GOVERNMENT OF ANDHRA PRADESH
HEALTH, MEDICAL & FAMILY WELFARE DEPARTMENT

Order No.126/COVID-19/2021 31/05/2021

COVID Instant Order No.126

Sub: Certain guidelines on Casirivimab and Imdevimab

Ref: 1. G.O.Rt. No. 184, HM&FW (B2) dept., Dt. 30.04.2021 Meeting of the AP State Expert Committee on Clinical Management of COVID-19, dated 22 May 2021
2. Consultation with Technical Committee dated 22 May 2021

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In view of current COVID-19 situation, Guidelines on Casirivimab & Imdevimab ishereby attached.

All Collectors & Special Officers are requested to take immediate necessary action.

Principal Secretary to Government

To

All the Collector and District Magistrates in the State for immediate action
All the Joint Collectors and Addl. District Magistrates (Development) for necessary action
All the DM&HO's in the State for necessary action and implementation

Anti-SARS-CoV-2 Monoclonal Antibodies: Casirivimab and Imdevimab

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Introduction

Casirivimab (previously REGN10933) and Imdevimab (previously REGN10987) are recombinant human monoclonal antibodies, produced by recombinant DNA technology, that bind to nonoverlapping epitopes of the S protein RBD of SARS-CoV-2. Following is the information available as on date from verifiable resources.

Many individuals with COVID-19 produce neutralizing antibodies to SARS-CoV-2 about 10 days after disease onset, with higher antibody levels observed in those with severe disease.Monoclonal antibodies targeting the S protein have the potential to alleviate symptoms and limit progression to severe disease in patients with mild to moderate COVID-19, particularly in those who have not yet developed an endogenous antibody response.

Casirivimab plus Imdevimab, are available for the treatment of mild to moderate COVID-19 in **NON-hospitalized patients with laboratory confirmed SARS-CoV-2 infection who are at high risk for progressing to severe disease and/or hospitalization**.

Storage

It has to be stored at $2^{O}C$ to $8^{O}C$.

Dosage

Casirivimab plus Imdevimab is approved at a combined dose of 1200 mg (600 mg of each drug) administered by intravenous infusion or subcutaneous route.

Indication

Combination of Casirivimab and Imdevimab indicated for restricted use in emergency situation, for the treatment of mild to moderate corona virus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with laboratory confirmed SARS-COV2 infection and who are at high risk of severe COVID-19 and does not require oxygen.

High risk is defined as:

- Age ≥60years
- Obesity
- Cardiovascular disease, includinghypertension
- Chronic lung disease, includingasthma
- Type 1 or type 2 diabetesmellitus
- Chronic kidney disease, including those ondialysis
- Chronic liverdisease
- Immunosuppressed, based on investigator's assessment. Examples include: cancer treatment, bone marrow or organ transplantation, immune deficiencies, HIV (if poorly controlled or evidence of AIDS), sickle cell anemia, thalassemia, and prolonged use of immune-weakeningmedications.

Not to be used

For patients hospitalized for COVID-19, there are no data showing benefit from treatment with Casirivimab and Imdevimab.

Therefore, Casirivimab and Imdevimabshould not be used in patients who:

- are hospitalized due to COVID-19,OR
- require oxygen therapy due to COVID-19,OR
- require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 relatedco-morbidity.

Note

1. The drug shall be supplied only on the prescription of Medical Specialist for in hospital/institutional use.
2. Written informed consent from each patient/or his representative prior to administration of the drug shall be obtained.
3. The informed consent form to be used should contain in a language understandable to the patient/or his representative the factual details about the drug, its restricted emergency use approval, alternative therapy available etc.

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