Verbal consent form / guide for clinician
For medicines used off-label or with provisional registration in the treatment of COVID-19

Consenting clinician may obtain verbal consent for more than one medicine at the same time; please tick the relevant medicine(s) below. Individual consent forms are also available on the NSW TAG website for each medicine and may be used instead.

Introduction

1. Introduce yourself to the patient/person responsible. Confirm relevant patient-identifying information.

Verbal consent information provision

2. *I'm here to provide information about the medicines that may be used to treat COVID-19 and get your consent for their use in you/ the person you are responsible for. Because COVID-19 is a new disease, there is less information than normal about some of the medicines used to treat it. It is important you understand the possible benefits and harms of the medicines.*
3. *You have been provided with Patient & Family Information Leaflet(s) which provides information about the medicines which may be used to treat COVID-19 in you /the person you are responsible for.*
   There may be a need to provide further explanation regarding use in some populations e.g. paediatrics and pregnancy/breastfeeding. Whenever possible, provide the relevant Patient & Family Information Leaflets to the patient/person responsible beforehand.

☐ ***Remdesivir (Veklury®)***	☐ ***Baricitinib (Olumiant®)***	☐ ***Tocilizumab (Actemra®)***
- Remdesivir is a new medicine that acts against viruses. It is provisionally approved for use in Australia for the treatment of COVID-19. More information about effectiveness & safety is needed before it is fully approved. *- It works by stopping the virus, which causes COVID-19, multiply in the body. If you have moderate to severe COVID-19, remdesivir may help you get better sooner & reduce your risk of dying.* *- Some possible side effects that might be experienced are listed in the information leaflet & include: [go through list].* *- There is a possibility of experiencing other unknown side effects when it is used in people with COVID-19.* *- We will closely monitor you while you are on this medicine.* *- Remdesivir is given by infusion into a vein, one dose a day, usually for 5 days.*	*- Baricitinib belongs to a group of medicines called Janus Kinase (JAK) inhibitors.* *- Baricitinib works by affecting the immune system to reduce inflammation & the effects of an over-activated immune system that can occur in severe COVID-19.* *- Baricitinib probably reduces the risk of dying.* *- The TGA has approved baricitinib to treat other immune conditions but not COVID-19 as yet.* *- Some possible side effects that might be experienced are listed in the information leaflet & include: [go through list].* *- There is a possibility of experiencing other unknown side effects when it is used in people with COVID-19.* *- We will closely monitor you while you are on this medicine.* *- Baricitinib is a tablet. It will be given to you to swallow whole with a glass of water (or through a nasogastric tube if you have this).*	*- Tocilizumab belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies modify the way the immune system works.* *- Tocilizumab reduces the effects of an over-activated immune system that can occur in severe COVID-19.* *- Tocilizumab probably reduces the risk of dying.* *- The TGA has approved tocilizumab to treat other immune conditions but not COVID-19 as yet.* *- Some possible side effects that might be experienced are listed in the information leaflet & include: [go through list].* *- There is a possibility of experiencing other unknown side effects when it is used in people with COVID-19.* *- We will closely monitor you while you are on this medicine.* *- Tocilizumab is given by infusion into a vein, usually one dose is used.*

4. *It is important for you to know and understand that:*
   - *there are no guarantees of the effectiveness of the medicines when used to treat COVID-19 and you /the person you are responsible for may not experience any benefit;*
   - *there are no guarantees of the safety of the medicines and they may cause side effects when they are used to treat COVID-19 and, even with careful precautions in place, unforeseen complications may occur; and,*
   - *although we will check for drug interactions, there is potential for drug interactions to occur.*
5. *Your consent to treatment with the medicines is voluntary. If you do not want to have treatment with the medicines, you do not have to. You can always change your mind about treatment and withdraw consent at any time; just let one of the members of the healthcare team know.*
6. *Do you have any questions in regard to the information provided, or any other questions about the medicines being used in the treatment of COVID-19?* If yes, answer any questions the patient may have. If no, continue to collect consent.

Patient confirmation of consent

7. *Now that I have provided you with this information, can you [state name of patient/person responsible] please confirm that you:*
   - *understand the proposed use of the medicines including the possible benefits and harms?*
   - *have had an opportunity to ask questions and you are satisfied with the answers you have received?*
   - *freely agree to treatment with the medicines [state names of medicines]?*
     - If no, thank the participant for their time and end the consent process.
     - If yes, ensure you record the date the verbal consent was collected (see documentation guide below).
8. *Thank you for your time.*

Documentation

Either print this form and sign the Doctor's Declaration below and place/scan in medical record OR copy and paste the Doctor's Declaration and insert into patent's electronic medical records with electronic sign-off. Include translator details (as below) if used.

Doctor's declaration: I have provided to the patient/the person responsible an explanation of the use of remdesivir/ baricitinib/ tocilizumab (remove non-applicable medicines), their potential benefits and harms and the relevant Patient Information Leaflets. I believe the information has been understood.

Doctor's name & designation: _____ **Signature:** _____ **Date:** ____/____/____

If Accredited Health Care Interpreter used, provide language, interpreter's name, ID#: _____

Signature: _____ **Date:** ____/____/____