

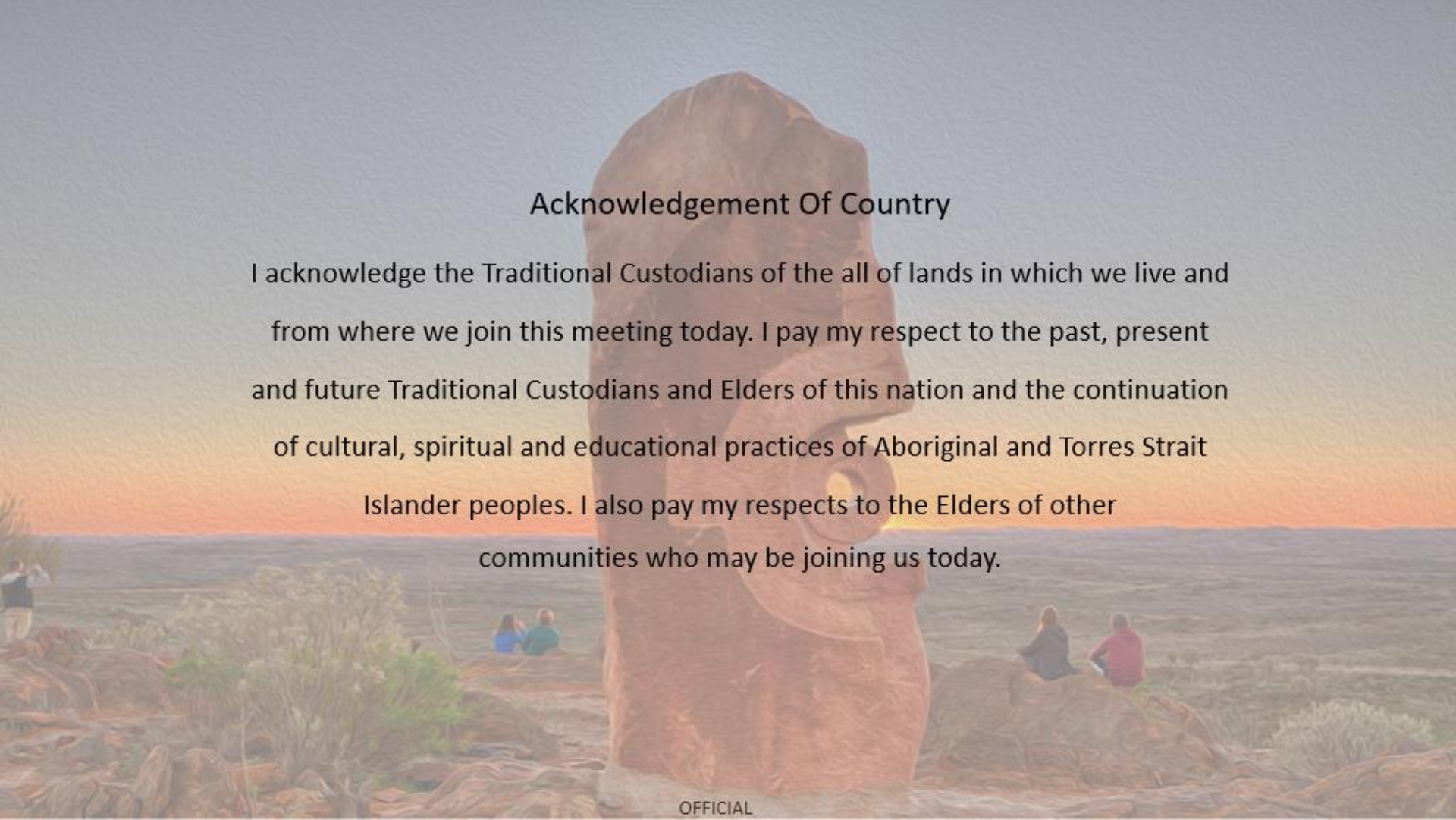
July 2022

COVID + Pathway Learning Network webinar series

Webinar 22:

Supporting community access for COVID Therapies

OFFICIAL



Acknowledgement Of Country

I acknowledge the Traditional Custodians of the all of lands in which we live and from where we join this meeting today. I pay my respect to the past, present and future Traditional Custodians and Elders of this nation and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples. I also pay my respects to the Elders of other communities who may be joining us today.

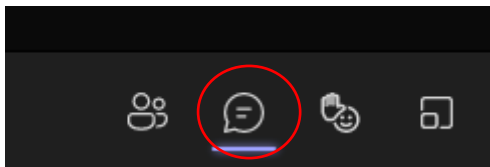
Webinar series purpose

- Showcase local clinicians who will share their experiences delivering the COVID + Pathways model
- Provide a forum for sharing and collaboration to support the delivery of best practice

* To share your services' experiences, innovations and learnings in delivering the COVID+ Pathway at an upcoming webinar email centresofclinicalexcellence@safercare.vic.gov.au

Before we start

Throughout the webinar you can ask questions by typing your question into the chat.



There will also be a dedicated time for questions and discussions.

The presenters will do their best to answer your questions at the end of the presentation.

This session will be recorded and made available on the SCV website.

Overview

Topic	Presenter
National COVID-19 Clinical Evidence Taskforce update	A/Prof Steve McGloughlin, <i>Director Department of Intensive Care & Hyperbaric Medicine Alfred Health: Associate Professor, School of Public Health and Preventive Medicine: Executive Director, National COVID-19 Clinical Evidence Taskforce</i>
Questions/Reflections	Facilitated by Briana Baass, <i>Chief Allied Health Officer, Safer Care Victoria</i>
Supporting safe access to early therapies to COVID positive people in the community	Professor Michael Dooley, <i>Director of Pharmacy, Alfred Health</i>
Update on prescribing pathways for <i>Evusheld</i>	Laura Hewett, <i>Principal Policy Officer, COVID+ Pathways Program, Department of Health</i>
Questions/Reflections	Facilitated by Briana Baass, <i>Chief Allied Health Officer, Safer Care Victoria</i>

National COVID-19 Clinical Evidence Taskforce update

A/Prof Steve McGloughlin, *Executive Director, National COVID-19
Clinical Evidence Taskforce*

OFFICIAL

Safer Care Victoria Webinar Taskforce Update

Steve McGloughlin

Director Department of Intensive Care & Hyperbaric Medicine, The Alfred
Associate Professor, School of Public Health and Preventive Medicine Monash University
Executive Director, National COVID-19 Clinical Evidence Taskforce

July 27, 2022

NATIONAL
COVID-19
CLINICAL
EVIDENCE
TASKFORCE

Meanwhile in Florida, the alligators have developed sign making skills.



UPDATED Vaccine language

- Replaced ‘up-to-date’ with vaccination language across all relevant adult recommendations.
- Vaccination status has been removed from the recommendation wording.
- Clinicians are encouraged to make treatment decisions based on an overall assessment of the likelihood of progression to severe disease, based on age and other risk factors, including whether an individual has received a COVID vaccine dose, or had a SARS-CoV-2 infection, in the last six months.

Impacted recommendations:

Updated adult recommendations to reflect the change in 'up-to-date' terminology include:

- Remdesivir (for adults with mild COVID-19)
- Nirmaltrevir plus ritonavir (Paxlovid)
- Molnupiravir (Lagevrio)
- Tixagevimab plus cilgavimab (Evusheld)
- Sotrovimab
- Pulse oximeters

UPDATED Risk classification tool

- In addition to the revised vaccine language, the risk classification tool has also been updated with changes to age and comorbidity criteria.
- To simplify clinical decision-making, the Taskforce guidance aims to help clinicians identify which patients are most likely to benefit from Paxlovid or Lagevrio, within the PBS eligibility criteria.
- In the absence of definitive evidence, this guidance is based on the consensus clinical expertise of the Taskforce.



Within the [eligibility criteria](#) for oral antiretrovirals provided by the PBS, the Taskforce has developed this guidance to help clinicians determine which people are most likely to benefit from these drugs. In the absence of definitive evidence, this guidance is based on the consensus clinical expertise of the Taskforce.

Comorbidities include:

- Respiratory compromise, including COPD, asthma and bronchiectasis
- Cardiovascular disease, including hypertension
- Obesity (BMI >30 kg/m²)
- Diabetes
- Renal failure



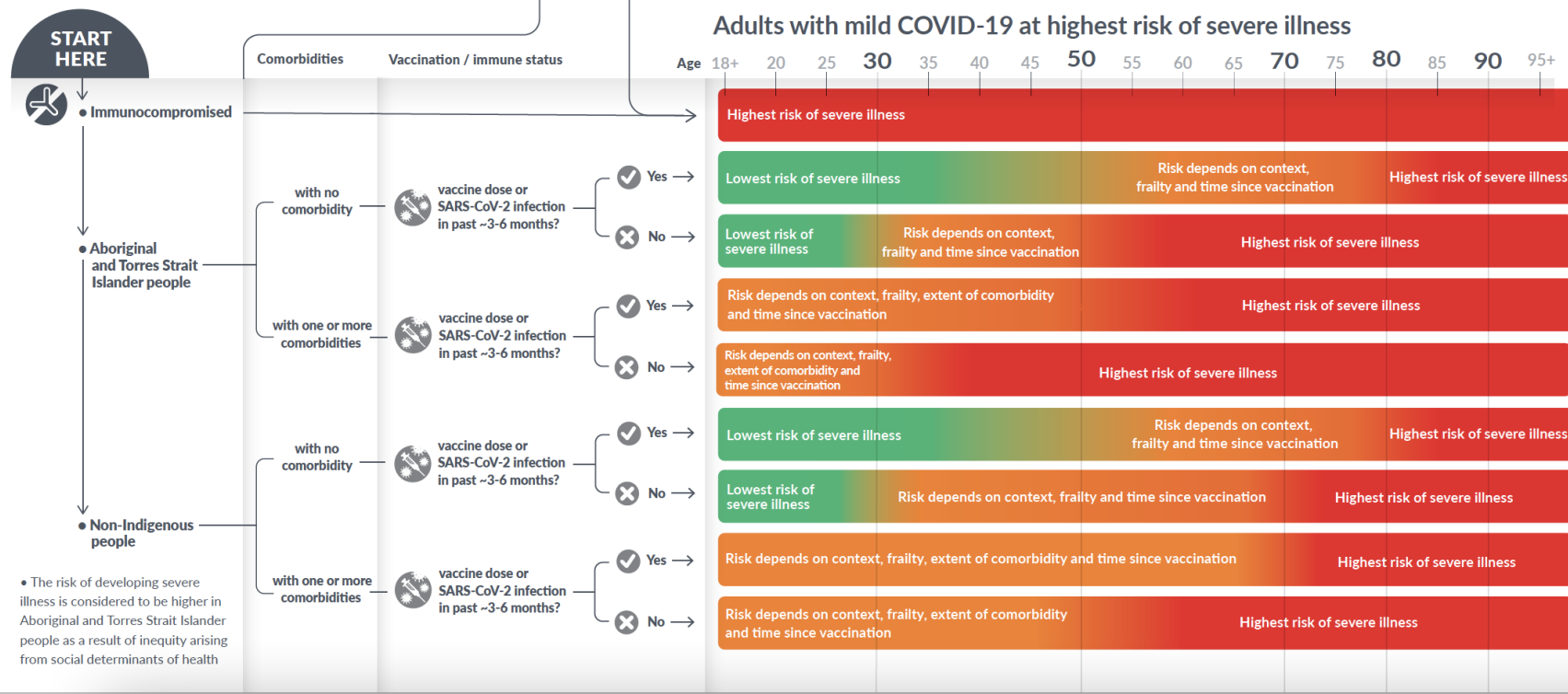
Immunocompromising conditions

- **Primary or acquired immunodeficiency:**
- **Haematologic neoplasms:** leukaemias, lymphomas, myelodysplastic syndromes
- **Post-transplant:** solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months)
- **Immunocompromised** due to primary or acquired (AIDS) immunodeficiency or Down syndrome

Immunosuppressive therapy (current or recent):

- Chemotherapy, whole body radiotherapy or total lymphoid irradiation
- High-dose corticosteroids (≥ 20 mg of prednisone per day, or equivalent) for ≥ 14 days
- Selected other potent immunosuppressive therapies (refer to [ATAGI advice](#))

Context: Also consider whether people are unlikely to be able to access higher level care due to geographical remoteness or other factors



DRUG TREATMENTS FOR AT RISK ADULTS WITH COVID-19 WHO DO NOT REQUIRE OXYGEN



Immunocompromising conditions

Primary or acquired immunodeficiency

- **Haematologic neoplasms:** leukaemias, lymphomas, myelodysplastic syndromes
- **Post-transplant:** solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months)
- **Immunocompromised due to primary or acquired (AIDS) immunodeficiency**
- **Other significantly immunocompromising conditions**

Immunosuppressive therapy (current or recent)

- **Chemotherapy,** whole body radiotherapy or total lymphoid irradiation
- **High-dose corticosteroids** (> 20 mg of prednisone per day, or equivalent) for > 14 days
- **Selected other potent immunosuppressive therapies** (refer to [ATAGI advice](#))

START
HERE

Adult with symptomatic COVID-19 who does not require oxygen and has one or more risk factors for disease progression



Risk factors for disease progression

- Older age (e.g. over 65 years, or over 50 years for Aboriginal and Torres Strait Islander people)
- Diabetes requiring medication
- Obesity (BMI > 30 kg/m²)
- Renal failure
- Cardiovascular disease, including hypertension
- Respiratory compromise, including COPD, asthma requiring steroids, or bronchiectasis
- See also immunocompromising conditions

For complete summaries of
treatment recommendations, refer to:

Drug treatments for adults with COVID-19

Drug treatments for pregnant or
breastfeeding women with COVID-19

Click to view
in the patient:

At particularly high risk of severe disease on the basis of advanced age, multiple risk factors, and vaccination status (including number of doses and time since last dose, or timing of most recent infection)?

Risk Classification Tool

Click to view

Treat symptoms
and observe.

Refer to clinical flow charts for:

Management of adults
with mild COVID-19

Click to view

or

Management of
adults with moderate
to severe COVID-19

Click to view

Is the patient:

Immunocompromised
or unvaccinated?

Is the patient:

Within 5 days of
symptom onset?

Is the patient:

Within 7 days of
symptom onset?

Is the patient:

Within 14 days of
symptom onset?

Are one or more treatments
accessible and the patient
has no relative or absolute
contraindications?

Is remdesivir accessible
and the patient has no
relative or absolute
contraindications?

Are inhaled cortico-
steroids accessible and
no absolute or relative
contraindications?

Consider
Inhaled corticosteroids
(budesonide or ciclesonide)

VERSION
4.0
PUBLISHED 21 JULY 2022



Consider

nirmatrelvir plus ritonavir (Paxdovid)
300 mg /100 mg PO bd for 5 days

Product type:

Antiviral (dual therapy)

Clinical evidence:

Adults in the EPIC-HR trial were treated within 5 days of symptom onset with oral nirmatrelvir/ritonavir 300mg/100 mg twice daily for 5 days

Administration considerations:

Nirmatrelvir and ritonavir tablets should be taken together orally every 12 hours for 5 days, with or without food.
[See full TGA PI](#)

Contraindications:

Severe renal or severe hepatic impairment. Concomitant use with drugs that are highly dependent on CYP3A for clearance or are potent CYP3A inducers. Hypersensitivity to active ingredients or other components of the product.

Drug interactions:

Multiple significant drug-drug interactions associated with CYP3A inhibition.
[See full TGA PI](#)
[See Liverpool interaction checker](#)

Pregnancy and conception:

Category B3. Do not use in pregnant women unless eligible to be enrolled in trials. Women of childbearing potential should avoid becoming pregnant during treatment and until 7 days after stopping treatment.

Breastfeeding:

Do not use in breastfeeding women unless eligible to be enrolled in trials. Breastfeeding can commence 7 days after the last dose.

Consider

remdesivir
200 mg IV on day 1 then 100 mg IV on days 2 & 3

Antiviral (monotherapy)



Adults in the PINETREE trial were treated within 7 days of symptom onset with three intravenous doses on consecutive days (200 mg on day 1, followed by 100 mg on days 2 and 3)



Remdesivir should be administered intravenously in healthcare facilities in which patients can be monitored very closely.
[See full TGA PI](#)



Hypersensitivity to active ingredients or other components of the product.



Do not use concomitantly with chloroquine phosphate or hydroxychloroquine sulphate.
[See full TGA PI](#)



Category B2. Should only be used during pregnancy if the expected benefit to the mother justifies the potential risk to the fetus. Women of childbearing potential must use effective contraception during treatment.



Developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for therapy and any potential adverse effects on the breastfed child.

Consider*

txigavimab plus cilgavimab (Evusheld)
300 mg/300 mg IM once

Monoclonal antibody (dual therapy)



Adults in the TACKLE trial were treated within 5 days of symptom onset with a single dose of Evusheld consisting of two intramuscular injections (300 mg txigavimab and 300 mg cilgavimab)



***Not approved by TGA for this indication.**
Single dose of 600 mg Evusheld consisting of two intramuscular injections (300 mg txigavimab and 300 mg cilgavimab).
[See full TGA PI](#)



Hypersensitivity to active ingredients or other components of the product.



No significant drug-drug interactions.



Category B2. Do not routinely use in pregnant women unless eligible to be enrolled in trials.



Do not use in breastfeeding women unless eligible to be enrolled in trials.

If previous options are not suitable or available.

molnupiravir (Lagevrio)
800 mg PO bd for 5 days

Antiviral (monotherapy)



Adults in the MOVE-OUT trial were treated within 5 days of symptom onset with 800 mg of molnupiravir twice daily for 5 days



Molnupiravir capsules should be taken orally every 12 hours for 5 days, with or without food.
[See full TGA PI](#)



Hypersensitivity to active ingredients or other components of the product.



No significant drug-drug interactions.



Category D. Do not use in pregnant women. Women should avoid becoming pregnant during treatment and until 4 days after stopping treatment. Men should use adequate contraception during and 3 months after treatment.



Do not use in breastfeeding women unless eligible to be enrolled in trials. Breastfeeding can commence 4 days after the last dose.

Recently published

ORAL ANTIVIRALS FAQS

To view the list of recommended treatments please refer to www.covid19evidence.net.au

AS AT 21 JULY 2022

What are antivirals?

Paxlovid (nirmatrelvir and ritonavir) and Lagevrio (molnupiravir) are oral medications which reduce the ability of SARS-CoV-2, the virus that causes COVID-19, to multiply in your body. The aim of using these medications is to reduce the chance of developing severe illness as a result of COVID-19.

Do they work?

Paxlovid

Evidence for the effectiveness of Paxlovid comes from a study that compared it with a placebo (an inactive treatment) in 2,246

Upcoming

- Awaiting publication of Panaromic trial results (molnupiravir)
- In vitro data re efficacy of treatments against dominant variants BA.4/5
- Soon to publish:
 - four new paediatric management flowcharts
 - New Care after COVID flowchart
- Evusheld treatment recommendation under review

We want to hear from you

NATIONAL
COVID-19
CLINICAL
EVIDENCE
TASKFORCE

DO YOU HAVE A CLINICAL QUESTION?

Your views help us to identify and prioritise questions to include in the living guideline.

Check if your
question is already
being considered

REVIEW LIST

Submit your
questions here

CLOSE FORM



Subscribe here to receive regular updates from the Taskforce

OPEN FORM

PERSONAL DETAILS

Name *

First

Last

Email *

Please enter your email, so we can follow up with you.

What is your clinical specialty or area? *

SUGGESTIONS

TOPICS AND QUESTIONS FOR CONSIDERATION BY THE TASKFORCE

NATIONAL
COVID-19
CLINICAL
EVIDENCE
TASKFORCE

PUBLISHED
06 AUGUST 2020

Feedback to date has included both a wide range of suggestions for questions and topics for inclusion, as well as advice on issues that are outside the scope of the guideline. These are described below.

Newly suggested clinical questions for consideration by the Guidelines Leadership Group

- In patients who are vitamin D deficient, should vitamin D supplements be prescribed to prevent COVID-19?
- In patients with mild COVID-19 who are at high risk of hospitalisation, what treatments can prevent progression to severe/critical COVID-19?
- In patients with mild COVID-19, does azithromycin prevent the progression to severe/critical COVID-19?
- In patients with mild COVID-19, does commencement of inhaled corticosteroids reduce risk of progression to severe/critical COVID-19?
- Should patients with severe COVID-19 pneumonia, who are not intubated, receive prone?
- What treatments should be used for anaemia that arises secondary to a COVID-19 infection?
- What assessment, surveillance and rehabilitation should recovered COVID-19 patients receive?

Newly suggested clinical questions that are out of scope

- What dose of rocuronium should be used when conducting rapid sequence intubation in patients hospitalised with COVID-19?
- How can we mitigate risk to health care workers during preoxygenation or oxygenation?
- How long does fatigue and shortness of breath persist post-COVID-19 infection?

New suggested topics for consideration by the Guidelines Leadership Group

- When should diagnostic tests be conducted to reduce false-negatives?
- Natural history of COVID-19
- Effect of social distancing measures on the provision and availability of volunteer support services

Topics that are already prioritised and are included in the living guideline and/or flowcharts, or are under review by the team

- Guideline**
 - Definition of disease severity
 - Disease monitoring and markers of clinical deterioration
 - Modifying Treatments
 - Antivirals
 - Other disease modifying treatments
 - Respiratory Support
 - ECMO
 - HFNO
 - Intubation
 - Monitoring & markers

Topics that are deprioritised at the moment but can be reviewed again

- Echocardiography
- Fluid management
- Medication management, including over the counter medicines and psychotropics
- Ambulance management and transport
- Nutrition care
- Sedation protocols
- Complementary, holistic and integrative medicine, including lifestyle interventions
- Aspirin as chemoprophylaxis
- Does open surgical tracheotomy compared to percutaneous

Cumulative list of suggested topics that are currently out of scope

- Care in the age of COVID-19
 - Sexual health in the age of COVID-19
- Infection prevention and control (currently being scoped with the Infection Control Expert Group (ICEG) of the Australian Government)
 - Aerosol generating procedures
 - Blood product management
 - Community-based prevention
 - Environmental cleaning
 - Home visits

OFFICIAL

Questions

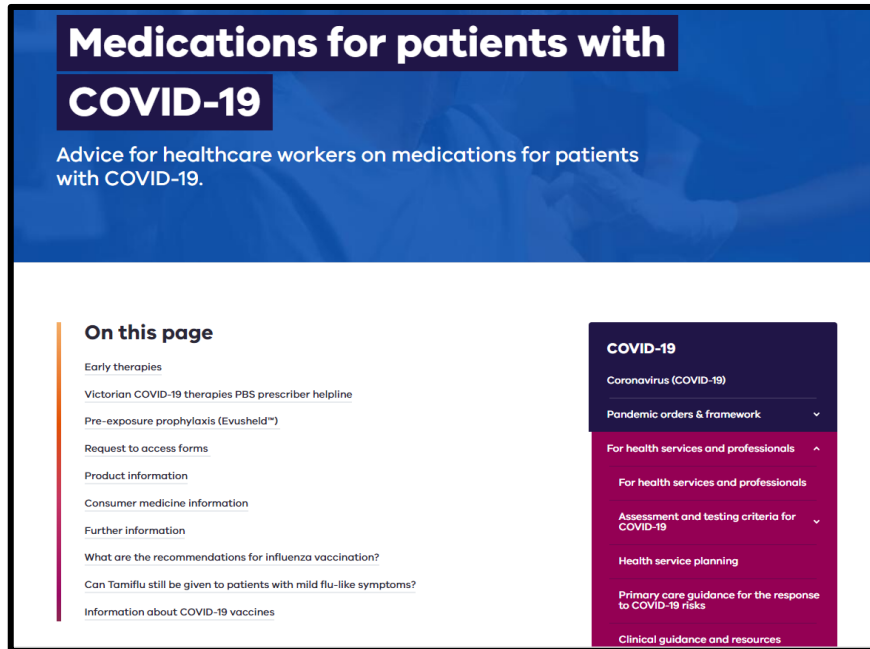
Please put your questions into the chat

Supporting safe access to therapies for COVID positive people in the community

Professor Michael Dooley, *Director of Pharmacy, Alfred Health*

Victorian COVID Therapies PBS Prescriber Helpline

COVID-19 early therapies - adults



Medications for patients with COVID-19

Advice for healthcare workers on medications for patients with COVID-19.

On this page

- [Early therapies](#)
- [Victorian COVID-19 therapies PBS prescriber helpline](#)
- [Pre-exposure prophylaxis \(Evusheld™\)](#)
- [Request to access forms](#)
- [Product information](#)
- [Consumer medicine information](#)
- [Further information](#)
- [What are the recommendations for influenza vaccination?](#)
- [Can Tamiflu still be given to patients with mild flu-like symptoms?](#)
- [Information about COVID-19 vaccines](#)

COVID-19

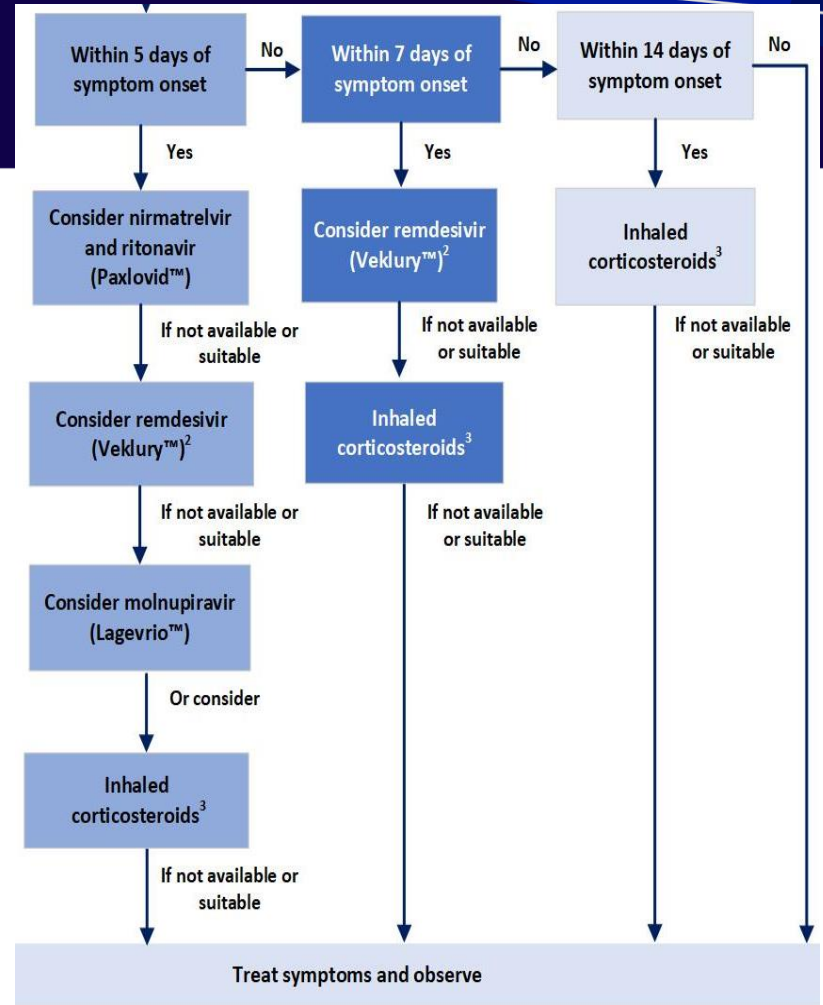
- [Coronavirus \(COVID-19\)](#)
- [Pandemic orders & framework](#)
- [For health services and professionals](#)
- [For health services and professionals](#)
- [Assessment and testing criteria for COVID-19](#)
- [Health service planning](#)
- [Primary care guidance for the response to COVID-19 risks](#)
- [Clinical guidance and resources](#)

<https://www.health.vic.gov.au/covid-19/vaccines-and-medications-in-patients-with-covid-19>

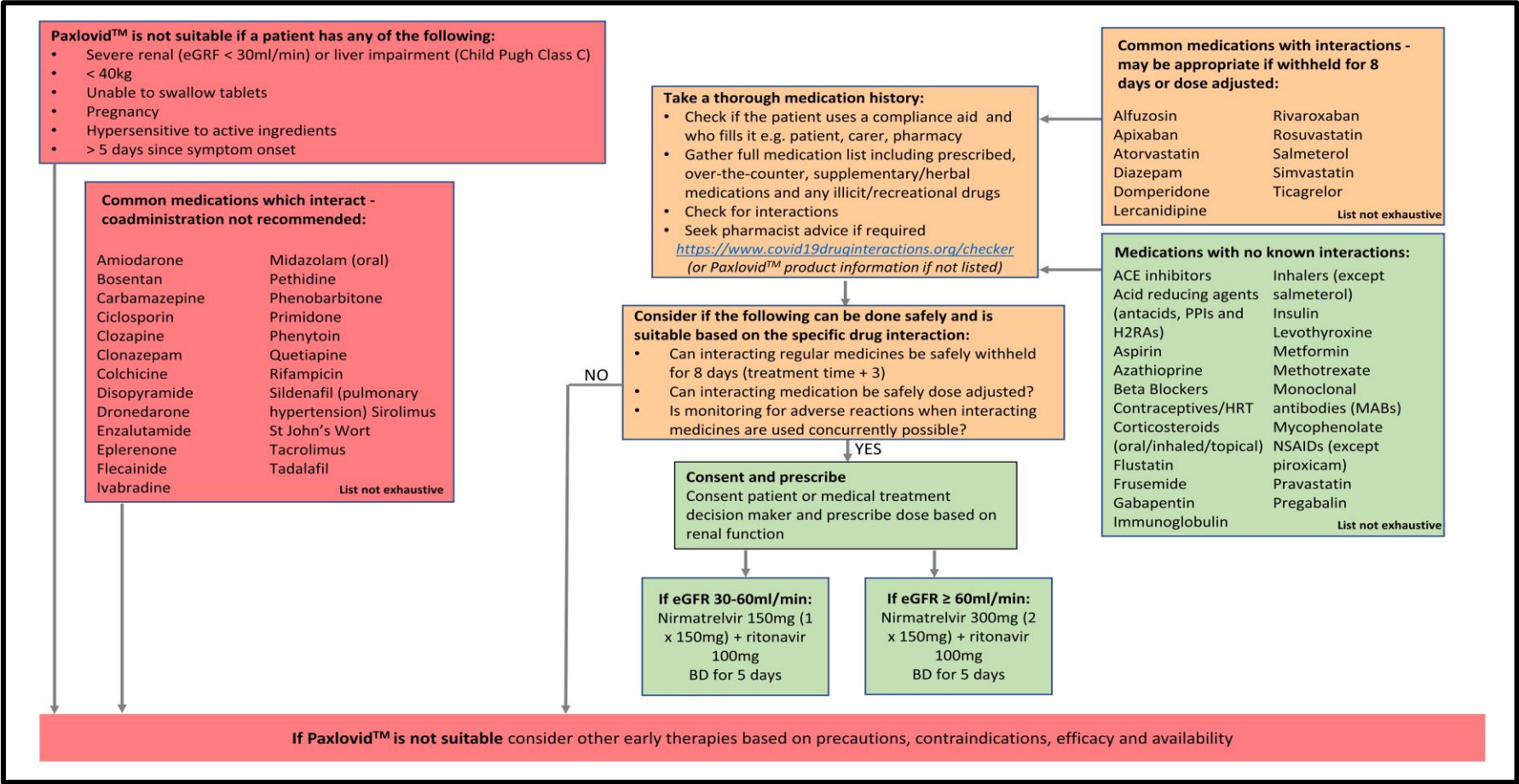
OFFICIAL

COVID-19 early therapies - adults

- [COVID-19 medications for at risk people who do not require oxygen](#)
- Clinical guidance to support prescribing
- Includes key prescribing information on administration, timing, precautions and contraindications and links to further information
- Includes Paxlovid™ flow chart
- Recent update to NMS prescribing criteria



Nirmatrelvir and ritonavir (Paxlovid™)



Victorian COVID Therapies PBS Prescriber Helpline

- Pharmacy helpline launched in May to support GPs in the prescription of oral antivirals nirmatrelvir and ritonavir (Paxlovid™) and molnupiravir (Lagevrio™)
- Now available to support Evusheld™ prescribing
- Staffed by Alfred Health pharmacists experienced in prescribing COVID-19 early therapies
- 7 days a week 8am-5pm
- (03) 8290 3801

Victorian COVID Therapies PBS Prescriber Helpline

Key focus

- Answer questions
- Advise on
 - Eligibility
 - Drug interactions
 - Choice of agent

Victorian COVID Therapies PBS Prescriber Helpline

Some numbers

- 863 calls as of 1400 yesterday
- Currently 30 – 35 calls a day
- Average duration of calls 5minutes
- 80% of calls metro Melbourne

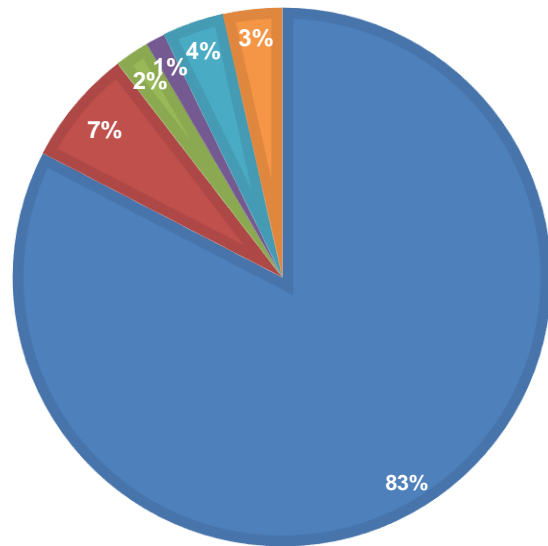
Victorian COVID Therapies PBS Prescriber Helpline

Some numbers

- 863 calls as of 1400 yesterday
- Currently 30 – 35 calls a day
- Average duration of calls 5minutes
- 80% of calls metro Melbourne

MODIFIED MONASH CATEGORY

■ 1 ■ 2 ■ 3 ■ 4 ■ 5 ■ Unknown

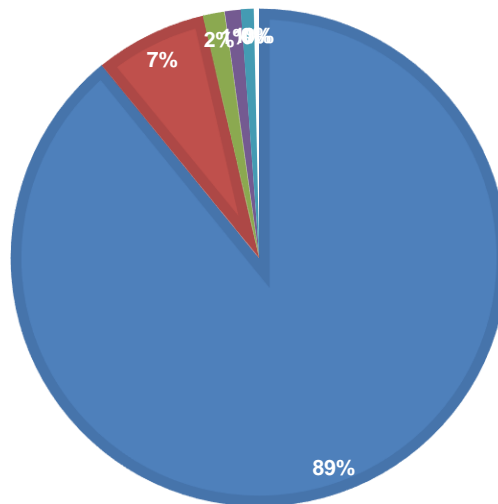


Victorian COVID Therapies PBS Prescriber Helpline

Some numbers

- 863 calls as of 1400 yesterday
- Currently 30 – 35 calls a day
- Average duration of calls 5minutes
- 80% of calls metro Melbourne
- 90% of callers are medical

CALLER PROFESSION



Victorian COVID Therapies PBS Prescriber Helpline

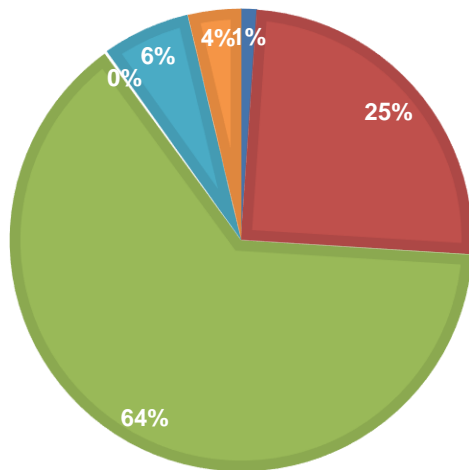
Reasons for calls

Call Reason	No.	Percentage
Eligibility	377	43.7%
Drug Interactions	250	29.0%
Choice of Agent	91	10.5%
Prescribing process	34	3.9%
Drug supply	29	3.4%
Dosing	26	3.0%
About the service	17	2.0%
Evusheld	14	1.6%
Referral process	11	1.3%
Contraindications	8	0.9%
Side effects	4	0.5%
Other	2	0.2%

Victorian COVID Therapies PBS Prescriber Helpline

ANTIVIRAL RECOMMENDED

■ Already on treatment ■ Molnupiravir ■ Paxlovid ■ Paxlovid (NMS) ■ Remdesivir ■ Yes (agent tbc)



95.4% prescribed

Victorian COVID Therapies PBS Prescriber Helpline

- Pharmacy helpline launched in May to support GPs in the prescription of oral antivirals nirmatrelvir and ritonavir (Paxlovid™) and molnupiravir (Lagevrio™)
- Now available to support Evusheld™ prescribing
- Staffed by Alfred Health pharmacists experienced in prescribing COVID-19 early therapies
- 7 days a week 8am-5pm
- (03) 8290 3801

Prescribing pathways for *Evusheld*

Laura Hewett, *Principal Policy Officer, COVID+ Pathways Program*
COVID-19 Health Service Operations

Pre-exposure prophylaxis for COVID-19: Evusheld™

Laura Hewett

Principal Policy Officer, COVID Positive Pathways

OFFICIAL



Department
of Health

OFFICIAL

Tixagevimab and cilgavimab (Evusheld™): Overview

- Monoclonal antibodies designed to block viral attachment and entry into cells
- For pre-exposure prophylaxis of COVID-19 in adults and children ≥ 12 yo (if weighing ≥ 40 kg)
- Only available in Australia through National Medical Stockpile (NMS)
- Treatment goal is to prevent COVID-19 infection in people who:
 - are moderately-severely immunocompromise or,
 - can not be vaccinated due to severe allergy

Evusheld™: Overview

- Limited stock received initially
- Clinical advice to the department on prioritisation and eligibility criteria
- Prioritisation considered relevant guidelines, therapeutic indications and is based on immunosuppressed patients ranked by risk (P1-3)
- Progressive expansions of eligibility criteria March – June to improve access

Evusheld™: Eligibility (Victoria)

- Heart/lung transplant recipients
- STEM cell transplant, CAR T-cell therapy recipients, kidney, pancreas/islet cell or liver transplant recipients within 12 months
- STEM cell transplant with GVHD or requiring significant ongoing immunosuppression for other reasons
- Kidney, pancreas/islet cell or liver transplant recipients requiring therapy for acute rejection or significant ongoing immunosuppression for other reasons
- Primary immunodeficiency syndromes
- Haematologic disorders that may affect B cell function eg. CLL, CMML, myelodysplastic syndrome, myeloma
- Unable to be immunised due to genuine, severe allergy if ≥ 65 years old (≥ 50 years old if Aboriginal) and not recently infected with COVID-19 within 3 months
- Haematological malignancies and are receiving active therapy
- HIV with a CD4 cell count < 50 cells/mm³
- Received B and T cell depleting therapies last 12 months

Evusheld™: Treatment clinics

- Slow uptake of Evusheld™ April-May
- 12 health services provided with funding to support administration of Evusheld™
- Focus on ensuring use of all stock expiring in July
- Various models of care

- Northern Health
- Eastern Health
- Western Health
- Peter MacCallum Cancer Centre
- Alfred Health
- Royal Melbourne Hospital
- Peninsula Health
- Monash Health
- Latrobe Regional Hospital
- GV Health
- Ballarat Health Services
- Bendigo Health

Evusheld™: Community prescribing pathway

- The department now stock doses of Evusheld™ in **selected** community (Supercare) and regional and rural hospital pharmacies
- GPs and non-GP specialists can prescribe Evusheld™ for eligible patients
- Patients can be dispensed Evusheld™ for free at participating pharmacies
- Option for administration at Supercare pharmacies by onsite nurses (6-10pm) or patients return to prescriber's clinic for administration

Evusheld™: Resources to support prescribing

- Evusheld™ community prescriber guide
- Evusheld™ FAQ for clinicians
- Evusheld™ patient fact sheet
- Dedicated community prescriber website with all of the above resources and locations of selected pharmacies
- Pharmacy helpline
- Consumer web content and comms to support awareness also in train

Evusheld™: Consumer content

- Evusheld™ information on eligibility and pathway to access
- Metro and regional pharmacies with Evusheld™ stock (including regional health service pharmacies)



Evusheld™: Next steps

- Ongoing communications re: pathways to access through consumer organisations and clinician associations
- Work with comms team to develop dedicated social media
- Ongoing review of stock levels
- Monitor evidence and national advice re: double dosing

Further information: Evusheld™

Early therapies and pre-exposure prophylaxis (Clinician resources):

<https://www.health.vic.gov.au/covid-19/vaccines-and-medications-in-patients-with-covid-19>

Community prescriber website:

<https://www.health.vic.gov.au/covid-19/evusheldtm-prescribing-resources-for-gps-and-specialists>

Consumer web content:

<https://www.coronavirus.vic.gov.au/covid-19-medicines>

DH Contact: covid+pathways@health.vic.gov.au

Questions

Please put your questions into the chat

Get in contact

- Please complete our poll questions that will appear on your screen or in the chat
- These webinars are scheduled on a monthly basis
- To receive MS Teams links to register for future webinars email us: centresofclinicaexcellence@safercare.vic.gov.au
- If you have specific questions relating to the COVID+ Pathways please email the Department of Health at covid+pathways@health.vic.gov.au

Resources

- [Learning Network webinar recordings and slides](#)
- COVID Clinical Shared Resources SharePoint page - Secure site for sharing, with permission, health service developed COVID-19 resources.
 - To register for access and to share resources contact centresofclinicaexcellence@safercare.vic.gov.au
- [Department of Health COVID-19 clinical guidance and resources](#)