Safety Alert 001/21

Critical disruption to the supply of tocilizumab

9 August 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
- Directors and Managers of Rheumatology

Deadline for completion of action – 10 August 2021

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

January 2022

Situation

- There is a current critical disruption to the supply of multiple presentations of tocilizumab injections due to increasing global demand in response to the COVID-19 pandemic.
- Tocilizumab is an interleukin-6 receptor blocker routinely used for conditions such as rheumatoid arthritis and is now strongly recommended for patients who are severely or critically ill with COVID-19 by the World Health Organization.
- NSW Health has attempted to source additional supply from other jurisdictions and countries, private healthcare facilities and the global sponsor with minimal success.
- The disruption to supply is expected to continue until at least early 2022 with future shipment dates currently uncertain.

Clinical recommendations

- Where indicated use the alternative immunomodulatory medicine, baricitinib, a Janus kinase inhibitor, for patients hospitalised with COVID-19 who require supplemental oxygen, high-flow oxygen and/or non-invasive ventilation including those who may be intolerant of steroid therapy.
- Baricitinib is an oral tablet formulation that can be dispersed to allow for administration via nasogastric or gastrostomy tube. See NSW Therapeutic Advisory Group (TAG) Guideline for more information.
- A **single dose** of tocilizumab should **ONLY** be given to patients hospitalised with COVID-19 when baricitinib is not suitable. Tocilizumab should only be used in:
  - critically ill patients requiring direct admission to ICU for mechanical ventilation,
  - pregnant or breastfeeding women, children and adolescents requiring supplemental oxygen,
  - patients in whom administration of medications via the oral/nasogastric route is not possible.
- A second dose of tocilizumab is **NOT** to be routinely administered to patients who have received one dose.
- Tocilizumab should **NOT** be administered to patients that have already commenced or completed a course of baricitinib.
- Clinicians are to follow patient management advice for the registered indications of tocilizumab published in the joint statement from the Australian Rheumatology Association, Arthritis Australia and TGA to conserve stock.
- Sarilumab is an alternative interleukin-6 receptor blocker which can be used for patients with a current diagnosis of COVID-19 requiring invasive ventilation. This may be accessible via the Therapeutic Goods Administration's Special Access Scheme and NSW Health is attempting to secure stock for addition to the HealthShare NSW stockpile.
- Remdesivir is the only treatment for COVID-19 that has received provisional approval for use in Australia from the Therapeutic Goods Administration – all other treatments are considered 'off-label'. Remdesivir is readily available with no current concerns of any disruption to supply.
- Clinicians are reminded that correct procedures must be followed if there is an intention to use a medicine for any indication other than those listed in the TGA-approved product information.
- Remdesivir, baricitinib and limited tocilizumab supply for COVID-19 treatment must be ordered through the HealthShare NSW stockpile.

The recommendations in this Safety Alert align with the TGA Medicine Availability Working Group statement released on 6 August 2021 (available here).

Actions required by Local Health Districts/Networks

1. Distribute this Safety Alert to all relevant clinicians/committees immediately upon receipt.
2. Acknowledge receipt of this Safety Alert and confirm distribution within 24 hours.
3. Ensure that the local Drug and Therapeutics Committee monitors the use of tocilizumab in the treatment of COVID-19.
4. Escalate concerns that are not able to be managed locally to CEC-MedicationSafety@health.nsw.gov.au