



NSW
Therapeutic
Advisory
Group Inc.

Advancing
quality use
of medicines
in NSW

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Baricitinib Adverse Events and Clinical Outcomes Report

It is recommended that this report form is completed within 2 weeks of baricitinib cessation, discharge, or death.

1. *Enter the 'code' unique to this patient
(use the same code that was selected in the IPU/prescribing declaration submission with suggested template Bari_LHD_MRN_DATEofADMISSION)

2. *What is today's date? (date format: dd/mm/yyyy)

Section A. Clinician's details

3. *Full name of clinician providing report

4. *Are you the same clinician who made the original IPU/prescribing declaration submission?

Yes (jump to question 9)

No (jump to question 5)

5. Clinician's email address

6. Clinician's contact phone number (extension and/or mobile number)

7. Clinician's specialty

Immunologist (jump to question 9)

Infectious Disease Physician (jump to question 9)

Intensivist (jump to question 9)

Respiratory Physician (jump to question 9)

Emergency Medicine Physician (jump to question 9)

Other, please specify (jump to question 8)

8. If other specialty, please specify

Section B. Patient Demographics

9. *Patient's initials

10. *Patient's MRN

11. *What date was the patient admitted to hospital? (date format: dd/mm/yyyy)

12. *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected)

- Age equal to or greater than 65 years
- Smoker, current and former
- BMI equal to or greater than 30 kg/m²
- Vascular (e.g. cardiovascular disease, cerebrovascular disease, hypertension - please specify in next question)
- Diabetes (please specify diabetes type in next question)
- Chronic respiratory disease (please specify in next question)
- Immunocompromised (e.g. HIV, transplant recipient, use of immunosuppressant(s) - please specify in next question)
- Cancer
- Neurologic conditions, including dementia
- Substance use disorder or mental health diagnosis (e.g. depression, bipolar disorder - please specify in next question)
- Other (please provide details in next question)
- No poor prognostic factors for COVID-19 identified

13. Please provide further details about any selected pre-existing poor prognostic factors

Section C. Baricitinib Details

14. *What date was baricitinib commenced? (date format: dd/mm/yyyy)

15. *Actual dosing of baricitinib treatment (i.e. dose and duration of therapy completed)

- 4 mg PO ONCE DAILY for 14 days (jump to question 17)
- 2 mg PO ONCE DAILY for 14 days (or equivalent dosing) (jump to question 17)
- 1 mg PO ONCE DAILY for 14 days (or equivalent dosing) (jump to question 17)
- Other (please provide details in next question) (jump to question 16)

16. If other, please specify dosing (i.e. dose, duration and reason)

17. *If the actual dosing was different to that proposed in the approved IPU/prescribing declaration, provide details (use N/A if dosing not different)

Also include information such as:

- treatment incomplete/ceased early
- still ongoing/additional doses planned
- dose was adjusted and why
- consent to treatment withdrawn
- contraindication identified
- adverse drug effect experienced (identify here and provide details in section E)
- death occurred

Section D. Other Therapy

18. *Was the patient acutely commenced on any of the listed therapies as a result of treatment for COVID-19? (more than one answer may be selected)

- Antiviral therapy
- Corticosteroid (not topical)
- Immunomodulator other than baricitinib
- Antibacterial therapy
- Antithrombotic therapy
- Antifungal therapy
- ACE inhibitor
- Sartan
- Statin
- Other COVID-19 modifying therapy (including pre-hospital therapy; specify in next question)
- Other therapy (specify in next question)
- The patient was not commenced on any of the listed medicines above

19. Provide details of relevant therapies selected in the previous question, including if it was COVID-19 specific therapy and/or part of a clinical trial

20. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient?

- No relevant drug interactions (jump to question 22)
- Yes, interaction(s) involving baricitinib (jump to question 21)
- Yes, interaction(s) involving other COVID-19 therapies (jump to question 21)

21. Provide details of drug interaction(s)

Section E. Possible or Likely Adverse Effects Due to Baricitinib

22. *Did the patient experience any adverse effects (possible or likely) due to baricitinib use?

Yes (jump to question 23)

No (jump to question 46)

23. Select the adverse effects, which were possible or likely due to baricitinib use (more than one answer may be selected)

Possible allergic reaction, including anaphylactic reactions and angioedema

Gastrointestinal perforation

Infection, out of keeping with clinical disease

Hepatotoxicity - increase in LFTs greater than or equal to 5 times upper limit of normal

Serious hepatotoxicity (including acute liver failure, hepatitis and jaundice or requiring liver transplant)

Severe leucopenia, out of keeping with clinical disease

Severe neutropenia, out of keeping with clinical disease

Severe lymphopenia, out of keeping with clinical disease

Anaemia, out of keeping with clinical disease

Thrombocytosis (not associated with thrombotic events)

Thrombosis

Hypercholesterolaemia

Hypertriglyceridaemia

Increased creatine kinase

Death

Other (please provide details in next section)

You are required to provide details for each adverse effect identified. If there are more than TWO adverse effects, a free text field to provide details of these additional adverse effects follows.

First adverse effect

24. What was the adverse effect?

(Name the adverse effect only, further details to be provided below)

25. What was the likelihood that this adverse effect was due to baricitinib use?

Possibly

Likely

Don't know

26. What was the timing of onset of the adverse effect after the initial baricitinib dose was administered (in hours/minutes as applicable)?

27. What was the severity of the adverse effect?
- Mild, no treatment required (jump to question 29)
 - Moderate to Severe, treatment required (jump to question 28)
 - Life-threatening (jump to question 28)
 - Don't know, no treatment required (jump to question 29)
-

28. Provide details of treatment given for the adverse effect including relevant laboratory results and/or diagnostic procedures

29. Has the patient recovered from the adverse effect?
- Yes (jump to question 30)
 - No (jump to question 31)
 - Don't know (jump to question 31)
-

30. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)?

31. Did the adverse effect prolong the hospitalisation or cause death?
- Yes
 - No
 - Don't know
-

32. Provide further details of the adverse effect (Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.)

33. Was a possible or likely second adverse effect experienced by the patient
- Yes (jump to question 34)
 - No (jump to question 45)
-

Second adverse effect

34. What was the adverse effect? (Name the adverse effect only, further details to be provided below)

35. What was the likelihood that this adverse effect was due to baricitinib use?
- Possibly
 - Likely
 - Don't know
-

36. What was the timing of onset of the adverse effect after the initial baricitinib dose was administered (in hours/minutes as applicable)?

37. What was the severity of the adverse effect?
- Mild, no treatment required (jump to question 39)
 - Moderate to Severe, treatment required (jump to question 38)
 - Life-threatening (jump to question 38)
 - Don't know, no treatment required (jump to question 39)
-

38. Provide details of treatment given for the adverse effect including relevant laboratory results and/or diagnostic procedures

39. Has the patient recovered from the adverse effect?
- Yes (jump to question 40)
 - No (jump to question 41)
 - Don't know (jump to question 41)
-

40. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)?

41. Did the adverse effect prolong the hospitalisation or cause death?
- Yes
 - No
 - Don't know
-

42. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.)

43. Were any other adverse effects due to baricitinib (possible or likely) experienced by the patient?
- Yes (jump to question 44)
 - No (jump to question 45)
-

Additional adverse drug effects (three or more)

44. Please provide a free text description of all additional adverse effects identified. Include the following information:

(If helpful, copy and paste the dot points below in your response)

- Name the adverse effect
- Likelihood that this adverse was due to baricitinib: [possibly/ likely/ don't know]
- Timing of onset of the adverse effect after initial baricitinib administration: [hours/minutes, as applicable]
- Severity of the adverse effect: [mild, no treatment required; moderate to severe, treatment required; life-threatening; don't know, no treatment required]
- Provide details of administered treatment for the adverse effect including relevant laboratory results and/or diagnostic procedures: [provide details or N/A]
- Recovery from the adverse effect? [yes/ no/ don't know]
- Time to recovery from the adverse effect: [minutes/hours/days]
- Prolongation of hospitalisation or caused death by adverse effect: [yes/ no/ don't know]
- Any other relevant details of the adverse effect (include results of relevant laboratory data and other investigations, monitoring required etc.)

Section E continued. Possible/Likely Adverse Effects Due to Baricitinib

45. Were adverse effect(s) reported?
- No
 - Yes, reported to both the TGA and the hospital's adverse events reporting system
 - Yes, reported within the hospital's adverse events reporting system
 - Yes, reported to the TGA
 - Not sure
-

Section F. Clinical Outcomes

46. *Select the current clinical status of the patient

Refer to National COVID-19 Clinical Evidence Taskforce [Living Guidelines https://covid19evidence.net.au/](https://covid19evidence.net.au/) for definitions of respiratory support requirements

- Not hospitalised, no limitations on activities (jump to question 51)
 - Not hospitalised, limitations on activities, home oxygen requirement, or both (jump to question 51)
 - Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons) (jump to question 52)
 - Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19-related or other medical conditions) (jump to question 52)
 - Hospitalised, requiring supplemental oxygen via low flow oxygen devices (jump to question 52)
 - Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices (jump to question 52)
 - Hospitalised, on non-invasive ventilation (NIV) (jump to question 52)
 - Hospitalised, on invasive mechanical ventilation (jump to question 53)
 - Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO) (jump to question 53)
 - Death (jump to question 48)
 - Other (jump to question 47)
-

47. If other clinical status, please provide details

48. Date of death (date format: dd/mm/yyyy)

49. Cause of death (as documented on death certificate)

- COVID-19 (jump to question 51)
 - Other (jump to question 50)
-

50. If other, specify cause of death as per death certificate

51. *Specify the total hospital length of stay (LOS) in days

52. *Did the patient require intensive care?

Yes (jump to question 53)

No (jump to question 54)

53. Please specify the ICU/PICU LOS in days (numeric field)

Section G. Additional Information

54. Optional: please include any other information relevant to this report if not captured elsewhere

E.g. consider including:

- requirements and duration of intubation or ECMO
- scores on admission to and discharge from ICU such as SOFA or APACHE 2 etc.
- development of respiratory failure
- development of multiorgan failure

55. What was the patient's COVID-19 vaccination status on admission?

Not vaccinated against COVID-19 (jump to end)

Partially vaccinated, received part of the vaccination course (jump to question 56)

Fully vaccinated, however second vaccine dose was within 2 weeks of admission (jump to question 56)

Fully vaccinated, however, patient was immunosuppressed prior to admission (jump to question 56)

Fully vaccinated (jump to question 56)

Other (please provide details below) (jump to question 56)

56. If known, provide details of:

- which vaccine they received,
- dates of any doses,
- details of immunosuppression if applicable

Submission

- You are now ready to submit the Baricitinib Adverse Events and Clinical Outcomes Report data.
- Please ensure you have completed all the questions marked with an asterisk*.
- Your local DTC/Pharmacy Dept. will contact you if any further information is required.

Thank you for your contribution.