Record of the COVID-19 Treatments Advisory Group Meeting held on 3 March 2022

The role of Advisory Groups and records of meetings

Note that this document is not necessarily a complete record of the COVID Treatments Advisory Group meeting; only the relevant portions of the meeting record relating to COVID Treatments Advisory Group discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

Conflicts of Interest are described and managed in accordance with section 7.2 of the PTAC Terms of Reference.

The COVID Treatments Advisory Group may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule; or

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule; or

(d) recommend that Pharmac discontinue funding of a pharmaceutical currently on the Pharmaceutical Schedule.

Advisory Groups give advice to Pharmac, including recommendations', based on the Groups' different, if complementary, roles, expertise, experience, and perspectives. Recommendations made by the COVID-19 treatments Advisory Group are in the context of COVID-19 treatments only. Pharmac is not bound to follow the recommendations made below.

The record of this Advisory Group meeting will be reviewed by PTAC at an upcoming meeting.

Attendance

Present
Jane Thomas
Tim Cutfield

1. Remdesivir access criteria

Proposal

1.1. The Advisory Group considered feedback and correspondence regarding the access criteria for remdesivir that had been implemented on 28 February 2022.

1.2. The Advisory Group took into account, where applicable, Pharmac's relevant decision-making criteria when considering this item.

Recommendation

1.3. The Advisory Group recommended that that the access criteria for remdesivir be temporarily updated as follows (changes in bold):

Initial application – any relevant practitioner Approvals valid for all applications meeting the following criteria:
All of the following:

1. Patient has confirmed (or probable) symptomatic COVID-19; and
2. Patient's symptoms started within the last 7 days; and
3. Any of the following:
   - 3.1. Immunocompromised individuals not expected to reliably mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection; or
   - 3.2. Patient is unvaccinated* and has **at least three** of the following: Aged 65 years or over, Māori or any Pacific ethnicity, or any of the comorbidities as listed below**; or
   - 3.3. Patient is vaccinated* and has **at least five** of the following: Aged 65 years or over, Māori or any Pacific ethnicity, or any of the comorbidities as listed below**; and
4. Either:
   - 4.1. Patient does not require supplemental oxygen (oxygen saturation >93%); or
   - 4.2. Patient does not require supplemental oxygen at saturations no lower than baseline for patients with chronic resting hypoxia; and
5. Not to be used in conjunction with other COVID-19 antiviral treatments; and
6. Treatment not to exceed five days.

Notes:
Treatment may be given in an inpatient or outpatient setting
* 'Vaccinated' defined as having received at least two vaccine doses more than seven days earlier.
** Comorbidities associated with a higher risk of severe outcomes are: severely immunocompromised, significant cardiac disease, uncontrolled hypertension, uncontrolled diabetes, chronic lung disease, chronic kidney disease, chronic liver disease, cancer, BMI 40 or higher. More detail available on the Ministry of Health website.

Discussion

1.4. The Advisory Group acknowledged again the particular impact of COVID-19 on Māori and Pacific people, older people, people who are immunocompromised, people with premorbid conditions (eg. lung disease, diabetes, heart disease, etc), and/or disabled people.

1.5. The Advisory Group noted that on the 28 of February 2022 the access criteria for remdesivir had been temporarily amended to facilitate wider access to remdesivir for the treatment of people with COVID-19. The Group noted that the access criteria for remdesivir would be reconsidered once oral antiviral treatments for COVID-19 were available.

1.6. The Advisory Group considered that there had been strong advocacy for access to remdesivir in the health sector, but that there was not sufficient capacity available to treat all the people with COVID-19 who would be eligible for remdesivir under the criteria implemented on 28 February 2022.

1.7. The Advisory Group discussed that the context of the outbreak of the Omicron variant of SARS-CoV-2 for the use of COVID-19 Treatments was different to the previous Delta variant outbreak, with a much larger number of people becoming infected but a much smaller proportion progressing to severe disease and requiring hospitalisation or ICU admission.

1.8. The Advisory Group considered that the access criteria for remdesivir should be similar to the proposed criteria for two oral COVID-19 treatments (nirmatrelvir with ritonavir and molnupiravir) currently being consulted on by Pharmac.

1.9. The Advisory Group considered that it would be important for remdesivir to be available to the patient groups identified in the 28 February 2022 criteria, including, people who are immunocompromised and not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection, people aged 65 years or over and people of Māori or any Pacific ethnicity and unvaccinated people.

1.10. The Advisory Group considered that risk factors for severe disease should be used to target remdesivir to the people within in these groups most likely to benefit from treatment.

1.11. The Advisory Group considered that the wording in criteria 3.2 and 3.3 referring to comorbidity should be amended to ensure it is clear that each individual comorbid medical condition would count as a separate risk factor for disease rather than being considered in aggregate.

1.12. The Advisory Group considered that as it is currently drafted, the number of people who would be eligible for remdesivir under the access criteria, in particular criterion 3.3, would far exceed the supply of remdesivir available.

1.13. The Advisory Group noted that age is the strongest indicator for risk of progression to severe disease and considered that unvaccinated people were another key group who could benefit from treatment with remdesivir.

1.14. The Advisory Group considered that Māori and Pacific ethnicity may be associated with and increased possibility of undiagnosed comorbidities, which if present would increase the risk of severe disease amongst these groups.

1.15. The Advisory Group considered that the number of comorbidities required for access to remdesivir should be increased to three comorbidities for people who have not been

vaccinated against COVID-19 and five comorbidities for people who have been vaccinated against COVID-19.

1.16. The Advisory Group considered it would be important to define the meaning of vaccination, and considered for the purpose of the access criteria the definition of vaccination used in the 28 February 2022 version of the access criteria was still applicable (two doses of vaccination against COVID-19 received more than 7 days earlier).