Record of the COVID-19 Treatments Advisory Group additional advice sought via email February 2022

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Following the Advisory Group's advice regarding nirmatrelvir with ritonavir in December 2021, the Group considered the recommended Special Authority criteria via email in February 2022. A summary of that advice is below:

The Group **recommended** the following Special Authority for nirmatrelvir with ritonavir and molnupiravir:

Special Authority for Subsidy
Initial application – from any relevant practitioner. Approvals valid for 2 weeks for 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 5 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 one of the following: Aged 65 years or over, Māori or any Pacific ethnicity, any comorbidity as listed below**; or
- 3.3. Patient is vaccinated* and has at least two of the following: Aged 65 years or over, Māori or any Pacific ethnicity, any comorbidity 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.

Notes:
* '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, history of smoking, BMI 40 or higher. More detail available on the Ministry of Health website

In making this recommendation:

1.1. The Committee noted updated evidence from the EPIC-HR trial and interim data from the EPIC-SR trial (Pfizer Media release. 2021; NCT04960202; NCT05011513). The Group noted that while there is no evidence to suggest that nirmatrelvir with ritonivir would not work in vaccinated individuals, they considered that the EPIC-SR evidence does not include enough detail to understand the utility of nirmatrelvir with ritonavir in the vaccinated population. Therefore, the Group considered that treatment should be targeted to those that the evidence supports would benefit most – ie. Unvaccinated individuals (with some exceptions, as detailed in the recommended SA criteria).

1.2. The Group noted that the number needed to treat to prevent one hospitalisation increases substantially with the inclusion of vaccinated individuals.

1.3. Members considered that high risk vaccinated patients are not categorically the same as high risk unvaccinated patients.

1.4. The Group noted that data remain limited and further consideration of the recommendations may be required in the future as the evidence evolves.

1.5. Members noted the NIH prioritisation of high risk patients and considered it reasonable to target tiers 1,2 and 3 for oral antiviral treatment, given currently secured stock volumes of molnupiravir and nirmatrelvir with ritonavir.

1.6. The Group noted the previous molnupiravir criteria recommendations made at the October 2021 meeting were made prior to the availability of full data, including the exclusion criteria for the clinical trial. Members noted that further relevant information now available is that vaccinated individuals were excluded from the trial.

1.7. The Group considered that it was appropriate to update the recommended Special Authority criteria for molnupiravir to be in line with those of nirmatrelvir with ritonavir, as both are oral antiviral COVID-19 treatments

1.8. The Group noted that as evidence continues to evolve, further consideration of these criteria may be required.