**Prif Swyddog Fferyllol**
**Chief Pharmaceutical Officer**

Llywodraeth Cymru
Welsh Government

To:
Local Health Boards and Velindre NHS Trust:

Chief Executives
Medical Directors
Nurse Directors
Directors of Public Health
Chief Pharmacists
Pharmacy procurement leads

Public Health Wales NHS Trust

Our Ref: AE/COVID

6 July 2020

Dear Colleague,

**Publication of an interim clinical commissioning policy: Remdesivir for patients hospitalised with COVID-19 (adults and children aged 12 years and older)**

**Background**
On 26 May, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a positive Scientific Opinion (SO) for remdesivir, a nucleoside-ribonucleic acid (RNA) polymerase inhibitor with broad-spectrum antiviral activity, in the treatment of COVID-19. The MHRA's decision allowed remdesivir to be used ahead of it being granted a marketing authorisation for the treatment of adults and adolescent patients aged ≥12 years and weighing at least 40kg hospitalised with suspected or laboratory confirmed SARS-CoV-2 infection and severe disease.

A Public Health Alert, (Ref: CEM/CPhA/2020/24) providing initial information about the EAMS for Remdesivir, including patient access criteria was subsequently distributed to NHS Wales.

**Update**
Following confirmation of a Conditional Marketing Authorisation (CMA) by the European Medicines Agency (EMA) for the use of remdesivir in the treatment of



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Caerdydd • Cardiff
CF10 3NQ Gwefan • website: www.wales.gov.uk

COVID-19, the scientific opinion given for remdesivir via the Early Access to Medicines Scheme (EAMS) put in place on 26th May 2020 has now lapsed.

From 3 July 2020, an interim clinical commissioning policy has been put in place to define routine access to remdesivir in the treatment of COVID-19 across the UK. The policy reflects the conditions of the CMA, but also includes secondary criteria to be used should there be limitations in the supply of remdesivir in the UK.

**Medicine Supply**

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 100mg 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 MHRA has confirmed that existing UK stocks remaining from either the SIMPLE research studies or the EAMS programme can be utilised.

Mutual aid arrangements should be used in the case of limited supply.

**Access criteria**

*Health board access to supplies of remdesivir*

The new interim clinical commissioning policy aims to identify those patients most likely to benefit from remdesivir i.e. those patients at the early stage of a COVID-19 infection who have a high probability of developing severe disease putting their lives at risk. Additional 'secondary' criteria have been included in the policy to guide clinicians and are only applicable should demand for remdesivir exceed supply.

*Eligibility criteria*

Patients will be eligible for treatment with remdesivir in accordance with the product licence. Eligibility criteria within the Remdesivir Summary of Product Characteristics (SmPC) include:

- 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

*Additional criteria*

In times of limited supply, additional criteria will be necessary in order to allocate remdesivir to those with the greatest capacity to benefit (patients in the earlier stages of respiratory failure). In this context the following criteria must also be met:

- 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.

*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).

Please see the full interim clinical commissioning policy for further details, including stopping criteria.

**Co-administration**

*Dexamethasone*
Dexamethasone should be considered in the management of hospitalised adult patients with COVID-19. There is no interaction of remdesivir with dexamethasone expected. For further information please visit the University of Liverpool COVID-19 Drug Interactions website: (https://www.covid19-druginteractions.org/checker) and see the Summary of Product Characteristics (SmPC) for remdesivir.

*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.

**Data Collection**

*Safety reporting*
Adverse Events (AEs), Serious Adverse Events (SAEs) and Special Situation reports (SSRs) (including pregnancies) should be submitted to Gilead Pharmacovigilance & Epidemiology (PVE): Email: Safety_FC@gilead.com ; Tel.: 01223 897 500

Pharmacovigilence - As the safety profile of remdesivir may not be fully established it is particularly important that any suspected adverse drug reactions are reported directly to the MHRA via the new dedicated COVID-19 Yellow Card reporting site.
https://coronavirus-yellowcard.mhra.gov.uk/

Data on all patients that receive remdesivir should be captured through the ISARIC 4C Clinical Characterisation Protocol case report form to support ongoing implementation and evaluation. The form can be downloaded at
https://isaric4c.net/protocols/ Clinicians in Wales should use the form listed under the 'Common' heading, currently CRF_9.4 28052020.pdf

**Supporting information**
More detailed information on the use of remdesivir with COVID-19 infection can be found at:

New England Journal of Medicine
https://www.nejm.org/doi/full/10.1056/NEJMoa2007764

Requests for further information on remdesivir supply can be submitted to UKICOVID-19@gilead.com

The ISARIC 4C (Coronavirus Clinical Characterisation Consortium) can be found at: https://isaric4c.net/

The SmPC for remdesivir 100mg concentrate for solution for infusion
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The SmPC for remdesivir 100mg powder for concentrate for solution for infusion
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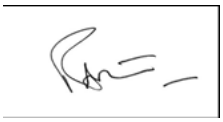
**Enquiries**

Welsh Government: COVID-19.Pharmacy.Prescribing@gov.wales

Yours faithfully,



**Dr Frank Atherton**
Prif Swyddog Meddygol/Cyfarwyddwr Meddygol, GIG Cymru
Chief Medical Officer/ Medical Director NHS Wales
Llywodraeth Cymru/
Welsh Government

**Andrew Evans**
Prif Swyddog Fferyllol/ Chief Pharmaceutical Officer
Llywodraeth Cymru / Welsh Government