MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES COVID-19 Testing Technical Advisory Group

Date:	11 November 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Daniel Bernal, Darryl Carpenter, Mark Ayson, Cheriyse Hope, Kelsey Bilek, Ian Town
Guests:	Aoife Kenny, Steve Wakeling
Apologies:	David Murdoch

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all members and attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group. Minutes of the last meeting (28 October 2021) were accepted.
2.0	**Update on Open Actions** *Proper communication channels for iwi and other stakeholders* • Pacific peoples have been engaged, and a person appointed to be the point of contact. This action can now be closed. *Progress on review recommendations* • Progress continuing; nothing significant to update.
3.0	**Testing Strategy** • Thanks were given for feedback. This, along with feedback from others internally and externally, helped to significantly overhaul the testing strategy into its latest version. Key issues about the strategy raised in the previous meeting were felt to be resolved. The focus for this version was the overall purpose and testing categories, and prioritisation, with particular focus on asymptomatic testing. • It was noted that the ministerial deadline for the testing strategy is 22 November 2021. • MOH are seeking approval from CT-TAG to sign the testing strategy out. A question was raised about how to get this done in a timely manner. ○ CT-TAG members agreed to a discussion amongst themselves early next week, with David chairing. This was to determine their group feedback on the strategy.

	○ The next Testing Strategy will be submitted to the group by Tuesday 16 November • A survey is underway to get a community perspective with a major focus on equity. This will inform what follows the strategy after 22 November. ○ Action: The chair requested this survey to be shared with the group for their awareness Chair opened the floor for discussion. • A member noted that feedback had been captured in the new version of the strategy • A member noted that the situation in Auckland is critical; the laboratories are beyond capacity and need some level of prioritisation before adding more categories that will increase testing demand. ○ A member noted a key function of the strategy should be to offer flexibility and enable prioritisation. ○ A member noted the 22 November ministerial deadline didn't feel soon enough, in relation to prioritisation and reduction in non-essential testing particularly for the Auckland region. ○ It was noted by MOH that a meeting with NHRCC discussed immediate priorities for testing strategy. There have been some approvals made. ○ The MOH noted that a meeting is being organised with NHRCC to discuss supply and demand options. ○ Action: The chair requested that these recommendations are shared with the group for their awareness. • A member questioned traveller, MIQ, and education setting testing, and the extra demand this will place on testing and what was being planned in these areas. ○ There is work being done in the border workers group. • A member asked if there were any updates regarding incorporating prioritisation into eOrders. ○ It was noted the team had IT capacity to do this. ○ A member noted Sysmex had been working on doing this, but progress has been slow. ○ Members agreed finding a functional way of doing this was a priority. ○ Action: A member requested an update and a timeline for e-ordering. **Actions:** • Feedback on testing strategy will provided to MoH after a meeting of Testing TAG on 16th Nov
4.0	**Evaluation Framework** • It was noted that this was similar to the previous version. The main part addressed was item 13 (selection criteria) and how additional criteria would fit in. • A member noted that the evaluation group previously used (ESR) was not the appropriate one to use. ○ It was clarified that ESR are coordinating but not conducting. ○ A member noted involving two entities may cause delays. • A member stated they were unsure from the framework what the trigger point was for further evaluation of the POC test. ○ It was agreed this was subjective. ○ An explanation was given that it would be done by STA as they went through the criteria. ○ A member asked if a laboratory person would be involved in this. ○ MOH advised that a laboratory background wasn't required to make these decisions, just a clear set of criteria for someone with a health science background to use. • A member was concerned about flooding the NZ market with hundreds of different tests, which would cause confusion among the public. The member recommended a high threshold for approving a test. • A member noted the storage requirements for these tests could be an important inclusion criterion – whether the manufacturer can store these or not. Hospital storage is running low. • For 13b (integrating reporting infrastructure) a member noted this was incorrect because these were not laboratory-based tests.

	○ It was noted that there are two different measures combined into one point: does the test comply with NZ standards and can the provider or user integrate this into reporting system. • A member noted one criteria that should be included is deliverability (i.e. supply of the kit), which didn't appear to be on the criteria. ○ Adding this would eliminate some of the kits out of the 100 that need evaluation. • It was noted that there will be questions on why/why not we are including some RATs and not others. • A member addressed item 3 (authorisation to import, supply and/or use 3 RATs) as being too broad: ○ It was explained this was a public health order. • The member asked whether laboratories could order kits from MOH on a continuous basis or does this need to be publicly funded. ○ It was agreed the supply and distribution for labs needs to be discussed through the National Network meetings or directly with the MOH testing team. • It was noted that sensitivity depends on who the kit is evaluated on (if they're symptomatic, or if they just want to go to a large social gathering). ○ A member agreed and suggested the wording in 10a should be clarified to say the specific population being tested or context for appropriate utilisation. ○ It was noted that this was taken from the WHO EDCE. ○ A member suggested that a comment be made about interpreting the context of sensitivity and specificity in NZ. ○ It was noted the urgency to commence evaluation of the large number of submissions to import devices. The chair asked if the group supported this framework ○ The group agreed to endorse this framework, noting the additional comments from the CT TAG and ○ Action: MOH to provide some examples to the CT TAG of how they evaluate the first few devices and recommend context for use.
5.0	**Ministry of Health Position Statements** 5.1 Position on saliva as a diagnostic sample • MoH explained that saliva could not currently be used by ESR for WGS, so the wording in the position statement was updated to reflect this. • A member noted they believed the diagnostic and operational capacity and turn around times of saliva testing are two different things. ○ This is not necessarily obvious to the public at large. • In MIQ, daily testing has started with a push to encourage workers to take up saliva testing. • The group agreed to accept the saliva paper, with a caveat that we don't have capacity to use it to the same extent as nasopharyngeal swabs for RT-PCR. 5.2 Position on use of rapid antigen testing and programme roll-out • A member asked whether there was a plan for implementation by businesses, such as a checklist. ○ A member noted there should be a normal POCT implementation process for community roll-out i.e., process, framework, requirements, operations. • A member noted labs require RATs for contingency planning. There have been conflicting statements about which RATs can be ordered. • A member asked if this TAG is implementing RATs for the community and businesses. ○ It was noted that this would managed by the MoH Testing and Supply team • A member noted equity didn't seem to be demonstrated in the roll-out.

	○ These groups (iwi) have not been included in pilots. ○ The roadmap needs to think about those groups and demonstrate prioritising high-vulnerable groups. ○ A member noted the Ministry could work with the DHBs to include these groups. • The group acknowledges that work will continue in this area. • The chair acknowledged Ministry staff are working hard to pull all of this together and further work is required.
6.0	**Any Other Business** • A member noted that labs in Auckland are conducting contingency planning in case TATs increase dramatically, to enable testing of priority samples. However, prioritisation tools are currently limited, e.g., currently unable to prioritise symptomatic Māori/Pacific peoples in the community. More work is required for e-ordering to prioritise symptomatic testing.
7.0	**Agenda Items for Next Meeting** None noted
8.0	**New Action Items Raised During Meeting** • Provide CT-TAG with updated testing strategy for review and feedback before Tuesday 16 November
Meeting closed at **2:33pm** Next meeting **25 November 2021 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
5	Work in progress in response to rapid review	Provide clarity on the proper communication channels for Iwi and other stakeholders to inquire about testing.	Darryl Carpenter	
		Provide an update on progress on review recommendation	Steve Wakeling	

Document 2

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES COVID-19 Testing Technical Advisory Group

Date:	25 November 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	Maia Brewerton, Patricia Priest, Susan Morpeth
Ministry of Health Attendees:	Christina Bir, Daniel Bernal, Darryl Carpenter, Mark Ayson, Cheriyse Hope, Kelsey Bilek
Guests:	Erika Kuhn, Kirkpatrick Mariner (project manager equity team)
Apologies:	Ian Costello, Jon Herries, David Murdoch, Pisila Fanolua, Christian Marchello, Tim Blackmore, Ian Town

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all members and attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group. Minutes of the last meeting (11 November 2021) were accepted, subject to the following amendments: • New action items: Provide CT-TAG with updated testing strategy for review and feedback before Tuesday 16 ~~October~~ November. • A member noted that labs in Auckland are conducting contingency planning in case TATs increase dramatically, to enable testing of priority samples. However, orders enabled prioritisation tools are currently limited, e.g., currently unable to prioritise symptomatic Māori/Pacific peoples in the community. More work is required for e-ordering to prioritise symptomatic testing.
2.0	**Update on Open Actions** • Close action item 2.0 – proper community channels for iwi • Provide testing strategy to CT-TAG for review & feedback – closed (final strategy shared in this meeting) • Share COVID-19 Testing Strategy Community Engagement survey with group
2.1	**Final Testing Strategy** • A member asked where the assumption of 60,000 tests per day came from and whether this assumes nationally and PCR testing. It was clarified that the Auckland regional number was 35,000 tests per day.

	○ MoH: that standing capacity came from 2% positivity rate which required a 60k standing capacity. It also takes into account the available capacity across the network – technical capability that would be available. ○ The group encourages further engagement with national laboratory group around assumptions. **ACTION:** MoH to continue engagement with national network and let them know what's going on. If there's an action on this, MoH will report back to CT TAG to ensure that it's done. • A member asked whether there were timelines in place for the strategy to be updated, given that it was described as a living document. ○ MoH: a regular cycle of review is anticipated that is consistent with other engagements, particularly to incorporate innovative technologies. The surveillance strategy sits above the testing strategy. The review is set for March, with an interim review before then to ensure the framework is appropriate for pre- and post-Christmas. ○ A member advocated for a review before March 2022. • A member asked whether there is an organisational design of strategies and plans, noting who is responsible / inputting into the work. This could be especially helpful to collectively outline what the strategies are, how they relate to each other, and what the timelines are on each. **ACTION:** create a standing item in the agenda for CT TAG to identify any changes and input that may be required for the testing strategy.
3.0	**Prioritisation via IT upgrades** • MoH: A line is being built into the LIZ registration screen that will give the ability to prioritise some tests. • Clinical advisors and lab IT team were consulted to develop these criteria. Factors to determine priority are the surv codes, are they close contact, are they in an isolating household, have had positive test in last 3 months? • Working with operational groups on the ground to address these tests for visual / physical cue i.e., stickers. However, ethnicity or other socio-demographic factors aren't currently reported in the priority criteria. Working with Kirk to ensure equitable outcomes in product design, but ultimately this will help with the prioritization. Will incorporate this on Friday and will go live first as a pilot with Waitemata and counties Manukau ○ A member asked why ethnicity is not included in prioritisation, highlighting its importance in ensuring an equitable approach. ○ MoH: E-swab ordering cannot incorporate ethnicity easily. Incorporating it into the e-ordering is technically very difficult at present and would result in a considerable delay to the roll-out of the revised e-ordering. Another option is to copy ethnicity information from a person's NHI. Incorporating ethnicity into the e-ordering form will be in the next phase of prioritisation development and will take approximately 4-6 weeks. ○ A member urged this to be done urgently rather than waiting for the next phase since there is no equity lens if these groups are not prioritised. ○ A member countered that any priority system will improve equity, even without ethnicity data, since the only way laboratories can prioritise currently is to manually prioritise hospital testing and that of close or household contacts. Community testing is not prioritised; many tests in this group are non-urgent, but they also include tests from Māori and Pacific people who are symptomatic. Prioritising symptomatic testing will also improve equity. • A member urged the Ministry to use NHI for ethnicity as this is generally more accurate than other processes. • A member asked whether this prioritisation plan will be national

	○ Prioritization system will ultimately be national. Most community testing centres and popup testing centres are on the e-ordering system. However, not all GPs are on the system. There are constraints with labs not using Delphic but working with them. • The Chair invites Erika Kuhn to feedback in future meetings and provide an overview of how they're addressing equity gaps nationally.
4.0	**Equity (introduction of new point of contact at MOH and community engagement)** • Kirk Mariner was introduced as the new point of contact • MoH: the aim is ensuring engagement and that a voice is coming through to the present equity lens. There are pockets within testing supply that address and implement equity well, and it's important to ensure to the COVID-19 directorate is linked up across the system to ensure equity as well. ○ A concern is that sometimes things are done so fast that equity is not possible. ○ Currently working on setting up engagement process for Māori, Pasifika, disability, and other priority populations so that they can be both key contributors and designers of the solutions.
5.0	**Operationalising selection criteria** • MoH: There is a specific item in Criteria #2 on test sensitivity that would be quite a limiting factor for selecting appropriate tests. Further, it's unlikely that independent clinical studies will meet that threshold. Most manufacturers are claiming sensitivity of 95%+ but in the real world, sensitivity is unlikely to be that high. There is a concern that the three kits already approved would not meet these criteria. ○ The Group suggested to re-word the criteria. Devices should have to meet the sensitivity/specificity thresholds following WHO guidelines. There need to be independent validation studies measuring sensitivity and specificity in addition to the manufacturers' claims. The Group raised the concern that if we don't include the WHO guidelines in the selection criteria, the NZ market will be flooded with too many RATs. • Note that the criteria outlines selection criteria for point of care tests (POCTs), as not all point of care tests are RATs. There were over 200 applications, which have been screened. The majority were RATs but there were also some antibody and rapid PCR tests. • A member noted that we urgently need point-of-care style rapid tests available, because of shortage of GeneXpert. The STA will begin reviewing rapid molecular tests. **ACTION:** MoH Testing Operations to share the RAT roll out plan with CT-TAG
5.1	**Horizon scanning/innovation intel report** • MoH: The Science and Technical Advisory team will be meeting fortnightly with a consultancy. The first meeting has just taken place but did not explore testing modalities in detail. • This is the first report that the consultancy has completed. They can conduct ad hoc requests aside from the fortnightly presentations and could look into rapid PCR tests at our request. • These reports will be released regularly and won't be included in the agenda but sent out as the Group wants. Note that the terms of the contractual arrangement with the consultancy means that while the information can be shared with the Testing TAG, it cannot be disseminated more widely. • A member asked why the US and UK were chosen as countries in the report. ○ MoH: these countries were chosen because they had extensive RAT strategies. For the next report, we have asked to see countries with similar strategies to NZ next e.g., Australia, Singapore, Taiwan. We would like more feedback on innovation on two tiers: one focussed on the future and another focussed on places that are especially innovative. ○ Member: There are two ways of being innovative: innovative tests and then innovative strategies. • In a higher prevalence environment, a PCR test may not be required following a positive result on a RAT. • A member asked what is meant by "decent" prevalence? What is that benchmark?

	• A member highlighted there are situations where the pre-test probability is high enough right now (e.g. households with one person infected and the other household members become unwell) where a positive result on a RAT doesn't need a confirmatory PCR test. • A member noted that there will be confusion among the public about whether positive RATs need to be confirmed with a PCR test. The MOH will need to give guidance on this.
6.0	**Recommendation #2 of Rapid review: strengthening leadership capacity and capability** • Testing Ops has opened a new position of Chief Testing Advisor and are progressing with recruitment. A significant amount of work is currently happening with the lab capacity regarding prioritisation and prevalence.
7.0	**Any Other Business** • Continue conversations about rollout of RATs
8.0	**Agenda Items for Next Meeting** • Testing strategy (standing item)
9.0	**New Action Items Raised During Meeting** • Share COVID-19 Testing Strategy Community Engagement survey with CT-TAG • MoH Testing Operations to share the RAT roll out plan with CT-TAG
Meeting closed at **2:37pm** Next meeting **25 November 2021 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
2	Testing Strategy	Share COVID-19 Testing Strategy Community Engagement survey with CT-TAG	Science & Insights	
3	Operationalising selection criteria	Share the RAT roll out plan with CT-TAG	Testing Operations	

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
5	Work in progress in response to rapid review	Provide clarity on the proper communication channels for Iwi and other stakeholders to inquire about testing.	Darryl Carpenter	
		Provide an update on progress on review recommendation	Steve Wakeling	
2	Testing Strategy	Provide testing strategy to CT-TAG for review & feedback	Science & Insights	

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 14 January 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Tim Cutfield
Attendees:	Andi Shirtcliffe, Anne Buckley, Derek Fitzgerald, Josh Wiles, Phoebe Currie
Guests:	Adrienne Martin
Apologies:	Susan Morpeth, Andrew Oliver, Daniel Bernal, Justine Lancaster, Ian Town, Mark Ayson, Therese Egan

1.0 Welcome and Accept Previous Minutes

Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group.

Minutes of the last meeting (10 December 2021) were accepted, subject to the following amendments on item 5.0 Paediatric Update (in red).

A paediatric update was provided, including Starship experience of the current Delta outbreak in Auckland.

- The Starship paediatric guideline *Covid-19 Disease in Children* is found here

  It continues to be monitored and updated. There is close liaison with colleagues in Sydney and at the Royal Children's' Hospital in Melbourne, both centres having more COVID-19 cases in children than seen in NZ to date. The guidelines include content on dexamethasone, remdesivir, tocilizumab, as well as a statement noting that there is no evidence to support the use of inhaled budesonide for community management of COVID-19 in children, however evidence regarding the use of inhaled steroids in high-risk children is under active ongoing review.

- The Royal Children's Hospital in Melbourne has developed a treatment pathway which includes sotrovimab & also management of Paediatric Inflammatory Multisystem Syndrome ~~(PIMS).~~ - Temporally associated with SARS-CoV-2 / Multisystem Inflammatory Syndrome of Children (PIMS-TS / MIS-C).

- Starship has developed a local PIMS guideline, drawing on local expertise / experience from multiple paediatric specialities (paeds ID, rheumatology, cardiology, ICU) and international clinical practice guidelines. It can be accessed here.

	Matters arising: • There were no matters arising.
2.0	**Therapeutics** **Pharmac Update** • COVID-19 Treatments Advisory Group meeting record from October has been published and is available on the Pharmac website. The meeting record for the December meeting is being finalised. The group is considering access criteria for a number of treatments. • Consultation on the Pharmac proposal on access criteria for two COVID-19 treatments (baricitinib and casirivimab/imdevimab) closed on Wednesday 12 January 2022. Pharmac is now working through feedback; themes so far include ensuring equity of access, other groups that might benefit, requirements for serology testing. • Pharmac has secured more stock of baricitinib and remdesivir which is currently in transit to Aotearoa New Zealand. • Pharmac is aware that oral antivirals (molnupiravir and Paxlovid) are anticipated and will release consultation on access criteria for these as well, aiming to provide as much time as possible for preparation as to how these might be administered. Tocilizumab • Pharmac has purchased a one-off supply of subcutaneous tocilizumab, which has been distributed to 9 DHBs across the country, alongside guidance on administration. Subcutaneous tocilizumab does not have regulatory approval. DHBs are able to decide how to use the medicine. Funding is in line with IV tocilizumab. • Pharmac released some IV tocilizumab stock to DHBs prior to Christmas, is working on resupply and continues to monitor usage. **Discussion** • A member asked about the estimated time of arrival for molnupiravir and Paxlovid. Pharmac noted that they need to go through the Medsafe approval process. Current expectations are that they may arrive in New Zealand in the coming months. • A member raised a question about potential supply of sotrovimab. Pharmac advised they are aware of increasing global demand and hope to achieve progress with GSK about NZ supply early this year. **Medsafe Update** • Medsafe facilitates applications and application pathways. Medsafe is reliant on companies making applications and responding to information requests to progress the approval process. • Molnupiravir – Merck have not submitted an application to Medsafe for molnupiravir. Medsafe are expecting to receive an application in February. US FDA have given molnupiravir an emergency use authorization (EUA). • Casirivimab/imdevimab (Ronapreve) was approved by Medsafe in December 2021- the first of the completely new medicines to be approved for treatment of COVID-19 in Aotearoa New Zealand. • Paxlovid – Medsafe is assessing information provided by Pfizer in response to questions. Pfizer is releasing ongoing clinical information. US FDA have given Paxlovid an EUA.

	• Remdesivir – Medsafe have almost finished the initial evaluation process. **Discussion** • Baricitinib: A member raised a question about the status of baricitinib. It was noted that baricitinib is not approved and no application from Eli Lily has been received by Medsafe. Pharmac noted that their understanding is that Eli Lily do not intend to make an application to Medsafe for approval. Supply was at Pharmac's request as an alternative to tocilizumab. • A member raised a question regarding the use of baricitinib. It was noted that currently it can be used under exceptional circumstances, and (pending access criteria) from 01 February 2022 it can be used via the standard section 29 processes. • A member raised a question regarding the Roche application for Ronapreve and dosing in hospitalised adults. Medsafe have approved what Roche applied for in the original application. **Airfinity/STA Update** • As requested previously, STA provided a summary of key reporting from Airfinity (7 January 2022) on therapeutics as well as an excerpt taken from a more comprehensive document 'Science and Technical Advisory Omicron Update, 11 January 2022'. Key content from the updates included: o US NIH changes to their guidance which included Paxlovid being the preferred outpatient treatment. o Several neutralisation studies showing Omicron resistance to Ronapreve. • A member raised a question regarding the definition of disease severity used in data reported in the Airfinity summary (slide: Overview of current approved COVID-19 treatment candidates and their status in the UK, EU & US). STA will provide clarification following review.
3.0	**Equity Considerations** • A member noted that equity feedback on Ronapreve has already been provided but emphasised that the idea of a therapeutics/administration centre as a general concept could be beneficial and it is likely that colleagues in Pacific health would be involved. • A member raised a question regarding the supply of remdesivir and whether it would be made available in the community, as the initial criteria was around hospital use. It was noted that National Institutes of Health (NIH) have recommended that remdesivir could be used as a treatment for non-hospitalised patients with COVID-19 who are at high risk of progressing to severe disease. Pharmac noted that the Special Authority criteria for remdesivir has yet to be finalised.
4.0	**Guideline Update** • The next planned update is 21 January 2022. The group met during the week and discussed a number of issues. Significant changes are not expected for the coming update. The draft 21 January update is currently being reviewed by the group. • Casirivimab + imdevimab (Ronapreve) - not included in the 21 January update as Pharmac access criteria yet to be finalised. Noted that the group provided a submission to the Pharmac consultation on baricitinib and Ronapreve which closed 12 January 2022. See 5.0 for further discussion on the submission. • Remdesivir - The group noted the PINETREE study definition of high risk is similar but different to studies for access to monoclonals. The group agreed that it is sensible to align a common definition of high risk, to simplify for the practitioner. Further discussion may be needed on this for future guideline updates.

	• The group noted that the guideline's definitions of mild, moderate and severe disease are slightly different to those used in some other guidelines. Noting as a group – no changes deemed necessary at this point. **Tocilizumab** • There was discussion about subcutaneous tocilizumab. It was noted that for COVID-19 treatment, IV tocilizumab was preferred and that converting subcutaneous tocilizumab for IV use is practically challenging and there is potential for error resulting in dose reduction. It was noted that the company have provided guidance on this process, but it was suggested by a member that the technical aspects prohibited its ready use in busy clinical environments. • Some members expressed the view that the clinical priority for use would be IV tocilizumab as preferred treatment, with baricitinib as an alternative. It was noted that this is the preference the group have signalled previously in meeting discussions. Subcutaneous tocilizumab was suggested for treatment of acute or critical covid and reserved for when neither IV or baricitinib are available and suitable for use (e.g., a person has contraindications for use of baricitinib). • A member suggested that it would be helpful to have further information on the stability of tocilizumab after conversion from subcutaneous to IV. Information on stability (how long the treatment is viable for) could inform other suggestions, such as possible use of a centralised centre/s completing the conversion required which could decrease pressure on clinical staff and the likelihood of errors.
5.0	**Pharmac Consultation Feedback** • The group submitted feedback to the Pharmac consultation proposal on access criteria for two COVID-19 treatments (baricitinib and casirivimab/imdevimab). • The baricitinib section of the submission largely noted that the eligibility criteria are mostly similar to the current guideline, the only difference being that the submission recommendation does not require raised inflammatory markers. • It was noted that the baricitinib access criteria for Pharmac matched tocilizumab criteria; and that there is a discrepancy regarding eligibility for tocilizumab between the criteria and the recommendations in the guidelines from this group. This will be reviewed once the access criteria are finalised. • The casirivimab/imdevimab (Ronapreve) section of the submission outlines several competing treatment tensions including: o the lifespan of usefulness is potentially limited due to the likelihood of an Omicron outbreak and the evidence suggesting Ronapreve does not neutralise Omicron. o there could be positive impacts for a large number of people in the community who could be eligible, however, the opportunity costs are large (e.g., redirecting limited health resources). o demands on serology also produce a competing priority for laboratories processing PCR tests to monitor the pandemic. **Discussion/Feedback** • The group noted that the likelihood of an Omicron outbreak adds complexity to the treatment situation and that it would be helpful to have a timeframe for when treatments are expected to arrive. Ronapreve

	• From an equity perspective it was noted that the timeline for an Omicron outbreak is unknown, however the Delta outbreak is continuing and using Ronapreve now could be beneficial. Māori and Pacific people have high case numbers of COVID-19, on top of the burden of comorbidities and deprivation. Any support that can be provided would be positive, however it is understood that there are logistical challenges. • Feedback was provided by a member from some Pacific medical practitioners in Auckland who commented that among the Pacific community there is a high double vaccination rate (with the caveat of immunocompromised and those who have not produced a good immune response). It was felt that establishment and resourcing of Ronapreve clinics in the community could be very challenging and not as beneficial once Omicron is in the community. • It was noted that: o There is work underway within the Ministry in relation to community use of therapeutics and further coordination and communication is expected in the coming weeks. o Demand for quick WGS to enable administration of Ronapreve in a timely manner also presents an equity issue due to processing times. o Setting up clinics and using Ronapreve now would be an opportunity to benefit patients and could also provide the logistical framework for administering other treatments in the future. o Ronapreve could be used in hospital quite quickly, however if there is not a system for an equivalent use in the community, this could present a dilemma for clinicians, with hospital admission needed for patient access to the treatment. o Once the final access criteria are released, further work may be needed to determine who should get the medicine and how. The group felt that the Therapeutics TAG could contribute to this discussion, but others, including primary care and rural hospitals are essential to the discussion/planning.
6.0	**Timeline for Oral Antivirals – Community** o It was noted that there is increasing global demand for Paxlovid and that the current timeline estimated by Pharmac for arrival in Aotearoa New Zealand is April 2022.
7.0	**Next Steps/Decisions Pending** • Guideline update planned for 21 January 2022.
8.0	**Any Other Business** • An attendee suggested that improved connections with the Ministry COVID Care in the Community team could assist their planning, particularly detailed discussion of when therapeutics might be expected. • A member noted that therapeutics and testing strategies need to be considered together, given efficacy is greatest when treatments are given early. Also, that testing strategies may change during the anticipated Omicron outbreak with greater use of rapid antigen tests rather than PCR confirmation.
9.0	**Agenda Items for Next Meeting** COVID Care in the Community team update
10.0	**New Action Items Raised During Meeting** STA to provide clarification on Airfinity slide data with respect to source of definitions of severity.

Meeting closed at **2:39pm**

Next meeting **28 January 2022 – 1:30pm to 2:30pm**

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Next update 21/01/22
18	Ronapreve – 'Position Statement'	10/12/21 Document to support use of Ronapreve in the community - to be developed in early 2022.	TBC	10/12 Action raised
19	Airfinity Update	STA to provide clarification on Airfinity slide data with respect to source of definitions of severity.	STA	14/01/2022 - Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
17	Equity Considerations	STA to circulate summary feedback from Pacific Pharmacist Group to Ministry (Pharmacy team).	STA	26/11 – Action raised 5/12/2021 Pacific Pharmacists' Assoc. feedback circulated to Ministry Clinical Pharmacy Lead and relevant others on Therapeutics TAG. 21/12/2021 Feedback document updated with

				additional context & recirculated. 21/12/2021 Action closed.

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 10 December 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Daniel Bernal, Derek Fitzgerald, Justine Lancaster, Josh Wiles, Ian Town, Mark Ayson, Phoebe Currie
Guests:	Therese Egan; Rachel Webb
Apologies:	Saleimoa Sami, Adrienne Martin

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (26 November 2021) were accepted. **Matters arising:** • There were no matters arising. The Chair thanked the group for their work during the year and noted their important contribution to the COVID-19 Response, including the ongoing work on the guideline Clinical Management of COVID-19 in Hospitalised Adults.
2.0	**Therapeutics** **Pharmac Update** • The Pharmac COVID-19 Treatments Advisory Group is meeting on 13 December with discussion planned on eligibility criteria for Ronapreve, other monoclonal antibodies from AstraZeneca and Celltrion, Pfizer's oral antiviral and remdesivir. • Baricitinib has been distributed to DHBs and ongoing supply is being progressed. • Additional supply of remdesivir is to be secured to meet potential need if access criteria changes. • Ronapreve – following initial supply early 2022, an additional supply is expected mid-year of a further 7,500 doses.

	• Pharmac is in ongoing discussions with various suppliers. Pharmac has negotiated an agreement for 60,000 courses of Pfizer's new oral antiviral protease-inhibitor treatment Paxlovid (nirmatrelvir+ritonavir). **Medsafe Update** • Medsafe provided an update on approval processes following receipt of an application from a drug company. • Ronapreve – Medsafe is currently assessing additional information the company has provided on request from Medsafe. • Paxlovid – Medsafe has received an application from the company and an initial assessment has been completed. Additional information has been requested from the company. • Remdesivir is under assessment by Medsafe. • Molnupiravir - Medsafe has not yet received an application from the manufacturer. **Airfinity/STA Update** • STA provided a summary of key reporting from Airfinity (3 December) on therapeutics, including content on molnupiravir, a list of recent papers, and the impact of Omicron and therapeutics. Feedback within the meeting was that both the content selection and length were appropriate for ongoing regular updates via the meeting from STA. • STA reported that there was a media briefing today (10 December) regarding therapeutics including mention of the Therapeutics TAG. The briefing was led by Ashley Bloomfield (DG, Ministry), Ian Town (Chief Science Advisor, Ministry) and Sarah Fitt (CEO Pharmac). The briefing can be found here.
3.0	**Equity considerations** • A document 'Wai 2477 Te Ora case' was circulated with the agenda for discussion. A member gave an update regarding this document and outlined key equity issues for discussion. The document has key statements about the Māori population in NZ that the NZ Māori Council identify as important: • [Māori] *are a younger, more mobile and socially active community with high essential worker status that dictate that we will be more likely to be in contact with COVID 19* • [Māori] *are an undervaccinated population and therefore more likely to be infected when exposed and to get sick* • [Māori] *have an 'older population who are more unwell' and therefore more likely to get very ill and/or die* • [Māori] *have a population who are generally more marginalised from various aspects of care and therefore harder to diagnose, contact trace and treat"* • It was noted that it is important to link these considerations to the mahi the Therapeutics TAG is doing, particularly what can be done to ensure that Māori have equitable access to therapeutics in the community. • Equity issues such as those mentioned above should be considered when developing eligibility criteria for therapeutics and modelling to support delivery of therapeutics. • It is important to have good information available about any therapeutics that are to be used in the community. For example, it would be beneficial to give information to Māori

	providers to disseminate, wananga or socialise, to increase understanding of what treatments are available and the reasons for engaging with treatment provision. **Discussion** • A member raised the importance of testing and case identification, given the short period post-onset in which many therapeutics offer effective treatment. The group agreed this was an integral equity consideration. • A member noted that a positive COVID-19 diagnosis in NZ currently carries a lot of stigma and that the group may have a role in reducing this stigma. Another member suggested that a video of whanau with 'lived experience' of COVID-19 could be a useful tool to reduce stigma. • The issue of potential treatment hesitancy in NZ was raised. Recent research in the USA included in the Airfinity summary information provided by STA showed that treatment hesitancy and vaccine hesitancy were not linked there. The group discussed the need to provide information for people who may be uncertain about treatments and require more certainty before engaging. • The group agreed it is important to increase health literacy about COVID-19, particularly when new treatments become available in the community. • It was noted that the Ministry is progressing work on misinformation and disinformation relating to vaccines which could be built on. The group agreed that misinformation about treatments could be a topic for discussion in the future. The Chair noted that it is important the group incorporates learnings from the vaccine programme and Waitangi Tribunal case into the Therapeutics TAG work.
4.0	**Guideline Update** • An update of the guideline was published on 3 December 2021 and is available here. • The update included a change to the layout of the immunomodulatory therapeutics section for moderate COVID-19 to indicate the preference for tocilizumab. • Preparation of content on Ronapreve for inclusion will be addressed once eligibility criteria are finalised by Pharmac. • The next planned update is 21 January 2022.
5.0	**Paediatric Update** A paediatric update was provided, including Starship experience of the current Delta outbreak in Auckland. • The Starship paediatric guideline *Covid-19 Disease in Children* is found here It continues to be monitored and updated. There is close liaison with colleagues in Sydney and at the Royal Childrens' Hospital in Melbourne, both centres having more COVID-19 cases in children than seen in NZ to date. The guidelines include content on dexamethasone, remdesivir, tocilizumab, as well as a statement noting that there is no evidence to support the use of inhaled budesonide for community management of COVID-19 in children. • The Royal Childrens' Hospital in Melbourne has developed a treatment pathway which includes sotrovimab & also management of Paediatric Inflammatory Multisystem Syndrome (PIMS). **Discussion**

	• There was discussion about the management of PIMS. At Starship an operational process has been established to enable multi-disciplinary discussion of suspected cases and there has been discussion with Pharmac regarding access to anakinra. • The group noted that it is likely significant numbers of PIMS would only be seen if there was high community transmission. • It was noted that there are central hubs where more advanced immunomodulation therapy is available. DHBs have stock of infliximab as an alternative therapeutic to anakinra, since this is used for other indications including rheumatoid arthritis and inflammatory bowel disease. A member commented that the shorter half-life of anakinra was why it was preferred in some overseas centres for PIMS.
6.0	**'Stocktake' of 2021 & focus for early 2022** Members discussed the work done this year and suggested areas of focus for early 2022. • A member noted that as already identified, equity is an ongoing focus. It was noted that equity can be considered by Pharmac in relation to criteria for access to each therapeutic; consideration in planning for delivery was also noted as very important from an equity perspective. • A member suggested the group maintain the link between testing and therapeutics, which will be increasingly important in first quarter of 2022 as more COVID-19 therapeutics become available including potential community use. • It was noted that as evidence emerges, the Ministry is progressing work exploring and planning community delivery of treatments. Guidance from this group may be required. It could be helpful to have position statements on treatments to support this work. • The group agreed that a position statement on Ronapreve would be helpful, particularly to consider the degree of immunosuppression and who needs to be prioritised. ACTION: Group to develop a position statement regarding the use of Ronapreve in the community following release of Pharmac eligibility criteria. • Members discussed the need for strategic thinking about the different therapeutics available and the need to evaluate the opportunity costs and practicalities, and risks and benefits of them as a group. • Members discussed the issue of potential drug-drug interactions with ritonavir (included in Paxlovid) and agreed that this is likely to need further consideration by the group in 2022 as this treatment becomes available. The STA Manager, on behalf of the Ministry, thanked the Therapeutics TAG for all of their work in 2021.
7.0	**Action Items Raised During Meeting** • A position statement on the use of Ronapreve in the community is to be developed in early 2022.
Meeting closed at **2:40pm** Next meeting **14 January 2022 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates

5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinb Guideline update published 3/12/21 Next update 21/01/22
17	Equity Considerations	STA to circulate summary feedback from Pacific Pharmacist Group to Ministry (Pharmacy team).	STA	26/11 – Action raised
18	Ronapreve – 'Position Statement'	10/12/21 Document to support use of Ronapreve in the community - to be developed in early 2022.	TBC	10/12 Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
16	STA/Airfinity Update	STA to provide key points of the Airfinity therapeutics surveillance information to Therapeutics TAG via scheduled meetings.	STA	26/11 – Action raised Summary Airfinity content provided 3/12/21 and will be provided to future meetings in a similar format. 3/12/21 Action closed.

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 26 November 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andrew Oliver, Adrienne Martin, Anne Buckley, Daniel Bernal, Derek Fitzgerald, Justine Lancaster, Josh Wiles, Mark Ayson, Phoebe Currie
Guests:	Adrienne Martin
Apologies:	Ian Town; Andi Shirtcliffe, Therese Egan

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (12 November 2021) were accepted. **Matters arising:** • There were no matters arising.
2.0	**Therapeutics** **Pharmac Update** • Baricitinib stock has arrived in country & has been distributed to several DHBs. Baricitinib is an unapproved medicine. Noted that the guideline does not currently indicate use is under Section 29. Requested be included in next update. • Pharmac is in discussions with multiple suppliers regarding different treatments, including with Pfizer and AstraZeneca. • Ronapreve: S9(2)(f)(iv) [redacted]

	There was an initial discussion about the draft criteria, including hospitalised patients and a specific group of community patients, but it was noted that this was confidential until the records are published. There will an opportunity for wider consultation on the criteria. This consultation typically identifies broader issues and practical matters eg. relating to delivery or serology testing, to be considered prior to the funding decision being made. Discussion • Members noted that if criteria include a requirement for serology testing in hospital patients this would increase pressure on the laboratory system. • Serology turnaround times are variable around the country. Provincial hospitals access to serology testing and turnaround times vary markedly compared to large metro hospitals and a member suggested this needs to be taken into account in the criteria. • Members noted that there needs to be a clear definition for immunosuppression/'severely immunocompromised'. An example is the criteria used to define immunosuppression for those recruited into the REMAP-CAP trial. **Medsafe Update** • Three products are under assessment – Ronapreve, remdesivir, Paxlovid. • Applications for molnupiravir and Evusheld have not been received yet. **Airfinity/STA Update** • STA provided an update on the Airfinity therapeutic surveillance information. • Airfinity provide fortnightly updates to STA on therapeutics in response to parameters set by STA as well as information on any specific questions asked. • STA can also summarise primary research for specific agents or request this information from Airfinity • The group noted that the amount of information is significant. A summary or indication of important points/new developments would be useful. ACTION: STA to provide key points of the Airfinity therapeutics surveillance information to Therapeutics TAG meetings.
3.0	**Equity considerations** • An update on the CAG group was requested – this is working on models of care for the community. Several people from within that group have expressed a willingness to liaise with Therapeutics TAG regarding practical considerations and primary care therapeutic management as needed. • The Therapeutics TAG noted the importance of having the infrastructure in place in the community to deliver treatments equitably, for Ronapreve or for other treatments going forward. • Eligibility criteria for medicines, including Ronapreve, need to be considered from an equity perspective. As noted in earlier discussion on Ronapreve, there are equity considerations regarding the geographic differences in serology testing turnaround time. • The Pacific Pharmacist group have provided feedback in response to engagement from the Therapeutics TAG via our Pacific representative.

	○ The group have reviewed the current Guideline and had no specific concerns or ideas but indicated they will have more to contribute as more treatments become available in the community. ○ General comments shared from the group included that better communication with community clinical pharmacists is required regarding notification of COVID-19 cases and dispensing of their medications. There is currently no standardised process notifying patients' pharmacist of a positive case. • It was noted that the Ministry is actively working on the Pharmacy primary care clinical model – mentioned in the meeting of 12 November with a draft document circulated to the group. ACTION – STA to circulate summary feedback from Pacific Pharmacist Group to Ministry (Pharmacy team).
4.0	**Guideline Update** • Latest Guideline Update was published on 22 November 2021 and included guidance on baricitinib use. Available here. • The Guideline subgroup were thanked for their ongoing input. It was acknowledged that the work of international guidelines in reviewing evidence greatly assisted the process of rapid updating. Of note - newer agents could potentially be available for use in NZ before they are included in international guidelines. • Next planned update is 03 December 2021 To be included: ○ Note that use of baricitinib is under Section 29 ○ Clarification points noted from subgroup feedback re. anticoagulation **Hospital use of Ronapreve – for inclusion in a future update** • This will be included in a coming guideline update to coincide with supply expected. Not planned for this update as supply not expected now before January. **Serology testing** An update on serology testing was included in this section as it has relevance to potential hospital use of Ronapreve. • The document 'CoV2 serology TAT summary for Therapeutics TAG from NZMN' was circulated with the agenda to inform discussion. • The document provides an update on the availability and turnaround time of SARS CoV-2 serology testing around NZ, current as at 15 November 2021. • The information was shared with the Therapeutics TAG by Dr Susan Morpeth, Chair of the NZ Microbiology Network (NZMN) and member of the group. • There are some parts of the country that are likely to have slow (inadequate) turnaround times for serology testing if required prior to initiating Ronapreve treatment. • Some labs have indicated they could expand their serology testing service, however a signal of the number of tests required would be needed for that to be considered. • Upscaling serology testing would put additional capacity pressure on the same labs and lab staff who are already increasing PCR testing capacity.

	• Potential delays in access to Ronapreve treatment and pressure on lab capacity are potential consequences of a serology testing requirement as part of the criteria for treatment with Ronapreve.
5.0	**Community use of Ronapreve** • The group noted that there would need to be a planned, collaborative approach to successfully roll out treatment in the community. • Information such as the NNT (number needed to treat) for specific patient groups would be helpful for planning & mobilising the system. There is a need to identify the population to target for service delivery. • From an equity perspective, a member suggested that if Ronapreve is available for community use, Māori, Pacific, and rural communities should have access to the treatment. • There was discussion regarding other treatments potentially being better suited for use in the community once available, such as sotrovimab, as given as an intramuscular injection. • There was further discussion regarding eligibility criteria for treatment and the different factors involved.
6.0	**Action Items Raised During Meeting** ACTION: STA to provide key points of the Airfinity therapeutics surveillance information to Therapeutics TAG via scheduled meetings. ACTION: STA to circulate summary feedback from Pacific Pharmacist Group to Ministry (Pharmacy team).
Meeting closed at **2:45pm** Next meeting **Friday 10 December 2021 – 1:30pm – 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply.	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinb Next update 03/12/21
16	STA/Airfinity Update	STA to provide key points of the Airfinity therapeutics surveillance information to	STA	26/11 – Action raised

		Therapeutics TAG via scheduled meetings.		
17	Equity Considerations	STA to circulate summary feedback from Pacific Pharmacist Group to Ministry (Pharmacy team).	STA	26/11 – Action raised

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 12 November 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Saleimoa Sami, Susan Morpeth
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Daniel Bernal, Derek Fitzgerald, Ian Town, Justine Lancaster, Josh Wiles, Phoebe Currie
Guests:	Therese Egan, Adrienne Martin
Apologies:	Michael Maze, Tim Cutfield, Mark Ayson,

1.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (29 October 2021) were accepted. **Matters arising:** • There were no matters arising.
2.0	**Update on Open Actions** The Chair invited comments but noted that most open actions would be discussed within the agenda. • The Therapeutic Technical Advisory Group Position Statement on Budesonide Use in COVID-19 was published on 29 October 2021. Link available here. Some feedback was received on paediatric use and whether the trial data could be extrapolated further to include children. The Chair noted that Starship are distributing advice nationally and suggested such feedback (received via STA) be directed to Starship advice and guidelines.
3.0	**Therapeutics** **Pharmac and Medsafe Updates** Pharmac Update

- Tocilizumab - closely monitoring stock with Roche and expecting January resupply. Working to get additional stock, either IV or SC - both are being used overseas. Pharmac will provide an update on whether any additional supply likely to be IV or SC.
- Baricitinib – stock may be received by end of November 2021. Sourced 500 treatment courses and working with supplier to source long term.
- Casirivimab + imdevimab (Ronapreve) – no update to provide. Expecting the advice from the Pharmac COVID Treatments Advisory Group to be out by next week.
- Pfizer antiviral – in discussions with Pfizer to negotiate an advance purchase agreement.
- Molnupiravir – 60000 doses already secured, working on paperwork.
- Evusheld - in discussions with AstraZeneca – confidentiality agreement signed.
- Lenzilumab – no update to provide.

Issues discussed:

Baricitinib/ tocilizumab

- Identified that guidance on baricitinib use needed to be added to clinical guideline as soon as feasible given likely availability as an alternative to tocilizumab. Tocilizumab is being sourced by Pharmac and is the preferred agent. Guidance needed regarding use of tocilizumab versus baricitinib in patient subgroups (eg, pregnancy, renal impairment) and order of preference for use would be helpful - particularly for clinicians who have limited experience working with COVID-19.
- Medsafe asked for comment on approval status: tocilizumab is currently approved for rheumatoid arthritis. As an approved medicine it can be prescribed for other indications. Baricitinib is not currently approved by Medsafe. Unapproved medicines can be used under Section 29.
- Tocilizumab – a member expressed concern about the complexity of using SC formulation to prepare an IV infusion based on the information provided by the company. It was suggested by the member that baricitinib be preferred over SC formulation of tocilizumab for the majority of ward-based care as per most international guidelines e.g. Australia.

  Noted by Pharmac that the issue of SC tocilizumab may need to be considered more fully with further discussion/advice sought.

Action: Guidance on use of baricitinib to be introduced into the guideline 'Clinical Management of COVID-19 in Hospitalised Adults' and next guideline update to be brought forward.

Ronapreve

- An update from Pharmac was sought by members on patient criteria Pharmac will be recommending (in general terms of wide access or patient subgroups only). Pharmac advised that this information has yet to be finalised and will be provided in the summary from the Pharmac COVID Treatments Advisory Group due out by next week which will be circulated to the Therapeutics TAG.
- Members raised specific issues relating to Ronapreve of relevance to clinical and health system use:
  - If Ronapreve is expected in advance of molnupiravir this may change the perspective on community use of Ronapreve.
  - Serology testing – will the recommended use require this. Implications for access to testing and treatment.

	▪ Information on the number needed to treat (NNT) for benefit for Ronapreve and other products of interest to the group and anticipated to be in the summary of information provided from the Pharmac advisory group October meeting.
4.0	**Equity considerations** **Oral antivirals** Initial thoughts on supporting models of care for delivering molnupiravir and oral antivirals in the community from an equity perspective: • Ensuing appropriate access to testing and fast processing times. Query whether saliva testing will be widely available. • Accessibility to treatments - offering antivirals to the patient within time needed for treatment benefit (for molnupiravir this is within five days of symptom onset). Also ease of access to medicine supply via pharmacy/ delivery etc. • Providing appropriate information, for example a patient information sheet on the treatment was suggested as desirable. Information provided through media channels was also suggested but it was recognised that messaging around the importance of vaccination was the key message to communicate. • Several barriers were discussed, such as hesitancy for testing, speed of access to test results, medical prescribing only (limited GP access in some rural areas); potential financial barriers (e.g. if script co-payment required; transport costs to testing centre etc.). • Ministry attendees noted that there was some work happening to address some of these barriers within the Care in the Community programme. There is also work progressing in the Ministry regarding Pharmacy Services. The draft document COVID-19 Primary Care Clinical Model – Pharmacy Services was circulated to indicate what community pharmacy can/may deliver. • A member suggested that it is likely that barriers may be faced by the index case in the household but that with proactive support/treatment as needed for the household as a whole, barriers to care could be reduced. • There was general discussion about the prescribing of medications. It was suggested by a member that COVID-19 therapies be added to the list of medicines able to be prescribed/ordered by non-medical practitioners to assist with capacity and accessibility issues. • A Ministry attendee suggested that there may be a need to prioritise treatments and a risk stratification may be required to understand the communities who may be at high risk and have accessibility barriers. • A member noted that the link between therapeutics and community testing is important, especially to facilitate the provision of a ‘bundle’ of services to people, rather than multiple channels and visits. **Letter to relevant Maori & Pacific professional organisations** • The letter requesting feedback for the Therapeutics TAG from Māori and Pacific health organisations is going out to all organisations this week and feedback will be reported to the next Therapeutics TAG meeting.
5.0	**Primary Care – progress in aligning work** • Chair attended the CAG group meeting where Therapeutics TAG Position Statement on Inhaled Budesonide Use was tabled for information. A list of members of the CAG interested in being part of a subgroup on therapeutics was collated at the meeting.

	• There was discussion about a Therapeutics TAG subgroup to act as a liaison group with CAG although it was noted that the CAG group itself is nearing the end of its planned work programme. Initial thinking is that the Therapeutics TAG could support with guidance on treatments for COVID-19 in the community and some members expressed interest in involvement if a Therapeutics TAG subgroup for this liaison purpose was formed.
6.0	**Guideline Update** • The guideline was updated on 05 November 2021. Link available here. • This was a substantive update, in particular in the inclusion of specific advice for management of COVID-19 in pregnancy. • A system for documenting changes made in each update and associated rationale has commenced with the 5 November update. This will be used prospectively and will assist with any queries. • The next planned monthly update is 03 December 2021. This update may include hospital use of Ronapreve. An earlier update later in November now seems required given baricitinib supply potentially in 1-2 weeks. A guideline subgroup meeting will be convened within the next week. **Action**: Next Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply.
7.0	**Patient Information Update** COVID Resources – Health Navigator • 'COVID-19 positive - Consumer resources for care in the community' was provided with the agenda as an update of what is being produced. It was noted several medication specific information sheets have been circulated without any changes needed which the group agreed was an indication of the quality of the work. The publication of these products into other language is still being followed up within the Ministry.
8.0	**Booklet – COVID-19 rehabilitation** Booklet titled '**Support for rehabilitation: self-management for COVID-19-related illness'** was provided with the agenda for information. • The booklet has been modified from the WHO version and brought into the Aotearoa New Zealand context. • Members suggested that the title could cause confusion for the intended audience. The booklet focuses on the post-acute phase however this could be misunderstood and cause a delay in seeking treatment. Comments received will be fed back to the author and the revised booklet will be brought back to the next meeting with a view to endorsement from the group if deemed appropriate.
10.0	**Agenda Items for Next Meeting** Booklet – COVID-19 rehabilitation – for discussion
11.0	**Action Items Raised During Meeting** **Action**: Next Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply.
Meeting closed at **2:30pm** Next meeting **Friday 26 November 2021 – 1:30pm – 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline Guideline update published 5/11/21 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply.	Tim Cutfield/STA	17/09 – Action raised Next update 26/11/21

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
12	Equity Considerations	Saleimoa Sami and Jessica Keepa to draft a letter to be distributed to Māori and Pacific health professional bodies	Saleimoa Sami and Jessica Keepa	01/10 – Action raised 15/10 – Action updated on item 2.0 of 15/10 meeting minutes 12/11 – Action updated on item 4.0 of 12/11 minutes. Closed 12/11.