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

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# Tocilizumab Streamlined IPU application 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).

- The form can only be completed in one session
    - You cannot save, close and return to this form at a later time (if you are called away, the form will remain open unless your browser is closed).
- Completion of the form takes approximately 5 minutes
- The Tocilizumab Drug Guideline provides guidance for tocilizumab use in hospitalised patients.
- Some sites will require peer review / multidisciplinary team consultation for approval to access tocilizumab, please undertake prior to completing this form.
- **Provide a response to each applicable question. Failure to provide responses may delay the processing of this form and subsequent supply of remdesivir.**

**1.** ***Enter an 'IPU application code' unique to this patient**

Suggest follow this template Toci_LHD_MRN_DATEofADMISSION
*e.g. Toci_WSLHD_0123456_05032021*

[Question ID: 43713]

## Section A. Patient Demographics

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

**3.** *Patient's MRN [Question ID: 25105]

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

- O Male
- O Female
- O Other

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

**6.** *Patient's weight (in kg) [Question ID: 43716]

**7.** *Patient location [Question ID: 43717]

- O ICU
- O Non-ICU

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

**8.** Has the patient received a COVID-19 vaccination? [Question ID: 43718]

- O Yes, has received a full course of a COVID-19 vaccine *(jump to question **9**)*
- O Partially, has received part of the vaccination course *(jump to question **9**)*
- O No *( jump to question **10**)*

**9.** Which vaccine did they receive? [Question ID: 43719]

**10.** *Date of symptom onset (date format: dd/mm/yyyy) [Question ID: 25111]

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

- O Positive
- O Pending
- O Indeterminate

**12.** *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.<br><br>Characteristics:<br><br>• prostration, severe asthenia, fever > 38 °C or persistent cough<br>• clinical or radiological signs of lung involvement<br>• no clinical or laboratory indicators of clinical severity or respiratory impairment |
| **Severe illness** | Patients meeting any of the following criteria:<br><br>• respiratory rate ≥ 30 breaths/min<br>• oxygen saturation ≤ 92% at a rest state<br>• arterial partial pressure of oxygen (PaO2)/ inspired oxygen fraction (FiO2) ≤ 300 |
| **Critical illness** | Patient meeting any of the following criteria:<br>Respiratory failure<br><br>• 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.<br>OR other signs of significant deterioration<br><br>• hypotension or shock<br>• impairment of consciousness<br>• other organ failure |

[Question ID: 43721]

The patient is:

- ○ Moderately ill *(jump to question **14**)*
- ○ Severely ill *(jump to question **14**)*
- ○ Critically ill *(jump to question **14**)*
- ○ Other *(jump to question **13**)*

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

**14.** *Current respiratory support requirements

Based on National COVID-19 Clinical Evidence Taskforce Living Guidelines definitions for respiratory support. (https://covid19evidence.net.au/ )
[Question ID: 43722]

- ◯ 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)

**15.** Please provide the evidence for systemic inflammation in this patient including the baseline CRP concentration. [Question ID: 43723]

**16.** *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected) [Question ID: 43745]

- ☐ Age equal to or greater than 65 years
- ☐ Current smoker
- ☐ BMI equal to or greater than 30 kg/m2 and less than 40 kg/m2
- ☐ BMI equal to or greater than 40 kg/m2
- ☐ Hypertension
- ☐ Hyperlipidaemia
- ☐ Other cardiovascular disease (please specify in next question)
- ☐ Cerebrovascular disease
- ☐ Diabetes
- ☐ Chronic respiratory disease (please specify in next question)
- ☐ Chronic kidney disease (eGFR < 60 mL/min/1.73 m2)
- ☐ Hepatic impairment
- ☐ Cancer
- ☐ Other (please provide details in next question)
- ☐ No poor prognostic factors for COVID-19 identified

**17.** Please provide further details about any selected pre-existing poor prognostic factors [Question ID: 43746]

## Section C. Reason for IPU application

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

**18.** *Select any clinical trials involving tocilizumab at your hospital (more than one answer may apply) [Question ID: 43724]

- ☐ REMAP-CAP
- ☐ Other (provide details in next question)
- ☐ No relevant clinical trials involving tocilizumab
- ☐ Don't know

**19.** If other, provide the name(s) of any relevant trial(s) involving tocilizumab below (put N/A if question not applicable) [Question ID: 25103]

**20.** *Please select reason for IPU application [Question ID: 43747]

- O Hospital not participating in relevant clinical trial *(jump to question **24**)*
- O Patient not eligible for relevant clinical trial (select reason for exclusion in follow up question) *(jump to question **22**)*
- O Other (please provide details) *(jump to question **21**)*

**21.** If other reason for IPU application, please provide details [Question ID: 25117]

**22.** Reasons for exclusion from clinical trial (more than one answer may be selected) [Question ID: 25118]

☐ Age

☐ Renal impairment

☐ Hepatic impairment

☐ Known or suspected pregnancy

☐ Platelet count

☐ Neutropenia

☐ COVID-19 severity

☐ Inpatient location

☐ Time in ICU

☐ Respiratory support requirements

☐ Current or previous use of one or more of the trial drugs during current hospitalisation or is on long-term therapy with the trial drugs prior to current hospitalisation

☐ Use or proposed use of medications that are contraindicated with one or more of the trial drugs

☐ Currently on other investigational agents with targeted immunomodulatory effects

☐ Known allergy or hypersensitivity to one or more of the trial drugs but not to tocilizumab

☐ Treating team deems enrolment in the study is not in the best interests of the patient

☐ Previous participation in the trial

☐ Pre-existing medical conditions (provide details in next question)

☐ Other (please provide details in next question)

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**23.** If other pre-existing medical conditions or any other reason(s) excluded the patient from an applicable clinical trial, provide details [Question ID: 25119]

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**24.** *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 [Question ID: 43729]

○ Yes

○ No

○ Pending

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# Section D. Contraindications, Precautions

**25.** *Contraindications for tocilizumab 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 tocilizumab drug guideline and the product information for further information)

Are any contraindications present? [Question ID: 43730]

- O No contraindications exist *(jump to question **27**)*
- O Contraindications exist, please describe below *(jump to question **26**)*

**26.** Describe contraindications [Question ID: 25125]

**27.** *Please select the following precautions for tocilizumab use in COVID-19 if they are present (more than one answer may be selected) [Question ID: 43731]

☐ Chronic or recurring infections or conditions pre-disposing to infections (please provide further details in next question)

☐ Use of concurrent immunosuppressive/anti-rejection therapy (please provide details in next question)

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

☐ Absolute neutrophil count < 2 x 10^9/L

☐ Platelet count < 100 x 10^9/L

☐ Severe haematological disorder

☐ Current or history of intestinal ulceration or diverticulitis

☐ Known or suspected pregnancy

☐ Other (please provide details in next question)

☐ No precautions present

**28.** Please provide further details of precautions that were selected [Question ID: 43732]

**29.** *A check for drug interactions is required prior to prescribing tocilizumab

**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. Consider the following:**

**(Refer to the tocilizumab 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 tocilizumab (more than one answer may be selected)
[Question ID: 43733]

- ☐ No drug interactions present
- ☐ Warfarin
- ☐ Antiepileptics e.g. carbamazepine, phenytoin
- ☐ Benzodiazepines
- ☐ Opioids, e.g. fentanyl, oxycodone
- ☐ Amiodarone
- ☐ Apixaban, clopidogrel, prasugrel, rivaroxaban, ticagrelor
- ☐ Interferon beta
- ☐ Other (please provide details in next question)

**30.** If other drug interaction(s), provide details [Question ID: 25129]

# Section E. Tocilizumab Dosing Information

The recommended dosing is according to weight.

| Weight | Dose |
|---|---|
| Patients >90 kg | 800 mg |
| Patients >65 and ≤90 kg | 600 mg |
| Patients >40 and ≤65 kg | 400 mg |
| Patients ≤40 kg | 8 mg/kg |

**31.** *Patient weight in kg (numeric field) [Question ID: 25122]

**32.** *Please nominate dose the patient is to receive: [Question ID: 43734]

- O 800 mg tocilizumab *(jump to question **34**)*
- O 600 mg tocilizumab *(jump to question **34**)*
- O 400 mg tocilizumab *(jump to question **34**)*
- O 8 mg/kg tocilizumab if patient weighs less than or equal to 40 kg (please provide dose in next question) *(jump to question **33**)*

**33.** *Enter (in mg) the calculated dose that you propose to use (numeric field) [Question ID: 25123]

# Section F. Other Proposed or Concurrent Therapy

**34.** *Please select if the following antivirals have been prescribed or there is a current plan to prescribe (more than one answer may be selected) [Question ID: 43735]

- ☐ No antivirals
- ☐ Remdesivir
- ☐ Other (please provide details in next question)

**35.** If other antiviral, provide details [Question ID: 25135]

**36.** *Please select if the any of the following corticosteroids (not topical) have been prescribed acutely or there is a current plan to prescribe [Question ID: 43748]

- ◯ No corticosteroids *(jump to question **38**)*
- ◯ Dexamethasone *(jump to question **37**)*
- ◯ Hydrocortisone *(jump to question **37**)*
- ◯ Methylprednisolone *(jump to question **37**)*
- ◯ Prednisone/Prednisolone *(jump to question **37**)*

**37.** If acute use or planned use of corticosteroid, provide dose and route details [Question ID: 25137]

**38.** *Please select if any of the following immunomodulators have been prescribed acutely or there is a current plan to prescribe [Question ID: 43749]

- ◯ No other current or planned immunomodulator *(jump to question **40**)*
- ◯ Anakinra *(jump to question **40**)*
- ◯ Other (please provide details in next question) *(jump to question **39**)*

**39.** If other immunomodulator, provide details [Question ID: 25139]

**40.** *Please select if antibacterial therapy has been prescribed or there is a current plan to prescribe (more than one answer may be selected) [Question ID: 25140]

- ☐ No antibacterial therapy current or planned
- ☐ Amoxicillin with clavulanic acid
- ☐ Amoxicillin
- ☐ Azithromycin
- ☐ Benzylpenicillin
- ☐ Ceftriaxone
- ☐ Doxycycline
- ☐ Gentamicin
- ☐ Piperacillin/tazobactam
- ☐ Other (please provide details in next question)

**41.** If other antibacterial therapy, provide details [Question ID: 25141]

# Section G. IPU Applicant's (i.e. Prescriber's) Details

**42.** *Prescriber's full name [Question ID: 43737]

**43.** *Prescriber's email address [Question ID: 43738]

**44.** *Prescriber's contact number (pager and/or extension and/or mobile number) [Question ID: 43739]

**45.** *Prescriber's specialty [Question ID: 43736]

- O Immunologist *(jump to question **47**)*
- O Haematologist *(jump to question **47**)*
- O Infectious Disease Physician *(jump to question **47**)*
- O Intensivist *(jump to question **47**)*
- O Respiratory Physician *(jump to question **47**)*
- O Other, please specify *(jump to question **46**)*

**46.** If other specialty, please specify [Question ID: 25094]

**47.** *Have you consulted another specialty clinician for a second opinion? [Question ID: 43751]

- O Yes *(jump to question **48**)*
- O No *(jump to question **49**)*

**48.** *Please provide name and specialty of the clinician who provided the second opinion. [Question ID: 25096]

**49.** If no to question 7, provide reason [Question ID: 25097]

**50.** *Have you obtained approval from your Head of Department? [Question ID: 25098]

- O Yes
- O No

**51.** *Do you have any conflicts of interest regarding this application to declare?

Tocilizumab (Actemra) is manufactured by Roche Products Pty Limited.
Financial or other interests resulting from contact with pharmaceutical companies, which may have a bearing on this submission may include:

- Gifts
- Industry paid food/refreshments
- Travel expenses
- Honoraria
- Samples
- Research support
- Other types of support

[Question ID: 43752]

- O Yes *(jump to question **52**)*
- O No *(jump to question **53**)*

**52.** Please describe conflict of interest [Question ID: 25100]

**53.** *Hospital Name [Question ID: 43740]

## Section H. Outcome reporting

**54.** *I agree to report any suspected adverse events and other clinical outcomes of this individual patient use

*[The DTC will provide you with a hyperlink to the 'Tocilizumab Adverse Events and Clinical Outcomes Report Form' for completion within 2 weeks of tocilizumab cessation, discharge or death.]* [Question ID: 43741]

- O Yes
- O No

## Section I. Additional Information

**55.** Optional: please include any other information relevant to this IPU application if not captured elsewhere [Question ID: 25147]

# Submission

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

1. You must email the DTC to notify them of your submission so that they can review and arrange supply of tocilizumab. **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 email: _____

DTC phone number: _____

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

Dear DTC,

An IPU application for Tocilizumab has been submitted for *[patient name, MRN]* for DTC review.
IPU application code: *Insert the unique IPU application code**
*Toci_[LHD]_[MRN]_[DATEofADMISSION] *(code entered at beginning of application form).*
The urgency for DTC review of the IPU application is: *(ASAP, <24 hours, 24-72 hours, other (provide detail))*

Kind regards,
Applicant / [Prescriber Name]

**Your local DTC or pharmacist will contact you with an outcome of your submission and arrange supply of tocilizumab, if approved.**

**The DTC will provide you with a hyperlink to the 'Tocilizumab Adverse Event and Clinical Outcomes Reporting Form' for completion within 14 days of tocilizumab cessation, discharge or death.**

**Thank you**