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1. Directors of Pharmacy
2. Medical Directors NHS Boards

14 June 2021

Dear Healthcare Professional,

COVID-19 THERAPEUTIC ALERT - REMDESIVIR FOR PATIENTS HOSPITALISED WITH COVID-19 (ADULTS AND CHILDREN AGED 12 YEARS AND OLDER)

Please see the attached updated information about the treatment of hospitalised patients with COVID-19 with remdesivir.

The UK interim clinical commissioning policy has been updated to allow an extended treatment duration and other exemptions for immunocompromised patients, clarify when a further treatment course might be given following readmission, and reflect exceptions in the eligibility criteria for patients with end-stage renal disease on haemodialysis. I would be grateful if you could cascade this information to relevant colleagues.

Could all Directors of Pharmacy please forward this alert to:-

- Hospital Pharmacists
- Community Pharmacists

Please could Medical Directors forward this alert to:-

- Accident & Emergency Departments
- Directors of Public Health
- Consultants in Communicable Diseases
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

COVID-19 Therapeutic Alert

CEM/CMO/2021/013

14 June 2021

This guidance updates and replaces the COVID-19 Therapeutic Alert CEM/CMO/2020/035 which was issued on 06 November 2020

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

Summary

Remdesivir has been available to UK clinicians treating hospitalised patients with COVID-19 since May 2020.

The [UK interim clinical commissioning policy](#) has been updated to allow an extended treatment duration and other exemptions for immunocompromised patients, clarify when a further treatment course might be given following readmission, and reflect exceptions in the eligibility criteria for patients with end-stage renal disease on haemodialysis.

Action

NHS acute trusts / health boards are asked to take the following immediate steps to support treatment of admitted patients with COVID-19:

1. Cascade the updated UK interim clinical commissioning policy to relevant clinical teams
2. Ensure that only patients with COVID-19 pneumonia are treated with remdesivir. In the absence of a confirmed virological diagnosis, remdesivir should only be used when a multidisciplinary team has a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis.
3. Ensure that clinicians prescribe a **maximum treatment course of 5 days** (this may be extended to a maximum of 10 days in significantly immunocompromised patients).
4. Ensure the full criteria as described in the remdesivir interim clinical commissioning policy are being applied by treating clinicians (please see section below).
5. Continue to adhere to the existing ordering, supply and reporting arrangements for remdesivir (including pre-authorisation through Blueteq™ in England).

Clinical Criteria

Clinicians are asked to prescribe within the scope of the product licence:

- Hospitalised with coronavirus disease 2019¹ (COVID-19)
- With pneumonia requiring low-flow oxygen (oxygen delivered by a simple face mask or nasal cannula at a flow rate usually up to 15 litres/minute).
- Adults, and adolescents 12 years and older who weigh 40kg and over
- Estimated glomerular filtration rate (eGFR) at least 30ml/minute
- Alanine aminotransferase (ALT) below 5 times the upper limit of normal at baseline.

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

Initiation of treatment

- The decision to initiate treatment with remdesivir should be made by the admitting care consultant².
- Remdesivir should not be initiated in patients who present to hospital more than 10 days after symptom onset (see later section on 'Immunocompromised patients' for how this criterion applies to this group).

Duration

- Patients should 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.

Dose

The recommended dosage is a single loading dose of remdesivir 200 mg intravenously on day 1, followed by a once daily maintenance dose of remdesivir 100 mg for the remainder of the treatment course, which should not exceed five days (see exemption in immunocompromised patients below).

Immunocompromised patients

For significantly immunocompromised patients³:

- A course of remdesivir can be extended to 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

¹ In the absence of a confirmed virological diagnosis, remdesivir should only be used when a multidisciplinary team have a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis.

² The decision to treat with remdesivir is not an emergency and should be made judiciously after assessment and in a timely manner.

³ Patients with a significant impairment of humoral immune response (antibody production) and/or cellular immune competence.

Stopping criteria

Remdesivir should be discontinued in patients who develop **any** of the following:

- ALT \geq 5 times the upper limit of normal during treatment with remdesivir (remdesivir may be restarted when ALT is $<$ 5 times the upper limit of normal)
- ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or international normalised ratio (INR)
- eGFR $<$ 30 mL/min (except in patients with end-stage renal disease on haemodialysis)

Please see the published [interim clinical commissioning policy](#) for further details, including initiation of treatment, risk assessment, reassessment and consideration in pregnancy. 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 is now only available in the powder form:

- 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:

- 100mg powder for concentrate for solution for infusion (Great Britain): <https://www.medicines.org.uk/emc/product/11597/smcp>
- 100mg powder for concentrate for solution for infusion (Northern Ireland): <https://www.medicines.org.uk/emc/product/12115/smcp>

Co-Administration

Corticosteroids

Administration of systemic dexamethasone or hydrocortisone is recommended in the management of patients with severe or critical COVID-19⁴. 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 can be found [here](#).

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>).

⁴ 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; \geq 60 in children less than 2 months; \geq 50 in children 2–11 months; and \geq 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

Distribution

NHS Trusts (NHS boards in Scotland and Wales)

Regional Medical Directors
Regional Chief Pharmacists
Lead/Senior Pharmacists and Regional Procurement Pharmacy Leads
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 who will escalate issues to the Regional Pharmaceutical Procurement Service or Pharmaceutical Directorate at the Department of Health if required. Further information can be obtained by contacting RPHPS.Admin@northertrust.hscni.net

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 following emails:
nss.nhssmedicineshortages@nhs.scot or medicines.policy@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.

Rapid policy statement

Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older) Version 3

14 June 2021

Introduction

In response to the public health emergency posed by coronavirus disease 2019 (COVID-19), NHS England, working with the Devolved Administrations (DAs), has established a rapid policy development process to aid clinicians in offering best care and advice to patients with or at risk of COVID-19 across the UK. This document sets out the interim clinical commissioning position for the use of remdesivir for patients with COVID-19.

Commissioning position

The proposal is: remdesivir is recommended to be available as a treatment option through routine commissioning for hospitalised patients (adults and children 12 years and older) with COVID-19 in accordance with the criteria set out in this document.

Equality statement

Promoting equality and addressing health inequalities are at the heart of the four nations' values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010 or equivalent equality legislation) and those who do not share it; and



- Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain language summary

COVID-19 is a disease caused by a coronavirus (named SARS-CoV-2) causing many different symptoms, the most common being fever, loss of sense of taste and smell and cough. Remdesivir (given intravenously) is an anti-viral medicine which has been shown to improve recovery time in some hospitalised patients. This policy outlines the commissioning criteria for the use of remdesivir to treat people with COVID-19 in hospital according to its licence and in line with current evidence.

Overview

The condition

COVID-19 manifests predominantly as a respiratory illness, of widely varying clinical severity. At the most severe end of the spectrum COVID-19 results in severe pneumonia and respiratory failure with the need for mechanical ventilation. Hyperinflammatory states leading to organ dysfunction beyond the respiratory tract, have also been well described.

Intervention

Remdesivir is an adenosine nucleotide prodrug that is metabolised intracellularly to form the pharmacologically active substrate remdesivir triphosphate. Remdesivir triphosphate inhibits SARS-CoV-2 RNA polymerase which perturbs viral replication. Remdesivir is given intravenously, once daily after an initial loading dose. Reported adverse effects include transaminase elevations, infusion related reactions (hypotension, nausea, vomiting, diaphoresis) and drug hypersensitivity (<https://www.medicines.org.uk/emc/product/11597/smpc>). Additional adverse events may become more apparent with more widespread use.

Clinical problem

Several medical treatment options for COVID-19 have been assessed in clinical trials, many of which are ongoing. Emerging evidence of these treatment options have been reviewed (including results from the WHO Solidarity trial) by a national clinical expert group, which has concluded that there is insufficient further evidence to change the current commissioning position on the use of remdesivir in the treatment of COVID-19 (Beigel et al, 2020; Goldman et al, 2020; Rochwerg et al, 2020; Spinner et al, 2020; WHO Solidarity trial consortium, 2020; Wilt et al, 2020).

Criteria have been developed to define access and eligibility for remdesivir treatment based on expert consensus, including:

1. Key steps along the COVID-19 clinical pathway at which actions and review are necessary
2. Specific eligibility criteria to be followed

Evidence summary

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>).

Implementation

Eligibility criteria

Patients are eligible for treatment with remdesivir within the product licence ([Great Britain](#) and [Northern Ireland](#), updated 2021). The patient characteristics are:

- Hospitalised with coronavirus disease 2019¹ (COVID-19)
- With pneumonia requiring low-flow² supplemental oxygen³ (see later section on ‘Immunocompromised patients’ for how this criterion applies to this group)
- Adults, and adolescents 12 years and older⁴ who weigh 40kg and over
- Estimated glomerular filtration rate (eGFR) at least 30 ml/minute
- Alanine aminotransferase (ALT) below 5 times the upper limit of normal at baseline.

Exemptions

- Patients with end-stage renal disease on haemodialysis are exempt from the eGFR treatment threshold above and can receive any form of supplemental oxygen
- See later section on ‘Immunocompromised patients’ for exemptions in this cohort

The following criteria have been developed based on expert consensus and should be followed. A clinical pathway is presented (Appendix 1) which include steps, review points and actions outlined by these criteria⁵.

- **Initiation of treatment**
 - The decision to initiate treatment with remdesivir should be made by the admitting care consultant⁶.

¹ In the absence of a confirmed virological diagnosis, remdesivir should only be used when a multidisciplinary team have a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis.

² Low-flow oxygen supplementation as defined in the [NICE COVID-19 Rapid Guideline: Managing COVID-19](#).

³ See SmPCs for Great Britain (<https://www.medicines.org.uk/emc/product/11597/smpc>) and Northern Ireland (<https://www.medicines.org.uk/emc/product/12115>)

⁴ Remdesivir is available for the treatment of children aged <12 years (weighing at least 3.5kg), and those aged 12- <18 years and weighing <40kg, through the company’s compassionate use scheme (this is at the discretion of Gilead Sciences)

⁵ Clinical judgement in the initiation, review, escalation and de-escalation of patients receiving remdesivir treatment should be supported where possible by multidisciplinary team assessment.

⁶ The decision to treat with remdesivir is not an emergency and should be made judiciously after assessment and in a timely manner.

- Remdesivir should not be initiated in patients who present to hospital more than 10 days after symptom onset (see later section on 'Immunocompromised patients' for how this criterion applies to this group).
- **Risk assessment**
 - Clinical judgement around treatment with remdesivir can be informed by a risk score. Those with a low 4C Mortality Score⁷ (0 to 3) are highly likely to recover without treatment with remdesivir.
 - Remdesivir should not be initiated in patients who present to hospital and are unlikely to survive (determined by clinical judgment). The 4C Mortality Score might be helpful in this assessment.
- **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.

Dose

The recommended dosage is a single loading dose of remdesivir 200mg intravenously on day 1, followed by a once daily maintenance dose of remdesivir 100 mg for the remainder of the treatment course, which should not exceed five days (see exemption in immunocompromised patients below).

Immunocompromised patients

For significantly immunocompromised patients⁸:

- 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

⁷ The 4C Mortality Score (available at <https://isaric4c.net/risk/>) is a validated risk stratification score, which can help inform clinical decision making for patients admitted to hospital with COVID-19 (Knight et al, 2020). Other clinical risk scores are available.

⁸ Patients with a significant impairment of humoral immune response (antibody production) and/or cellular immune competence.

- The criterion on the need for supplemental oxygen requirement does not apply

Pregnancy

Remdesivir should be avoided in pregnancy unless clinicians believe the benefits of treatment outweigh the risks to the individual (please see SmPC for further information).

Monitoring

Renal and liver function should be monitored carefully during treatment with remdesivir as clinically appropriate.

Stopping criteria

Remdesivir should be discontinued in patients who develop **any** of the following:

- ALT \geq 5 times the upper limit of normal during treatment with remdesivir (remdesivir may be restarted when ALT is $<$ 5 times the upper limit of normal)
- ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or international normalised ratio (INR)
- eGFR $<$ 30 mL/min (except in patients with end-stage renal disease on haemodialysis)

Safety reporting

Any suspected adverse drug reactions (ADRs) for patients receiving remdesivir should be reported directly to the MHRA via the new dedicated COVID-19 Yellow Card reporting site at: <https://coronavirus-yellowcard.mhra.gov.uk/>

Co-administration

Administration of systemic dexamethasone or hydrocortisone is recommended in the management of patients with severe or critical COVID-19⁹. 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 can be found [here](#).

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>).

⁹ 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; \geq 60 in children less than 2 months; \geq 50 in children 2–11 months; and \geq 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.

Governance

Data collection requirement

Provider organisations in England should register all patients using prior approval software (alternative arrangements in Scotland, Wales and Northern Ireland will be communicated) and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

Clinical outcome reporting

Hospitals managing COVID-19 patients are encouraged to submit data through the ISARIC 4C Clinical Characterisation Protocol (CCP) case report forms (CRFs), as coordinated by the COVID-19 Clinical Information Network (CO-CIN) (<https://isaric4c.net/protocols/>).

Effective from

This policy will be in effect from the date of publication.

Policy review date

This is an interim rapid clinical policy statement, which means that the full process of policy production has been abridged: public consultation has not been undertaken. This policy may need amendment and updating if, for instance, new trial data emerges, supply of the drug changes, or a new evidence review is required. A NICE Technology Appraisal or Scottish Medicines Consortium (SMC) Health Technology Assessment or All Wales Medicines Strategy Group (AWMSG) appraisal of remdesivir for COVID-19 would supersede this policy when completed.

Definitions

COVID-19	Refers to the disease caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus.
Mechanical ventilation	A life support treatment which helps people breathe when they are not able to breathe enough on their own.
Extra Corporeal Membrane Oxygenation	A life support machine for people who have a severe and life-threatening illness that stops their heart or lungs from working properly.

References

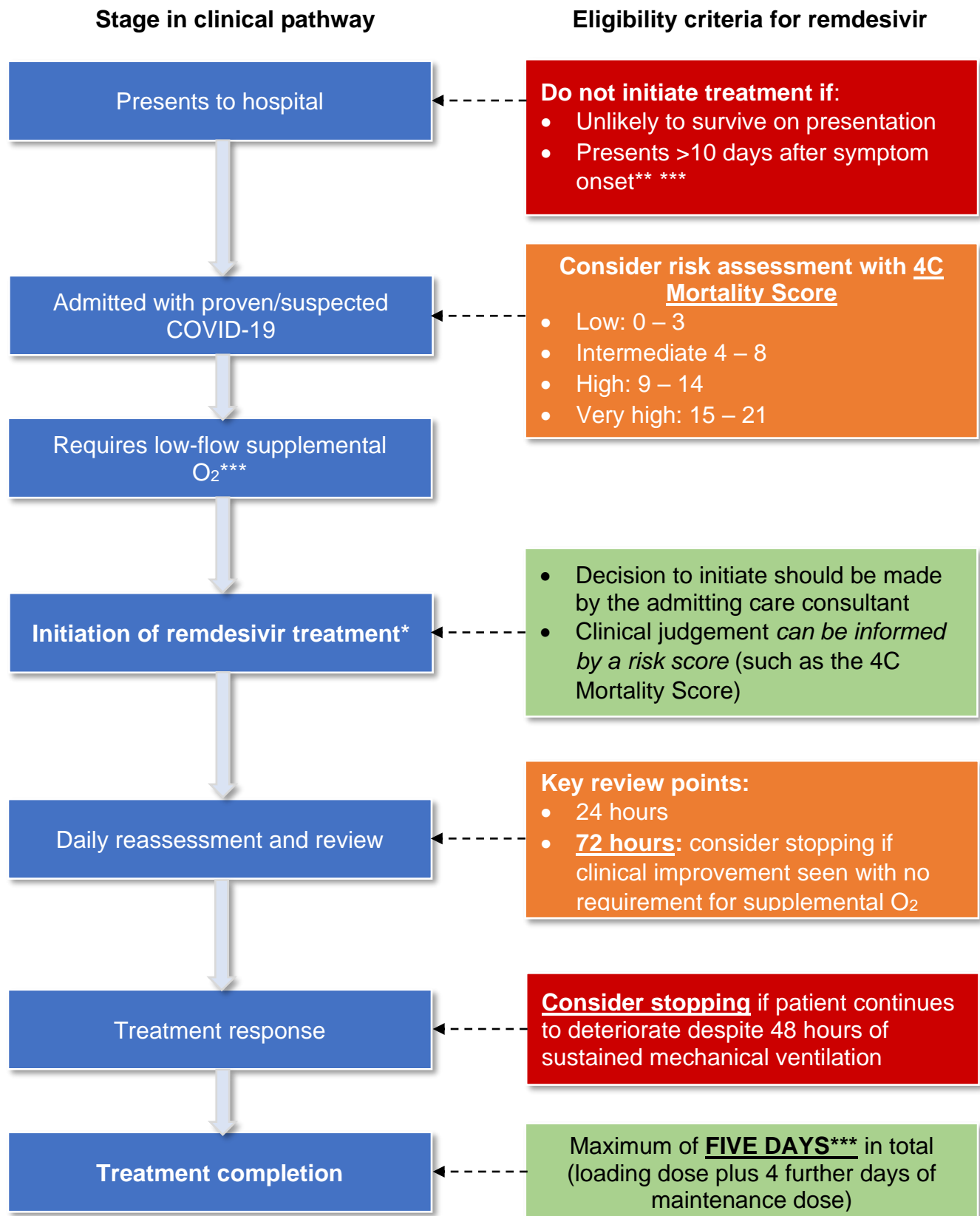
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Appendix 1

Clinical pathway and criteria for the use of remdesivir in patients hospitalised with COVID-19 (adults and children 12 years and older)



*There should be careful consideration before initiating remdesivir treatment

**Unless patient is readmitted with COVID-19 (see main policy document)

***See additional comments on immunocompromised patients and those on haemodialysis in main policy document