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NSW TAG NSW Therapeutic Advisory Group Inc. | Advancing quality use of medicines in NSW

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ONLINE FORM COMPLETION ENCOURAGED WHENEVER POSSIBLE

Sotrovimab Prescribing Declaration/Streamlined IPU application form for applicant (prescriber) completion

Please read before you begin:
Familiarise yourself with the questions and the information required in this online form BEFORE proceeding. (Scroll down to view all questions).

- Some sites may require peer review / multidisciplinary team consultation for approval to access sotrovimab. If this is required, please undertake prior to completing this form.
- **Please provide a response to each starred* question. Failure to provide responses may delay the processing of this form and subsequent supply of sotrovimab.**
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1. ***Enter a 'code' unique to this patient**
Suggest follow this template Sotrovi_LHD_MRN_DATEofREQUEST
e.g. Sotrovi_WSLHD_0123456_31082021

2. Name of hospital providing health services to the patient and where this form is being submitted to

Section A. Patient Demographics

3. *Patient's initials [Question ID: 43714]

4. *Patient's MRN (or other unique identifying number if applicable) [Question ID: 59177]

5. *Patient's Gender [Question ID: 25107]

- O Male
- O Female
- O Other

6. *Patient's Date of Birth (preferred) or Age [Question ID: 43715]

7. *Current patient location

- O Home (jump to question **9**)
- O Residential Care Facility (RCF) (jump to question **9**)
- O Disability Group Home (jump to question **9**)
- O Special Health Accommodation (jump to question **9**)
- O Hospital-inpatient (jump to question **9**)
- O Hospital-outpatient (jump to question **9**)
- O Other (please provide details in next question) (jump to question **8**)

8. If other patient location please provide details [Question ID: 59179]

Section B. COVID-19 Infection Status, Severity of Illness, Immune Status and Criteria for Sotrovimab Access

9. *COVID-19 Test Result [Question ID: 25112]

- O Positive
- O Pending
- O Indeterminate

10. *Please select if the patient acquired their infection in any of the following settings [Question ID: 59690]

- O Hospital
- O Residential aged care facility
- O Disability group home
- O Prison
- O Other high risk healthcare setting (provide details below)
- O Not acquired in any of the above settings
- O Don't know

11. Provide details of other high risk healthcare setting where infection was acquired [Question ID: 59691]

12. *Current severity of Illness.

Definition of disease severity from the National COVID-19 Clinical Evidence Taskforce Living Guidelines https://covid19evidence.net.au/	
Mild illness	Adults not presenting any clinical features suggestive of moderate or severe disease or a complicated course of illness. Characteristics: • no symptoms • or mild upper respiratory tract symptoms • or cough, new myalgia or asthenia without new shortness of breath or a reduction in oxygen saturation
Moderate illness	Stable adult patient presenting with respiratory and/or systemic symptoms or signs. Able to maintain oxygen saturation above 92% (or above 90% for patients with chronic lung disease) with up to 4 L/min oxygen via nasal prongs. Characteristics: • prostration, severe asthenia, fever > 38 °C or persistent cough • clinical or radiological signs of lung involvement • no clinical or laboratory indicators of clinical severity or respiratory impairment

The patient is:

- O Mildly ill (jump to question **14**)
- O Moderately ill (jump to question **14**)
- O Other (jump to question **13**)

13. If other severity of illness, provide details [Question ID: 25114]

14. *Please indicate the nature the patient's reduced immunity to COVID-19.
(*See Sotrovimab drug guideline for immunosuppression criteria)

The patient:

- O has not been vaccinated (jump to question **16**)
- O has received only one vaccination dose (jump to question **16**)
- O has received two vaccination doses but last dose was within the last 2 weeks (jump to question **16**)
- O Is fully vaccinated but is immunosuppressed* (please provide further details in the next question) (jump to question **15**)

15. Please provide further information about the patient's immunosuppression status:

For the purposes of criteria to access sotrovimab, immunosuppressed patients are those that
a) have a primary or acquired immunodeficiency such as haematological neoplasms, are post-transplant [solid organ (on immunosuppressive therapy) or haematopoietic stem cell transplant within 24 months], or have HIV/AIDS or other significant immunocompromising condition, or
b) are on/have been on recent immunosuppressive therapy such as chemotherapy, radiotherapy, high dose corticosteroids (equivalent to 20 mg or more of prednisone per day for 14 days or more) or are on biologic immunotherapies including most disease-modifying anti-rheumatic drugs (DMARDs).

16. *Please select any pre-existing risk factors for progression of COVID-19 (select all that apply)

☐ Diabetes (requiring medication)

☐ Obesity (BMI greater than 30 kg/m2)

☐ Chronic kidney disease (i.e. eGFR less than 60 mL/min/1.73m2)

☐ Congestive heart failure (New York Heart Association (NYHA) class II or greater)

☐ Chronic obstructive pulmonary disease (history of chronic bronchitis, chronic obstructive lung disease, or emphysema with dyspnoea on physical exertion)

☐ Moderate-to-severe asthma (requiring an inhaled steroid to control symptoms or prescribed a course of oral steroids in the previous 12 months)

☐ Age greater than 35 years (Aboriginal and/or Torres Strait Islander person)

☐ Age greater than or equal to 55 years (for Non-Aboriginal and/or Torres Strait Islander person)

☐ Other (please provide details in next question)

☐ No risk factors for progression of COVID-19 --> this application is outside streamlined IPU criteria for approval - please discuss further with your DTC

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17. *I confirm that:

	Yes ("Yes" responses meet the Restricted Formulary Criteria/Streamlined IPU criteria)	No ("No" responses mean that this submission will be evaluated as an IPU application and further information will be required)	Other ("Other" responses mean that this submission will be evaluated as an IPU application and further information will be required)
The onset of COVID-19 symptoms in this patient is within the last 5 days	◯	◯	◯
The patient does NOT require oxygen	◯	◯	◯
The patient has reduced immunity to COVID-19	◯	◯	◯
The patient has one or more of the risk factors for progression of COVID-19 (as selected in the previous question)	◯	◯	◯

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18. If answered other to any of the questions within the previous question, please provide details below [Question ID: 59701]

N.B. You may attach supporting documents to this application e.g. further evidence (if required) in an email sent to the DTC.

Section C. Patient Consent

19. Has informed patient consent been obtained and documented in the medical record?

For patient information leaflets and consent forms, visit the NSW TAG COVID-19 Resources webpage

- ◯ Yes
- ◯ No
- ◯ Pending
- ◯ Not sure

Section D. Contraindications

(At the time of writing 2/9/21, there are no known relevant precautions or drug interactions for sotrovimab)

20. Does the patient have a known hypersensitivity including anaphylaxis to sotrovimab or any of the excipients (histidine, histidine hydrochloride monohydrate, sucrose, methionine, polysorbate 90), Chinese hamster ovary cell products or other recombinant human or humanised antibodies?

(Refer to sotrovimab drug guideline for further information)

- ◯ Yes - use is contraindicated
- ◯ No

Section E. Sotrovimab Dosing Information

21. *Where is sotrovimab being administered to the patient?
(if applicable, document facility name and/or service type)

22. *Please nominate dose the patient is to receive:

- ○ 500 mg IV sotrovimab x 1 dose (jump to question **24**)
- ○ Other dose (please provide details in next question) (jump to question **23**)

23. If other dose proposed, please provide details below

Section F. Prescriber's Details

24. *Prescriber's full name

25. *Prescriber's email address

26. *Prescriber's contact number (pager and/or extension and/or mobile number)

27. *Prescriber's specialty (if Other, please specify)

- O Infectious Disease Physician (jump to question **29**)
- O Respiratory Physician (jump to question **29**)
- O Emergency Medicine Physician (jump to question **29**)
- O Other, please specify (jump to question **28**)

28. If other specialty, please specify

29. If applicable at your site, have you consulted another specialty clinician for a second opinion?

- O Yes (jump to question **30**)
- O No (jump to question **31**)
- O Not required at my site (jump to question **32**)

30. Please provide name and specialty of the clinician who provided the second opinion.

31. If no second opinion sought, provide reason

32. If applicable at your site, have you obtained approval from your Head of Department?

- O Yes
- O No

Section G. Additional Information

33. Optional: please include any other information relevant to this Prescribing Declaration/IPU application if not captured elsewhere

Pharmacovigilance:

- You may be contacted at a later time for information about clinical outcomes of the patient who received this medicine
- Adverse events related to medicines should be reported to the TGA and via the hospital ims+ or Riskman system

Submission

Before clicking 'Submit', please ensure you have responded to all the questions marked with an asterisk*.

1. You must email the DTC/Pharmacy Dept. to notify them of your submission so that they can review and arrange supply of sotrovimab. See quick email hyperlink and email template below.

2. Click on the relevant hyperlinked email below to open an email window to write a submission email.

DTC/Pharmacy Dept. email: *[ ]*

DTC/Pharmacy Dept. phone number: *[ ]*

Include in the email the following details at a minimum (*suggest copy & paste and then complete the template below*):

Dear DTC/Pharmacy Dept.,

A Prescribing Declaration/IPU application for Sotrovimab has been submitted for *[patient name, MRN]* for DTC review.

Patient code: *Insert the unique code* Sotrovi_[LHD]_[MRN]_[DATEofADMISSION] *(code entered at beginning of form).*

Kind regards,

[Prescriber Name]

Your local DTC or pharmacist will contact you with the outcome of your submission and arrange supply of sotrovimab, if appropriate/approved.

Thank you