SOP Remdesivir for hospitalised patients with hospital-onset COVID-19 using NHS criteria 30 May 2022

East Kent Hospitals University NHS Foundation Trust

Team caring for patient determine patient may be suitable for treatment

- Please see the CAS alert. Decisions to actually treat must be at a consultant level for adults and by Paediatric MDT process for children (aged 12 to 17 years) and meet the following criteria after 13th June 2022 :
- SARS-CoV-2 infection is confirmed by lateral flow test or polymerase chain reaction (PCR) test within the preceding 5 days AND Hospitalised for indications other than for the management of acute symptoms of COVID-19; AND the patient is a member of a 'highest' risk group (as defined in the Department of Healthand Social Care commissioned Independent Advisory Group Report) OR COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by multidisciplinary team [MDT] assessment)
- Results of creatinine, LFT, FBC, chest radiology and genotyping PCR taken (unless other factors preclude genotyping).
- Only Sotrovimab may be used within 5 days* of symptom onset. Combination treatment with an nMAB and an antiviral is NOT routinely recommended.

Exclusion criteria applied

- Patients are excluded if ANY of the following apply:
  - Adolescents (aged 12-17 years) weighing less than 40kg
  - Children aged under 12 years
  - Known hypersensitivity reaction to the active substances or to any of the excipients of sotrovimab as listed in the respective Summary of Product Characteristics (SmPC)
  - Previously received treatment with sotrovimab during this course of infection unless nMAB within a post-exposure prophylaxis (PEP) or pre-exposureprophylaxis (PrEP) trial
  - New supplemental oxygen requirement specifically for the management of COVID-19 symptoms

Cautions considered

- Cautions should be explicitly considered and appropriately documented in medical record:
  - Please refer to the respective Summary of Product Characteristics (SmPC) for sotrovimab for special warnings and precautions for use. This includes use in pregnacy and with breast feeding.
  - Neutralising monoclonal antibodies (nMABs) are not intended to be used as a substitute for vaccination against COVID-19.
  - Refer to current vaccination guidelines with respect to timing of vaccination post treatment

Supply & Monitoring or Appeals process

- Therapy should be given to eligible patients as early as possible to maximise benefit. Eligible patients from psychiatric or community hospitals may need transfer to the Trust
- Pharmacy will only supply from the Trust's notified allocation after completion of the criteria form and where the patient can be cared for in a ward environment where the medicine can be supplied and administered safely after risk assessment. The Specialist Pharmacy Services institutional readiness documents are the standard reference. While respiratory wards, paediatric wards, Marlow ward, surge ITUs and ITU are the initial default clinical areas, all adult wards, A&E and other areas may be designated.
- Appeal if above process challenged by any party to the decision to treat:
- The responsible CMO or on call Trust Medical Officer will evaluate the reason for the appeal and identify if benefit according to NHS interim position statement is possible on balance of probability. If supply is possible from allocation, authorisation will occur.

NOTE: From December 2021 neutralising Monoclonal Antibodies (Sotrovimab) are effectively decommissioned in this group of patients (not available given 5 days since symptom onset criteria which would be very rare). This SOP remains available for Remdesivir reference alone.
Appropriate verbal or best interests' consent is to be documented in medical record. The list of list of qualifying conditions is complex and in some cases may require extra tests/actions such as when intravenous immunoglobulin has been given recently. MDT decision making if necessary, should be supported by CMO guidance and the interim commissioning criteria. *Treatment commencement may be extended up to a maximum of 7 days from symptom onset if clinically indicated. Improving patients should not be treated. The fact and date of administration must be stated at all handovers of care including transfer or discharge where in addition dose and time must be conveyed for procedure and preparation as in CMO guidance. Clinicians must ensure that additional data collection requirements are met for the purpose of surveillance, audit and evaluation around the use of nMABs.
Infusion-related reactions (IRRs) reactions, including hypersensitivity reactions may occur usually within 24 hours of administration. If an IRR occurs, consider interrupting, slowing or stopping the infusion and administer appropriate medications and/or supportive care. All suspected adverse reactions must be reported on the COVID-19 specific yellow card system AND on DATIX.
The aseptic preparation, supply, transportation and administration are governed by national protocols adapted for Trust use and must be adhered to. The aseptic worksheet and clinical area preparation record are to be retained in the clinical record. Infusions prepared aseptically in pharmacy should be protected from light during storage and transport to the clinical area, and should be protected from vibration and excessive movement. The bags must not be shaken. Infusions (always case with sotrovimab) prepared in a clinical area must be used immediately. Deviation or wastage must be reported on DATIX.
The dose of sotrovimab is 500mg in this indication to be administered as a single intravenous infusion given over a minimum of 30 minutes and never infused concomitantly in the same intravenous line with other medication. Administration requires double checking by appropriately trained staff. A 0.2 micron inline filter must be used with appropriate monitoring of patient during the time of the infusion.

V1 Gold approved 5/4/21 V3.1 CMO approved 30 Dec 2021 V3.2 13 June 2022 Author: Dr M L Jenkinson