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Sotrovimab: Verbal consent form / guide for clinician

Written consent forms for sotrovimab and other COVID-19 medicines are also available on the NSW TAG website 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 a new medicine, sotrovimab, which may be used to treat some cases of mild or moderate COVID-19 and get your consent for its use in you/the person you are responsible for. It is important you understand the possible benefits and harms of sotrovimab.*

3. *You have been provided with the Patient & Family Information Leaflet which provides information about sotrovimab to treat COVID-19 in you /the person you are responsible for.*
   Whenever possible, provide the relevant Patient & Family Information Leaflets to the patient/person responsible beforehand. There may be a need to provide further explanation regarding use in some populations e.g. adolescents.

Sotrovimab (Xevudy®)
- Sotrovimab is a new medicine that acts against the COVID-19 virus. It is provisionally approved for use in Australia to treat mild to moderate COVID-19 in people who do not need oxygen but are at risk of COVID-19 becoming more severe. More information about its effectiveness & safety is needed before it is fully approved in Australia. *- Sotrovimab works by blocking the virus entering human cells and multiplying in the body. If it is used within 5 days of onset of COVID-19 symptoms, sotrovimab probably reduces the risk of being admitted to hospital or dying.* *- So far, sotrovimab has shown a good safety profile. Some possible side effects that might be experienced are listed in the information leaflet. They include reactions while sotrovimab is being given such as fever, chills, itchiness, rash, headache or dizziness. Very rarely, a person receiving sotrovimab has had a severe allergic reaction and needed treatment. Immediately tell the doctor or nurse looking after you if you think you are having a side effect.* *- Because it is a new medicine, there is a possibility of experiencing other unknown side effects when it is used in people with COVID-19.* *- Sotrovimab is given by infusion into a vein over 30 minutes. We will closely observe you for one hour after the infusion has been given, to check for any immediate side effects.*

4. *It is important for you to know and understand that:*
   - *there are no guarantees of the effectiveness of sotrovimab 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 sotrovimab and it may cause side effects when used to treat COVID-19 and, even with careful precautions in place, unforeseen complications may occur; and,*
   - *this is a new drug with no known drug interactions. However, sotrovimab can reduce effectiveness of vaccines given recently before or after treatment. (Please ask your doctor about your future vaccinations when you have recovered from COVID-19).*

5. *Your consent to treatment with sotrovimab is voluntary. If you do not want to have treatment with sotrovimab, you do not have to. You can always change your mind about treatment and withdraw consent at any time; just let one of the healthcare team members know.*

6. *Do you have any questions in regard to the information provided, or any other questions about sotrovimab 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 sotrovimab including the possible benefits and harms?*
   - *you have had an opportunity to ask questions and you are satisfied with the answers you have received?*
   - *you freely agree to treatment with sotrovimab?*
     - 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. *Do you agree to be contacted in the future to check on how you are and how you felt after receiving sotrovimab?* ◯ Yes / ◯ No
   If yes, *what is your phone number please:* _____

9. *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 the Doctor's declaration (below) and paste into patent's electronic medical records (with appropriate edits) 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 sotrovimab, their potential benefits and harms and the relevant Patient Information Leaflets. I believe the information has been understood. The patient/person responsible has/has not agreed (delete/strikethrough as appropriate) to be contacted in the future.

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

If Accredited Health Care Interpreter used, provide language, Translator's Name, ID#: _____
Signature: _____ **Date:** ____/____/____