

Directorate of Health Services
Satpura Bhawan, Bhopal

IMPORTANT

No./IDSP/ 2020/ 15 04

Bhopal, Date 04/ 09/2020

To,

1. All Collectors, MP.
2. All Chief Medical & Health Officer, MP.
3. All Civil Surgeons cum Hospital Superintendent, MP.
4. President, MP Nursing Home Association, MP.
5. President, IMA, MP.

Sub: - Regarding clarification on use of investigational therapies in COVID-19 patients.

Ref: - 1. MoHFW Revised guidelines on clinical management: COVID-19 (Version-3) dated 13/06/2020 and Updated clinical management protocols for COVID-19 (Version-4) dated 03/07/2020.

2. National e-ICU on COVID-19 Management, FAQs on COVID-19 from AIIMS, eICUs dated 01/09/2020

In reference to the context it is stated that MoHFW vide its revised guidelines on clinical management: COVID-19 (Version-3) dated 13/06/2020 and Updated clinical management protocols for COVID-19 (Version-4) dated 03/07/2020 has mentioned use of investigational therapies in COVID-19 based on limited available evidence and in a defined subgroup of patients. **The State clarifies that indiscriminate use of these of such therapies is to be strictly curtailed.**

The use of Tocilizumab, Remdesivir and Favipiravir in COVID-19 patient is clarified as below: -

1. Inj. Remdesivir

- i. Remdesivir is an investigational therapy mentioned by the MoHFW under Emergency Use Authorization (EUA) to be considered in COVID-19 patients with moderate disease on Oxygen therapy only when the following contraindications are ruled out: -
 - o AST/ALT > 5 times upper limit of normal
 - o Severe renal impairment (GFR<30 ml/min/ m² or need for Hemodialysis)
 - o Pregnant or Lactating Women
 - o Children < 12 y
- ii. The drug dose is recommended as 200 mg iv on D1 followed by 100 mg iv daily x 5 days.
- iii. **It is reiterated that Remdesivir is an experimental therapy approved by DCGI in view of the ongoing pandemic therefore, it should NOT be used as empirical therapy for suspected cases.** The drug should be used only in COVID patients, where clinical indicated.
- iv. There is no evidence to support the use of Remdesivir in asymptomatic COVID-19 patients with co-morbidities.

2. Inj. Tocilizumab

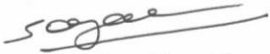
- i. MoHFW has mentioned Off Label use of Tocilizumab in COVID-19 patients with moderate disease having progressively increasing Oxygen requirement & in patients on mechanical ventilation not improving with steroids.

- ii. Special considerations for its use include raised inflammatory markers (CRP, Ferritin, IL-6), Presence of secondary infections and neutropenia and rule out of active infections and Tuberculosis.
- iii. The recommended drug dosage is 8 mg/kg (Max 800 mg at a time) in 100 ml NS over 1 hour & repeated once after 12-24 hours (if needed).
- iv. It is noteworthy that Inj. Tocilizumab has been approved by DCGI on compassionate ground in view of ongoing pandemic. However, it is an experimental therapy with limited role and should be used only in patients with cytokine syndrome after ruling out active infections.
- v. **Tocilizumab should not be used in a highly suspect patient who is COVID negative.**
- vi. **It should be not used as empirical therapy for suspect cases nor it should be used in asymptomatic patients with co-morbidities.**

3. **Tab. Favipiravir**

- i. It is observed that clinicians are resorting to use of Tab. Favipiravir in mild or asymptomatic COVID-19 patients to prevent disease progression.
- ii. It is evidence based that majority of this cohort (mild or asymptomatic COVID-19 patients) recover with just supportive care and monitoring and usually require no specific therapy.
- iii. **Evidence is weak for the use of Favipiravir and is currently not recommended in National guidelines.**

It is directed that the investigational therapies of COVID-19 be used with utmost caution and judiciously. **Prior informed and written consent be taken from the patient/caregivers before instituting such experimental drugs in COVID-19 patients.** Such patients opting for the use of the above-mentioned investigational drugs may self-pay for the therapy.

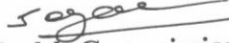

(Dr. Sanjay Goyal)
Health Commissioner
Directorate of Health Services
Madhya Pradesh

Bhopal, Date 04/09/2020

No./IDSP/2020/1505

Copy for kind information & necessary action: -

1. Addl. Chief Secretary, DoPHFW & DoME, Mantralay, Vallabh Bhawan, Bhopal, MP.
2. All Divisional Commissioners, MP.
3. State Surveillance Officer, IDSP, MP.
4. State Nodal Officer for COVID Control Room, DHS, MP for upload of directive on <http://mphealthresponse.nhmmp.gov.in/covid/orders>.


Health Commissioner
Directorate of Health Services
Madhya Pradesh