Safety Notice 020/21

Remdesivir 100 mg injection – disruption to supply

9 September 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Drug and Therapeutics Committees
- Directors of Medical Services
- Directors of Pharmacy
- Directors and Managers of Intensive Care Units
- Directors and Managers of Respiratory Services
- Directors and Managers of Infectious Diseases

Expert Reference Group

Content reviewed by:

- Chief Pharmacist Unit
- Clinical Leads of ICU, ID and Respiratory Communities of Practice
- HealthShare NSW
- State Preparedness and Response Branch

Clinical Excellence Commission

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Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

December 2021

Situation

- There is a potential disruption to the supply of remdesivir (Veklury®) 100 mg powder for injection due to increasing global demand in response to the COVID-19 pandemic. The clinical criteria to access remdesvir needs to be followed judiciously to ensure optimal usage of available stock.
- Remdesivir is a nucleotide analogue prodrug that inhibits RNA polymerases. It has received provisional approval for the treatment of COVID-19 from the Therapeutic Goods Administration (TGA) and is the only antiviral drug recommended to treat COVID-19.
- Access to remdesivir for NSW Health facilities is via the NSW Health stockpile.

Inclusion criteria

Remdesivir is conditionally recommended by the National COVID-19 Clinical Evidence Taskforce for hospitalised patients with moderate to severe COVID-19 who require oxygen but **not ventilation**. The criteria to access remdesivir include:

- age ≥ 18 years (or 12–17 years weighing ≥ 40 kg)
- oxygen saturation (SpO2) ≤ 92% on room air and requiring supplemental oxygen
- alanine aminotransferase (ALT) < 5 x upper limit of normal (ULN) and/or ALT < 3 x ULN and bilirubin < 2 ULN.

Exclusion criteria

Patients are unable to receive remdesivir if they have:

- evidence of multiorgan failure including but not limited to coagulopathy (significant thrombocytopenia), hepatic failure (elevated bilirubin) or renal failure (low urine output or estimated glomerular filtration rate (eGFR) < 30 mL/min), or significant cardiomyopathy (low cardiac output)
- renal failure (eGFR < 30 mL/min or dialysis or continuous venovenous haemofiltration)
- been mechanically ventilated for longer than 48 hours at time of application
- commenced extracorporeal membrane oxygenation (ECMO).

Clinical recommendations

- Use remdesivir early in the illness, where most benefit is gained.
- In anticipation of a potential shortage, prioritise remdesivir for patients with the following characteristics (in addition to the inclusion criteria above), who would be of the clearest benefit:
  - lung infiltrates on imaging
  - requiring ongoing low-flow oxygen supplementation at baseline (remdesivir has less benefit in patients on high flow oxygen compared to low flow oxygen).
- Treatment with remdesivir is for a maximum of five days – treatment beyond five days did not improve outcomes in clinical trials.
- Remdesivir should not be commenced in patients already on ventilation as no difference in recovery rate was observed in trials compared to placebo per the Product Information.

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians/committees.
2. Ensure that the local Drug and Therapeutics Committee:
   a. Monitors the use of remdesivir in the treatment of COVID-19 ensuring that only patients meeting the inclusion criteria receive the medication.
   b. Prioritises supply to patients for whom treatment is of clearest benefit; and treatment is for a maximum of FIVE days.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au **within 24 hours.**