Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2020/013 Issued 29/09/2020

Remdesivir for patients hospitalised with COVID-19 (adults and children aged 12 years and older) – Supply Disruption

Summary

An interim clinical commissioning policy has been in place since 3 July 2020, defining routine access to remdesivir in the treatment of COVID-19 across the UK, following confirmation of a Conditional Marketing Authorisation (CMA) by the European Medicines Agency (EMA).

Due to increased demand against available supply, clinicians are now asked to apply the full eligibility criteria as set out within the associated Central Alerting System (CAS) alert CEM/CMO/2020/028(U), last published on 3rd September 2020, and listed below.

Clinicians are also asked to adhere to a standard treatment course of 5 days.

Action

Acute Provider Trusts / Health Boards are asked to take the following immediate steps to support the maintenance of continued supply over the coming weeks:

1. Undertake a stocktake of vials of remdesivir and minimise stock held at ward level. Share the stock position with the trust / hospital and regional procurement pharmacy lead / chief pharmacist. A percentage of stock will be held centrally to support allocation to areas of greatest need, using the principles of mutual aid. This will cover the UK, Crown Dependencies and Overseas Territories.
2. Only order stock where the regional procurement pharmacy lead has advised that there is a confirmed allocation.
3. Ensure only patients with COVID infection are treated with remdesivir. Patients should normally have a confirmed positive polymerase chain reaction (PCR) test but may otherwise be treated where a COVID 19 PCR test is negative but there is a very strong index of suspicion of it being a false negative based on CT Chest showing typical COVID features, a positive antibody test with no previous history suggestive of COVID19 prior to this admission (will only occur 7-14 days minimum after onset) or classical case definition symptoms for COVID19 and contacts making pre-test probability high.
4. Ensure that clinicians prescribe a **maximum treatment course of 5 days**. Further expert clinical advice is currently being taken to clarify the circumstances in which an extended course of up to a total of 10 days might be clinically indicated.
5. Ensure the full criteria as described in the COVID-19 Therapeutic Alert for access to remdesivir are being applied by treating clinicians (see below).

Clinicians are asked to prescribe within the following criteria (this includes the additional criteria to be applied given the limited supply scenario):

- Hospitalised with coronavirus disease 2019 (COVID-19)
- With pneumonia requiring supplemental oxygen
- Adults, and adolescents ≥ 12 years of age and ≥ 40 kg

- eGFR ≥ 30ml/min
- Alanine Aminotransferase (ALT) below 5 times the upper limit of normal at baseline
- At the time of decision to treat with remdesivir patients should not be receiving ongoing mechanical ventilation or ECMO. Patients who present with an initial rapid deterioration can, however, be considered for treatment with remdesivir.
- Multi-disciplinary team assessment should determine if patients not suitable for escalation would benefit from initiation of treatment with remdesivir.
- If patients on remdesivir require escalation, continuation of the drug should be considered by multi-disciplinary team assessment.

Please see the published interim clinical commissioning policy for further details, including consideration in pregnancy and stopping criteria. The published clinical access criteria may be further refined on the basis of expert clinical advice, as required.

Product Details

Remdesivir is supplied to the UK by Gilead. The medicine comes in two forms:

- Remdesivir 100 mg concentrate for solution for infusion (each vial contains 100 mg of remdesivir, each mL of concentrate contains 5 mg of remdesivir).
- Remdesivir 100 mg powder for concentrate for solution for infusion (each vial contains 100 mg of remdesivir, after reconstitution, each vial contains 5 mg/mL of remdesivir solution).

The summaries of product characteristics (SmPCs) for remdesivir can be found here:

- concentrate for solution for infusion: https://www.medicines.org.uk/emc/product/11596/smpc
- powder for concentrate for solution for infusion: https://www.medicines.org.uk/emc/product/11597/smpc

Co-Administration

Corticosteroids
Administration of systemic dexamethasone or hydrocortisone is recommended in the management of patients with severe or critical COVID-19[1]. Corticosteroids are not suggested in non-severe COVID-19 disease. Updated WHO guidance on the use of systemic corticosteroids in the management of COVID-19 is available.

There is no interaction of remdesivir with either dexamethasone or hydrocortisone expected. For further information please visit the University of Liverpool COVID-19 Drug Interactions website (https://www.covid19-druginteractions.org/checker).

Hydroxychloroquine
Coadministration of remdesivir and chloroquine phosphate or hydroxychloroquine sulphate is not recommended based on in vitro data demonstrating an antagonistic effect of chloroquine on the intracellular metabolic activation and antiviral activity of remdesivir.

Background

Remdesivir use has increased in the last few weeks. While further increases in stocks will be made available to the UK over the autumn and winter period, in order to manage that supply during a peak demand period, it has been agreed that the additional criteria set out in the CAS alert, specifically developed in anticipation of future demand, should now be enacted.

Distribution

NHS Trusts (NHS boards in Scotland and Wales)
Regional Medical Directors
Regional Chief Pharmacists
Lead/senior pharmacists
Trust/Hospital Medical Directors to circulate to medical and nursing staff managing COVID-19 patients.

Enquiries

England
Enquiries from NHS trusts in England should in the first instance be directed to your trust pharmacy team who will escalate issues to the Regional Chief Pharmacist and national teams if required. Further information can be requested from the dedicated email address: england.spoc-c19therapeutics@nhs.net.

Northern Ireland
Enquiries from hospitals in Northern Ireland should in the first instance be directed to your hospital pharmacy team.

Scotland
Enquiries from hospitals in Scotland should in the first instance be directed to your hospital pharmacy team who will escalate issues to the Scottish Government's Medicines Policy Team if required. Contact should be made using the email address - CPO-COVID19@gov.scot.

Wales
Enquiries from hospitals in Wales should in the first instance be directed to the health board's Chief Pharmacist who will escalate issues to the Pharmacy and Prescribing Team at Welsh Government if required. Enquiries to the Welsh Government should be directed to: COVID-19.Pharmacy.Prescribing@gov.wales.

[1]Within the WHO guidance, severe COVID-19 is defined as:

- oxygen saturation < 90% on room air.
- respiratory rate > 30 breaths per minute in adults and children > 5 years old; ≥ 60 in children less than 2 months; ≥ 50 in children 2–11 months; and ≥ 40 in children 1–5 years old.
- signs of severe respiratory distress (i.e. accessory muscle use, inability to complete full sentences; and in children, very severe chest wall indrawing, grunting, central cyanosis, or presence of any other general danger signs).

Critical COVID-19 is defined by the criteria for acute respiratory distress syndrome (ARDS), sepsis, septic shock or other conditions that would normally require the provision of life-sustaining therapies, such as mechanical ventilation (invasive or non-invasive) or vasopressor therapy.