Also, the Expert Committee has received many requisitions for patients for whom drugs can not be used.

To overcome these problems and to ensure ready supply Tocilizumab/ New drugs/ Investigational drugs/ Off label drugs following SOP may be considered.

- a. Regional stock points will be created at OSMCL under CDM&PHOs of Bhubaneswar (BMC), Cuttack(CMC), Balasore, Ganjam, Angul, Sambalpur, Sundargarh, Bargarh, Koraput and Balangir and telephone numbers of these district level stock points must be shared with the MD(OSMCL)/ DMET(O) and Chairman, Expert Committee,
- b. Only drugs included in National Guidelines will be considered for supply from the Govt. stock depending upon its availability.
- c. Since the drugs used as off-label drugs are not approved drugs, it will be the sole responsibility of the treating physician to decide the use of off-label drugs for use in COVID 19 patients. He/She must take due diligence on the eligibility of the candidates for the administration of Tocilizumab or any other new drugs while taking the decision on their use. The Govt will not owe any responsibility for such use by the treating physician.
- d. Adequate counseling of the patients/ attendants must be done with respect to possible results/ adverse effects before prescription of Tocilizumab/ New drugs and consent must be obtained from patients or his/her attendants.
- e. The requisition accompanied by duly complied revised proforma (enclosed) must be sent to MD,OSMCL (mdosmcl.od@nic.in, 9437048177) with a copy to the DMET(O) (dmetbbsr4@gmail.com, 9437044645) and Chairman, Expert Committee (bidyutdas@hotmail.com, 9437275220) and CDM & PHOs of the designated districts through Email and Whatsapp to enable the committee for a recommendation for issue of the drug. In emergency conditions, the treating physician may consult the Chairman, Expert Committee, or DMET(O) over the phone during odd hours to facilitate the early provision of such drugs.
- f. The Expert Committee after scrutinization of records will recommend for the issue of the drugs to OSMCL/ and also to the CDM&PHOs of the designated districts within a reasonable time.
- g. The recommendation can also be done by the DMET(O) during exigencies.
- h. The Hospital Administration will be responsible for retaining the empty used vials for verification and will return them on demand.
- a. Utilization Certificate must be submitted by the Hospital Administration within 48 hrs of the issue of the drugs and will submit the case records after completion of the treatment when required for audit.
- j. In the event of non-use, Tocilizumab must be returned to OSMCL or other issuing centers within 48 hrs. Retention of the stock received is strictly prohibited.

This will come into effect immediately and supersedes all earlier orders.

Yours faithfully,


Additional Chief Secretary to the Government

Proforma for screening eligibility for use of TOCILIZUMAB

(to be filled by the treating physician)

Date:

Name of patient:

Age/Sex:

Body weight:

COVID report:

1. Name of center treating the patient:
2. Duration of illness:
3. Date of first drop in SpO2 below 92% on room air:
4. Duration of onset of severe disease (SpO2< 92 on room air/ Resp rate> 30/min):
5. Whether admitted in ICU/HDU (yes/no):
6. Whether on HFNC/ NIV/ Mechanical ventilation:
7. Current Oxygen saturation:
8. Type of steroid received:
9. Dose and duration of steroid given:
10. Does the patient have any suspected bacterial (raised serum procalcitonin)/ fungal/ tubercular infection?
11. Has the patient received immune-suppressant therapy (other than steroid) like Baricitinib, Tofacitinib, Itolizumab, Bevacizumab, Anti-TNF, any other biologic?
12. If yes, indicate the type of immunosuppressant and date of administration.
13. Has the patient received tocilizumab or similar drugs earlier? If yes, indicate date:
14. Basic investigation reports of the patient (done within last 48 hours):
 - a. CBC: HB.....,TLC.....,DC(N.....L.....M.....B.....), TPC.....
 - b. LFT: ALT....., AST
 - c. HIV/ HBsAg/ Anti-HCV:
 - d. CRP (quantitative) (specify units):
 - e. Serum Procalcitonin (specify control cut-off):
15. (a) Has the patient/ family member/ attendant been counseled and consent obtained
- (b) If yes, mode of consent taken: written/ Whatsapp/ E-mail/ any other modality

Signature of the treating physician:

Name, Designation, and seal of the treating physician:

Contact no.

Countersignature with the seal of the Hospital Superintendent/ AMO:

Contact no:

Documents to accompany the proforma: (Desirable)

1. COVID report
2. Prescription of treating physician
3. Photocopy of Case Sheet
4. Photocopy of investigations

N.B:

1) Since Tocilizumab is used as an off-label drug, it is the responsibility of the treating physician to adequately counsel the patients/relatives & to obtain consent before administration of the drug.

It is the duty of the treating physician to ensure eligibility for tocilizumab before administration.

2) In case of incomplete proforma, the assessment for a judicious recommendation of tocilizumab will not be possible.

3) The Hospital administration must submit utilization certificate to OSMCL through email & will submit the detailed case record if required

4) The Hospital Administration must submit case records of the patient receiving the drug after completion of treatment on demand for audit.

5) The Hospital should retain the used empty vials for return on demand.

Co: