WATAG
THERAPEUTICS ADVISORY GROUP

WACA
COMMITTEE FOR ANTIMICROBIALS

Position Statement

UPDATED 31/07/20

Pharmacological management of COVID 19

31st July 2020

The World Health Organisation has declared a global pandemic caused by the SARS-CoV-2 coronavirus. The resulting disease ("COVID-19") is characterised by a respiratory syndrome and can cause severe disease. The mainstay of therapy is supportive care. Currently there is limited robust evidence available for the specific treatment options that have been used for COVID-19 in addition to supportive care.

Remdesivir has been shown to reduce the time to recovery in hospitalised patients with SARS-CoV-2 related pneumonia requiring supplemental oxygen.[1] However, no benefit on mortality was demonstrated. On the basis of these data, the TGA has granted provisional approval[2] to remdesivir for the treatment of Coronavirus Disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older weighing at least 40kg) with pneumonia, requiring supplemental oxygen. Stock for use outside of a clinical trial can only be obtained from the Federal Government Department of Health on a patient-specific basis if the criteria listed here[3] are met. Clinicians wishing to obtain supply of TGA-registered remdesivir for a patient should contact their local Drugs and Therapeutics Committee, pharmacy department or infectious diseases team for advice as local procedures for procurement may vary.

There is an urgent need to collect comparative data on off-label investigational pharmacotherapy for the pre- or post-exposure prophylaxis or treatment of COVID-19 infections to inform the clinical management of patients infected with COVID-19. Furthermore, some of the pharmacological options currently being trialled internationally are used for established, TGA approved, evidence-based indications outside of COVID-19. Injudicious use or hoarding of these therapies could cause harm to patients and the health system.

For these reasons the WA Committee for Antimicrobials continues to recommend that any off-label prescribing of pharmacotherapy intended to treat or prevent COVID-19, should only be used as part of approved, randomised and controlled clinical trials. These trials should be coordinated in a state-wide approach. All medications used as part of a clinical trial should be procured as per the relevant trial protocol. It is acknowledged that this is a rapidly changing area.

Those wishing to seek guidance on specific pharmacological treatments or supportive therapies, including dexamethasone, should consult the Australian guidelines for the clinical care of people with COVID-19.[4] These guidelines are regularly updated and maintained by the National COVID-19 Clinical Evidence Taskforce.

WACA advice aligns with World Health Organisation (WHO)[5] and The Australian and New Zealand Intensive Care Society (ANZICS)[6], maintains the principles of antimicrobial stewardship and the safe and quality use of medicines. This also ensures any impact on patients already using off-label investigative therapies is minimal.

In the uncommon situation where a Drug and Therapeutics Committee does consider approving use of off label therapies to treat COVID-19 disease outside of a clinical trial, WACA recommends reference to the Council of Australian Therapeutics Advisory Groups (CATAG) 'Rethinking medicines decision making: Guiding principles for the quality use of off-label medicines'.[7]

Christopher Etherton-Beer
Chairperson
WA Therapeutic Advisory Group (WATAG)

Owen Robinson
Chairperson
WA Committee for Antimicrobials (WACA)

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2. https://www.tga.gov.au/media-release/australias-first-covid-treatment-approved
3. https://www.health.gov.au/sites/default/files/documents/2020/07/criteria-for-access-to-remdesivir-based-on-global-expanded-access-program_0.pdf
4. https://app.magicapp.org/#/guideline/4361
5. https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected
6. https://www.anzics.com.au/wp-content/uploads/2020/03/ANZICS-COVID-19-Guidelines-Version-1.pdf
7. http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf