Baricitinib for patients hospitalised due to COVID-19 (adults and children aged 2 years and over)

University Hospitals of Leicester NHS
NHS Trust

Trust Ref: B16/2022

1. Introduction

Baricitinib (Olumiant) is a selective and reversible Janus kinase (JAK) 1 and 2 inhibitor, licensed as an anti-inflammatory treatment for rheumatoid arthritis, atopic dermatitis and severe alopecia areata. JAK-inhibitors are thought to control high levels of cytokines and inflammation, seen in patients with severe SARS-CoV-2 infection.

Data from the RECOVERY trial demonstrates that baricitinib reduces the risk of death when given to hospitalised patients with severe COVID-19, with a relative risk reduction of 13% vs usual care. The benefit of baricitinib was consistent regardless of which other COVID-19 treatments the patients were also receiving, including corticosteroids, tocilizumab, or remdesivir.

The Patients hospitalised due to COVID-19 are eligible for treatment with if the criteria listed below are met. Decision to initiate treatment with baricitinib should be made by the consultant in charge of the patient's care.

2. Scope

This guideline outlines patient eligibility for baricitinib, the prescribing and review requirements, and the procedure to obtain baricitinib for UHL patients that are hospitalised **due to** symptoms of COVID-19.

This guideline applies to all UHL staff involved in the prescribing and administration of baricitinib for adult and paediatric patients aged 2 years and over with COVID-19.

3. Recommendations, Standards and Procedural Statements

3.1 Patient selection

Patients are eligible for treatment with baricitinib if they meet ALL of the following criteria:

- COVID-19 confirmed by testing or where the MDT agree that there is a high level of confidence that COVID-19 is most likely diagnosis.
- Aged 2 years and over
- Receiving supplemental oxygen or respiratory support for the treatment of COVID-19.
- Receiving dexamethasone or an equivalent corticosteroid unless contraindicated.
- Viral pneumonia syndrome* is present

* In general, viral pneumonia should be suspected when a patient presents with:
  -Typical symptoms (e.g. influenza-like illness with fever and muscle pain, or respiratory illness with cough and shortness of breath); AND
  -Compatible chest X-ray findings (consolidation or ground-glass shadowing); AND
  -Alternative causes have been considered unlikely or excluded (e.g. heart failure, bacterial pneumonia).

NB: The use of baricitinib in COVID-19 is off label.

Exclusion criteria:

- Known hypersensitivity to baricitinib;

- eGFR <15 mL/min/1.73m^2 **OR** <30 mL/min/1.73m^2 if the individual being treated is less than 9 years old.
- Receiving dialysis or haemofiltration
- Absolute neutrophil count (ANC) less than 0.5 x 10^9 cells/L
- Active tuberculosis*
- Pregnancy or breastfeeding.

*All patients considered for baricitinib treatment should be screened for Latent TB Infection (LTBI) via Interferon Gamma Release Assay testing (Quantiferon test on ICE). Screening should not delay treatment, but patients found to be positive for LTBI should be referred for preventative LTBI treatment.

Baricitinib may be administered in combination with IL-6 inhibitors, tocilizumab or sarilumab (as well as corticosteroids, unless contraindicated), according to clinical judgement in patients with severe or critical COVID-19.

If an IL-6 inhibitor is not deemed suitable, or eligibility criteria (for an IL-6 inhibitor) are unmet, baricitinib treatment may still be considered.

3.2 Blueteq prior registration

All prescriptions for baricitinib must be registered with Blueteq (NHSE web-based approval platform) prior to prescribing. The process is described below:

- Go to: https://www.blueteq-secure.co.uk/Trust/default.aspx
- Register for an account if you do not already have one, or log in to an established account.
- Please note registration can be completed using normal UHL email address and should take no longer than a few minutes. You may need to wait for your account to be activated so ideally this step should be completed ahead of need to treat an individual patient.
- Select “Patient” then “Add” from the left hand side of the menu bar.
- Complete the details in the Add High Cost Drugs Patient panel. If the Patient is not currently registered with a GP select “Unregistered NHSE patients as the GP surgery.
- Select “Add request” from the Patient menu bar.
- Make a note of the Blueteq authorisation number – this is required by Pharmacy to release the medication
- The blueteq number should be annotated on the prescription.
- A Blueteq user guide for clinicians is available on Insite

3.3 Dosage and administration

Age	Renal function	Dose
≥9	eGFR ≥60 mL/min/1.73m^2	4mg ONCE DAILY
≥9	eGFR 30 to 60 mL/min/1.73m^2	2mg ONCE DAILY
≥9	eGFR 15 to 30 to mL/min/1.73m^2	2mg ONCE DAILY on ALTERNATE DAYS
2 to <9	eGFR ≥60 mL/min/1.73m^2	2mg ONCE DAILY
2 to <9	eGFR 30 to 60 mL/min/1.73m^2	2mg ONCE DAILY on ALTERNATE DAYS

Course length is 10 days (or until discharge if sooner)

Baricitinib should be taken orally with or without food, and may be taken at any time. If a patient is unable to swallow tablets or administration is only possible via enteral feeding tubes refer to Appendix 1.

Individuals who are being considered for treatment under this policy, who are already taking baricitinib for a licenced indication at the dose of 4mg per day, should not receive additional baricitinib doses. However, if such individuals are already taking baricitinib at a dose of 2mg per day, the dose may be increased for the recommended treatment interval as described in this policy provided all eligibility criteria are met and provided the increased dose is deemed clinically appropriate (which includes the patient not being within the dose reduction categories described above).

3.4 Drug interactions

Baricitinib dose should be reduced by one dose level (per table above) if co-administered with a strong Organic Anion Transporter 3 (OAT3) inhibitor such as probenecid. If patient is already on the lowest dose level consider discontinuation of interacting drug.
There is no interaction expected between baricitinib with the other commissioned COVID-19 treatments. For further information please visit the University of Liverpool COVID-19 Drug Interactions website.

3.5 Co-administration

Use of baricitinib in the treatment of COVID-19 should be considered as 'additive' to the use of an IL-6 inhibitor (tocilizumab or sarilumab), rather than an alternative.

A patient may be given an IL-6 inhibitor after treatment with baricitinib has been commenced (or vice versa), according to clinical judgement.

3.6 Safety reporting

It is vital that any serious suspected adverse reactions are reported directly to the MHRA via the new dedicated COVID-19 Yellow Card reporting site

3.7 Monitoring, tracking and follow-up

Treatment with baricitinib can lower the ability of the immune system to fight infections. All handovers of clinical care (including between hospitals if patients are transferred, between levels of care and clinical teams within hospitals, and between hospitals and primary care) must explicitly mention that baricitinib has been given.
Discharge letters to primary care should explicitly record the treatment that has been given, together with the dose and date of administration. The following **SNOMED codes should be used** to support evaluation and to inform subsequent treatment decisions:

Administration of Baricitinib
Procedure code: 47943005 |Administration of anti-infective agent (procedure)|
Presentation:

- 2mg tablets - 34625211000001109
- 4mg tablets - 34346011000001104

3.8 Supply

Once Blueteq has been completed baricitinib should be ordered via your ward pharmacist. When your ward pharmacist is unavailable it should be ordered via the on-site dispensary pharmacist, or if out of hours via the on-call pharmacist (contacted via switchboard)

4. Education and Training

No new skills required to implement the guideline.

5. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
Blueteq completed for each prescription	Reviewed by pharmacist	Ongoing – real time	Professionally checking pharmacist

6. Supporting Documents and Key References

Interim Clinical Commissioning Policy: Baricitinib for Patients Hospitalised due to COVID-19 . NHSEI November 2022
Summary of Product Characteristics: Olumiant 4 mg tablets. Eli Lilly and Company Limited September 2022

7. Key Words

COVID, COVID-19, SARS-COV-2, Baricitinib, Blueteq

This line signifies the end of the document

This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Mohammed Karolia	**Job Title:** Deputy Chief Pharmacist
Reviewed by:	Mohammed Karolia	
Approved by:	**Policy and Guideline Committee**	**Date Approved: 28 June 2023**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
February 2023	2	Mohammed Karolia	Previous COVID-19 guideline transferred to PGC template.

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**