

Remdesivir Prescribing Guide

Version 2

Introduction

Remdesivir is recommended to be available as a treatment option through routine commissioning for hospitalised patients (adults and adolescents 12 years and older with body weight at least 40 kg) with COVID-19 in accordance with the criteria set out in this document.

An evidence review conducted by the National Institute for Health and Care Excellence (NICE) on 5 June 2020 indicated some benefit with remdesivir compared with placebo for reducing supportive measures – including mechanical ventilation – and reducing time to recovery in patients with mild, moderate or severe COVID-19 disease who are on supplemental oxygen treatment (<https://www.nice.org.uk/advice/es27/evidence>).

Initiation criteria

Clinicians should only prescribe remdesivir within the following criteria (this includes the additional criteria to be applied given the limited supply scenario):

Patients are eligible for treatment with remdesivir within both product licences (Great Britain and Northern Ireland, updated 2021). The patient characteristics are:

- ☒ Hospitalised with coronavirus disease 2019 (COVID-19)
- ☒ With pneumonia requiring low flow supplemental oxygen. (See later section on 'Immunocompromised patients' for how this criterion applies to this group).
- ☒ Adults, and adolescents 12 years and older who weigh 40kg and over
- ☒ Estimated glomerular filtration rate (eGFR) at least 30ml/minute (Patients with end-stage renal disease on haemodialysis are exempt from the eGFR treatment threshold)
- ☒ Alanine aminotransferase (ALT) below 5 times the upper limit of normal at baseline.
- ☒ The decision to initiate treatment with remdesivir should be made by the admitting care consultant.
- ☒ **Remdesivir should not be initiated in patients who present to hospital more than 10 days after symptom onset.** (See duration section below on 'Immunocompromised patients' for how this criterion applies to this group).
- ☒ Clinical judgement around treatment with remdesivir can be informed by a risk score. Those with a low 4C Mortality Score⁵ (0 to 3) are highly likely to recover without treatment with remdesivir.

Exemptions

- ☒ Patients with end-stage renal disease on haemodialysis are exempt from the eGFR treatment threshold above.
- ☒ See later section on 'Immunocompromised patients' for exemptions in this cohort.

Duration

- ☐ All patients must receive a maximum of 5 days of remdesivir in total (comprising a loading dose plus 4 further days of maintenance doses).
- ☐ Patients re-admitted with COVID-19 (and meeting the eligibility criteria above, with the exception of the requirement on the timing from symptom onset) are permitted a second course of up to 5 days upon readmission.
- ☐ Significantly immunocompromised patients (see below) are eligible for an extended course of remdesivir (up to 10 days), if agreed following multidisciplinary team assessment.

Reassessment and review

The use of remdesivir should be reassessed daily. Consider stopping remdesivir if:

- ☐ The patient clinically improves and no longer requires supplemental oxygen 72 hours after commencement of treatment; or
- ☐ The patient continues to deteriorate despite 48 hours of sustained mechanical ventilation.

Supplying remdesivir

All requests for remdesivir must be discussed with either the ward pharmacist or the on call pharmacist out of hours. The pharmacist will confirm the patient meets the commissioning criteria and then complete the BlueTeq form which is a requirement prior to initiating treatment with remdesivir. There is no requirement for an MDT to approve each request of remdesivir anymore.

The pharmacists will provide the code to the clinical team who can then prescribe this on the ePMA system. An approved BlueTeq form **must be completed** prior to supply being made as it helps to ensure the Trust has appropriate stock available.

Dosage

The suggested dosage in adults and adolescents not requiring invasive ventilation and/or ECMO is a single dose of remdesivir 200 mg on Day 1 followed by once-daily maintenance doses of remdesivir 100 mg for 4 days. Significantly immunocompromised patients may be treated up to 10 days with remdesivir.

Remdesivir is to be administered via intravenous infusion in a total volume of up to 250 mL sodium chloride 0.9% over 30 to 120 minutes. The giving set should be flushed with 30mL sodium chloride 0.9% after each infusion. Remdesivir can be administered via a large peripheral or central line.

Immunocompromised patients

The commissioning policy for remdesivir defined immunocompromised patients as those with a significant impairment of humoral immune response (antibody production) and/or cellular immune competence

For significantly immunocompromised patients:

- ☐ a course of remdesivir can be extended to a maximum of 10 days.

- ☐ the criterion on time between symptom onset and treatment initiation does not apply.
- ☐ the criterion on the need for supplemental oxygen requirement does not apply.

Monitoring

Patients **must have** baseline U&E's and liver function test checked prior to initiating therapy and whilst on remdesivir treatment.

Renal impairment

The pharmacokinetics of remdesivir have not been evaluated in patients with renal impairment. Patients must have an eGFR determined before dosing and daily while receiving remdesivir.

Hepatic impairment

The pharmacokinetics of remdesivir has not been evaluated in patients with hepatic impairment. It is not known if dosage adjustment is needed in patients with hepatic impairment.

Remdesivir should not be initiated in patients with $ALT \geq 5$ times the upper limit of normal at baseline. Remdesivir should be discontinued in patients who develop $ALT \geq 5$ times the upper limit of normal during treatment with remdesivir or ALT elevation accompanied by signs of symptoms of liver inflammation or increasing conjugated bilirubin or alkaline phosphatase.

Adverse events

Most commonly reported adverse event from the clinical trials was elevated transaminases hence the requirement for daily monitoring.

Documentation Controls

Development of Guidelines:	Dominic Moore Lead Pharmacist – Commissioning& High Cost Medication
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