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

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ONLINE FORM COMPLETION ENCOURAGED WHENEVER POSSIBLE

Baricitinib Prescribing Declaration OR Streamlined IPU application

Please read before you begin:

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

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

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

7. *COVID-19 Test Result

- O Positive
- O Pending
- O Indeterminate

8. *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 **10**)
- O Severely ill (jump to question **10**)
- O Critically ill (jump to question **10**)
- O Other (jump to question **9**)

9. If other severity of illness, provide details

10. *Current respiratory support requirements

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

- ◯ 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)

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 to the DTC

11. *Please confirm that the patient:

- meets the current National COVID-19 Clinical Evidence Taskforce recommendation for use of baricitinib for adults hospitalised with COVID-19

*Current as at 26/08/21, the Taskforce gives a conditional recommendation for use of baricitinib for **adults** hospitalised with COVID-19 who require supplemental oxygen, high-flow oxygen and/or non-invasive ventilation.*

Baricitinib is the preferred immunomodulator medicine for COVID-19 during constrained supply of other immunomodulators e.g. tocilizumab and sarilumab, unless it 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).

- O Yes (jump to question **12**)
- O No --> this submission may be outside criteria for use - please discuss further with your DTC

12. *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

13. *Does the patient have a known hypersensitivity to baricitinib or any of the excipients in the product?

- O Yes - use is contraindicated
- O No (jump to question **14**)

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

- ☐ Risk factors for infection
- ☐ Risk factors for thrombosis
- ☐ Risk factors for haematological toxicity
- ☐ Risk factors for gastrointestinal perforation
- ☐ Recent immunisation with live vaccine (please provide details in next question)
- ☐ Renal impairment (between 15-60 mL/min/1.73m2)
- ☐ Hepatic impairment
- ☐ Other (please provide details in next question)
- ☐ No precautions present

15. Please provide further details of precautions that were selected

16. *A check for drug interactions is required prior to prescribing baricitinib

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 baricitinib drug guideline for links to other drug interaction checkers).

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

☐ No drug interactions present

☐ Immunomodulatory agents (please provide details in next question)

☐ Gemfibrozil (use a lower dose of baricitinib if gemfibrozil is being taken by patient)

☐ Probenecid (use a lower dose of baricitinib if probenecid is being taken by patient)

☐ Clozapine (increased risk of agranulocytosis)

☐ Other (please provide details in next question)

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

Section E. Baricitinib Dosing Information

The recommended dosing is: **4 mg PO ONCE DAILY for up to 14 days, or until hospital discharge (whichever comes first).**

Dose adjustments:

- Renal impairment:
  - Halve dose to 2 mg orally once daily when eGFR = 30 - 60 mL/min/1.73m2.
  - Reduce dose to 1 mg orally once daily when eGFR = 15 - 30 mL/min/1.73m2.
- Patients taking strong OAT3 inhibitors, such as probenecid or gemfibrozil:
  - Halve the dose

18. *Please nominate dose and duration of therapy that the patient is to receive: [Question ID: 59780]

○ 4 mg PO ONCE DAILY for up to 14 days

○ 2 mg PO ONCE DAILY for up to 14 days (or equivalent dosing)

○ 1 mg PO ONCE DAILY for up to 14 days (or equivalent dosing)

○ Other dose of baricitinib --> this submission may be outside criteria for use - please discuss further with your DTC

Section F. Prescriber's Details

19. *Prescriber's full name

20. *Prescriber's email address

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

22. *Prescriber's specialty

- O Immunologist (jump to question **24**)
- O Infectious Disease Physician (jump to question **24**)
- O Intensivist (jump to question **24**)
- O Respiratory Physician (jump to question **24**)
- O Emergency Medicine Physician jump to question **24** ()
- O Other, please specify (jump to question **23**)

23. If other specialty, please specify

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

- O Yes (jump to question **25**)
- O No (jump to question **26**)
- O Not required at my site (jump to question **27**)

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

26. If no second opinion/specialty advice sought, provide reason

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

- O Yes
- O No

28. *Hospital Name

Section G. Additional Information

29. 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 starred* questions.

1. You must email the DTC/Pharmacy Dept. to notify them of your submission so that they can review and arrange supply of baricitinib. 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 Baricitinib has been submitted for *[patient name, MRN]* for DTC/Pharmacy Dept. review.

Patient code: *Insert the unique code**

*Bari_[LHD]_[MRN]_[DATEofADMISSION] *(code entered at beginning of form).*

Kind regards,

[Prescriber Name]

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

Thank you