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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

Sarilumab Prescribing Declaration Form OR Streamlined IPU Application Form

Please read before you begin:

- Some sites may require peer review / multidisciplinary team consultation for approval to access sarilumab. If this is required, please undertake prior to completing this form.
- **Provide a response to each starred* question. Failure to provide responses may delay the processing of this form and subsequent supply of sarilumab.**

1. ***Enter a 'code' unique to this patient**
Suggest follow this template Sari_LHD_MRN_DATEofADMISSION
e.g. Sari_WSLHD_0123456_02092021

Section A. Patient Demographics

2. *Patient's initials

3. *Patient's MRN

4. *Patient's Gender

- O Male
- O Female
- O Other

5. *Patient's Date of Birth (preferred) or Age

6. *Patient location

- O ICU
- O Non-ICU

7. *Hospital Name

Section B. COVID-19 Infection Status and Severity of Illness

8. *COVID-19 Test Result

- O Positive
- O Pending
- O Indeterminate

9. *Current severity of Illness.

Definition of disease severity from the National COVID-19 Clinical Evidence Taskforce Living Guidelines https://covid19evidence.net.au/

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
Severe illness	Patients meeting any of the following criteria: • respiratory rate ≥ 30 breaths/min • oxygen saturation ≤ 92% at a rest state • arterial partial pressure of oxygen (PaO2)/ inspired oxygen fraction (FiO2) ≤ 300
Critical illness	Patient meeting any of the following criteria: Respiratory failure • Occurrence of severe respiratory failure (PaO2/FiO2 ratio < 200), respiratory distress or acute respiratory distress syndrome (ARDS). This includes patients deteriorating despite advanced forms of respiratory support (NIV, HFNO) OR patients requiring mechanical ventilation. OR other signs of significant deterioration • hypotension or shock • impairment of consciousness • other organ failure

The patient is:

- O Moderately ill (jump to question **11**)
- O Severely ill (jump to question **11**)
- O Critically ill (jump to question **11**)
- O Other (jump to question **10**)

10. If other severity of illness, provide details

11. *Current respiratory support requirements

Based on National COVID-19 Clinical Evidence Taskforce Living Guidelines definitions for respiratory support. (https://covid19evidence.net.au/)

N.B. It is recommended to commence sarilumab within 24 hours of commencing supplemental high-flow oxygen, non-invasive ventilation or invasive mechanical ventilation

- ◯ Hospitalised, requiring supplemental oxygen via low flow oxygen devices
- ◯ Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices
- ◯ Hospitalised, on non-invasive ventilation (NIV)
- ◯ Hospitalised, on invasive mechanical ventilation
- ◯ Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO)

Section C. Prescribing Declaration/Criteria for Streamlined IPU application & Patient Consent

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

12. *Please confirm that the patient:

- meets the current National COVID-19 Clinical Evidence Taskforce recommended criteria for commencement of sarilumab in adults hospitalised with COVID-19, AND
- is unable to have baricitinib due to contraindications/appropriateness (see below), AND
- is not pregnant, breastfeeding or aged < 18 years (these patients will require tocilizumab).

Current as at 26/08/21, the Taskforce gives a conditional recommendation for use of sarilumab for the treatment of COVID-19 in adults, who require high-flow oxygen, non-invasive ventilation or invasive mechanical ventilation.
Baricitinib is the preferred immunomodulator medicine for COVID-19 during constrained supply of other immunomodulators (e.g. tocilizumab and sarilumab), unless baricitinib is contraindicated or not appropriate (e.g. pregnant/breastfeeding women, children and adolescents, oral/NG administration not possible, severe renal impairment eGFR<15 mL/min/1.73m2 or requiring dialysis).
If an IL-6 inhibitor must be used and sarilumab is available, appropriate and not contraindicated, it is the preferred IL-6 inhibitor during tocilizumab shortage.

O Yes (jump to question **13**)

O No --> this submission may be outside criteria for use - please discuss further with your DTC

13. 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

O Yes

O No

O Pending

O Not sure

Section D. Contraindications, Precautions

14. *Contraindications for sarilumab use include:

- Hypersensitivity including anaphylaxis to components in product, Chinese hamster ovary cell products or other recombinant human or humanised antibodies
- Sepsis or active, severe infections from non-COVID-19 pathogens
  (Refer to sarilumab drug guideline & the product information for further information)

◯ No contraindications exist (jump to question **16**)

◯ Contraindications exist, please describe below (jump to question **15)**

15. Describe contraindications

16. *Please select the following precautions for sarilumab use in COVID-19 if they are present (more than one answer may be selected)

☐ Risk factors for infection

☐ Risk factors for haematological toxicity

☐ Risk factors for gastrointestinal perforation

☐ Recent immunisation with live vaccine (please provide details in next question)

☐ Hepatic impairment including abnormal liver enzymes (transaminases 3-5 times the upper limit of normal)

☐ Other (please provide details in next question)

☐ No precautions present

17. Please provide further details of precautions that were selected

18. *A check for drug interactions is required prior to prescribing sarilumab

Potential drug interactions have not been investigated in patients with COVID-19. It is prudent to minimise the concurrent use of any nonessential medications whenever possible and consider whether medication doses may require adjustment during hospitalisation.
(Refer to the sarilumab drug guideline and University of Liverpool interactions checker for further information).

Please select if the patient is prescribed/is likely to be prescribed any of the medicines which may potentially interact with sarilumab (more than one answer may be selected)

☐ No drug interactions present

☐ Immunomodulatory agents (other than corticosteroids - please provide details in next question)

☐ Clozapine (increased risk of agranulocytosis)

☐ Warfarin

☐ Apixaban, rivaroxaban; clopidogrel, ticagrelor

☐ Antiepileptics e.g. carbamazepine, phenytoin

☐ Benzodiazepines

☐ Opioids, e.g. fentanyl, oxycodone

☐ Amiodarone

☐ Other (please provide details in next question)

19. If other drug interaction(s), provide details

Section E. Sarilumab Dosing Information

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

○ 400 mg IV sarilumab x 1 dose (jump to question **22)**

○ Other dose (please provide details in next question) (jump to question **21)**

21. If other dose proposed, please provide details below

Section F. Prescriber's Details

22. *Prescriber's full name

23. *Prescriber's email address

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

25. *Prescriber's specialty

- O Immunologist (jump to question **27**)
- O Haematologist (jump to question **27**)
- O Infectious Disease Physician (jump to question **27**)
- O Intensivist (jump to question **27**)
- O Respiratory Physician (jump to question **27**)
- O Other, please specify (jump to question **26**)

26. If other specialty, please specify

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

- O Yes (jump to question **28**)
- O No (jump to question **29**)
- O Not required at my site (jump to question **30**)

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

29. If no second opinion sought, provide reason

30. If required at your site, have you obtained approval from your Head of Department?

- O Yes
- O No

Section G. Additional Information

31. 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 sarilumab. 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/PU application for Sarilumab has been submitted for *[patient name, MRN]* for DTC review.
Patient code: *Insert the unique code* Sari_[LHD]_[MRN]_[DATEofADMISSION] *(code entered at beginning of the form).*
Kind regards,
[Prescriber Name]

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

Thank you