Consent Factsheet
Use of medicines for COVID-19 in NSW Health facilities

Background
'*Health Practitioners… have a legal obligation to provide patients (or substituted decision makers) with information, including warnings, about any material risks involved in a proposed… treatment.*' See NSW Health Consent to Medical and Healthcare Treatment Manual, Section 4.1

General principles
- Where use of a medicine for COVID-19 is proposed, the patient must be provided with information on the known benefits and harms, and the potential for unknown adverse effects or unintended consequences, to enable them to make an informed choice about consenting to treatment.
- The relevant patient and carer factsheet and Consumer Medicines Information leaflet (links below) should be provided. Sufficient time should be given for the patient/carer to read and understand the information provided and to ask any questions.
- Four criteria must be met to ensure consent is valid:
    - the patient giving consent must have **capacity**
    - the consent must be **freely given**
    - the consent must be **sufficiently specific** to the treatment proposed – specific information relevant to the medicines available for the management of COVID-19 in NSW is provided below.
    - the consent must be **informed**.
- Regardless of how consent is obtained (verbally, written or implied by a person's conduct), it is important to document this in the patient's medical record. Documentation should include details of the consent conversation, information provided to the patient as a part of obtaining consent and the presence of an accredited interpreter (if applicable).

Provisionally approved medicines
For the COVID-19 medicines that are provisionally approved by the Therapeutics Goods Administration (TGA) in Australia and use is in accordance with the Approved Product Information – verbal consent is sufficient.

As of 22 June 2022, the following medicines are provisionally approved (see this page for up-to-date information) and available in NSW for use in the treatment or prevention of COVID-19. Despite these medicines having provisional approval, clinicians should consider the SARS-CoV-2 variant being targeted and the possibility of reduced efficacy. Refer to the relevant Product Information for the approved indications and dosing regimens.

Active pharmaceutical and brand name	Product Information	Consumer Medicines Information	Patient and carer factsheet
Casirivimab plus imdevimab (Ronapreve)	Ronapreve PI	Ronapreve CMI	Ronapreve factsheet
Molnupiravir (Lagevrio)	Lagevrio PI	Lagevrio CMI	Lagevrio factsheet
Nirmatrelvir plus ritonavir (Paxlovid)	Paxlovid PI	Paxlovid CMI	Paxlovid factsheet
Remdesivir (Veklury)	Veklury PI	Veklury CMI	Veklury factsheet
Sotrovimab (Xevudy)	Xevudy PI	Xevudy CMI	Xevudy factsheet
Tixagevimab plus cilgavimab (Evusheld)	Evusheld PI	Evusheld CMI	Evusheld factsheet
Tocilizumab (Actemra)	Actemra PI	Actemra CMI	Actemra factsheet

Off-label use of medicines
The National COVID-19 Clinical Evidence Taskforce (NCCET) makes evidence-based recommendations for use of medicines in the treatment and prevention of COVID-19. Some of these recommendations are off-label (contrary to the manufacturer's approved indication for use or dosing regimens)**,** for example use of:
- baricitinib for COVID-19 (patient and carer factsheet available here) (see NCCET recommendations)
- nirmatrelvir plus ritonavir in children and adolescents (see NCCET conditional recommendation)
- tixagevimab plus cilgavimab for the treatment of COVID-19 (see NCCET recommendations),

The fact that use is off-label **must** be drawn to the patient's attention. The prescriber must explain the clinical rationale for choosing that treatment as part of the consent process. This information must be recorded as part of the consent process. See NSW Health Consent to Medical and Healthcare Treatment Manual, Section 4.8.1
- Where off-label use is in accordance with the NCCET recommendations, consent is required but does not necessarily need to be written.
- For off-label use which is NOT in accordance with NCCET recommendations, consent is required, and it is recommended that it is written.

Links
- NSW Health Consent to Medical and Healthcare Treatment Manual
- Consent for Medical Procedure/Treatment (Adults and Mature Minors)
- Consent for Medical Procedure/Treatment (Minors)