Emergency Use Authorization (EUA) of Baricitinib (Olumiant®)

1. Overview of EUA of Baricitinib for the Treatment of COVID-19

a. Baricitinib is a selective JAK 1 and 2 inhibitor currently approved by the FDA for the treatment of patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. It is not FDA approved for the treatment of COVID-19.

b. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of baricitinib alone for the treatment of COVID-19 for hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Baricitinib is not FDA-approved for these indications.

2. Which Patients May Benefit from Baricitinib?

a. Clinical benefits of baricitinib were most apparent in patients requiring high flow nasal cannula (HFNC) or non-invasive ventilation (NIV). Mortality was significantly decreased with baricitinib alone in comparison to standard of care in COV-BARRIER.

b. For more detailed information, please refer to the baricitinib monograph as well as IDSA and NIH guidelines

c. Parkland Antimicrobial Stewardship subcommittee and Pharmacy &Therapeutics (P&T) Committee approved the following criteria for non-formulary requests based on available literature and guidelines

Approval Criteria
• Confirmed COVID-19 • Requiring high flow nasal cannula (HFNC) or non-invasive ventilation (NIV) • Low-flow oxygen or mechanical ventilation/ECMO only if contraindicated for steroids

3. Baricitinib is NOT Recommended in the Following Patients

a. ALT/AST > 10 x ULN

b. Significant immunosuppression, including recent use of other biologic immunomodulating drugs

c. An uncontrolled, serious bacterial, fungal, or non-SARS-CoV-2 viral infection

d. Absolute neutrophil count < 500 cells/µL

e. Absolute lymphocyte count < 200 cells/µL

f. Patients who have severe acute kidney injury or ESRD (eGFR < 15mL/min) and/or are on dialysis

g. Prior hypersensitivity reactions to baricitinib

4. Dosing and Monitoring

a. Baricitinib 4 mg once daily (orally) for 14 days or until hospital discharge

b. Discharge should not be held to complete baricitinib therapy

c. Patients must have eGFR, AST/ALT, and CBC with differential checked at baseline and monitored daily thereafter to dose adjust for abnormal renal, hematological, and hepatic laboratory values (see table)

Laboratory Analyte	Laboratory Analyte Value	Recommendation (Adults)
eGFR	≥ 60 mL/min/1.73 m^2	• 4 mg once daily
	30 to < 60 mL/min/1.73 m^2	• 2 mg once daily
	15 to < 30 mL/min/1.73 m^2	• 1 mg once daily
	< 15 mL/min/1.73 m^2 or end-stage renal disease (ESRD) or on dialysis	• Not recommended
Absolute lymphocyte count (ALC)	≥ 200 cells/µL	• Maintain dose
	< 200 cells/µL	• Consider interruption until ALC is ≥ 200 cells/µL
Absolute neutrophil count (ANC)	≥ 500 cells/µL	• Maintain dose
	< 500 cells/µL	• Consider interruption until ANC is ≥ 500 cells/µL
Aminotransferases	If increases in ALT or AST are observed and drug-induced liver injury is suspected	• Interrupt baricitinib until the diagnosis of DILI is excluded

d. Serious side effects may include venous thrombosis, including pulmonary embolism, and bacterial infections
e. Avoid use of live vaccines with baricitinib
f. If serious hypersensitivity reaction occurs, discontinue baricitinib while evaluating the potential causes

5. Mandatory FDA Requirements for Prescribing EUA Baricitinib

a. Patient Communication Requirement
   - Review the information in the "**Fact Sheet for Patients, Parents and Caregivers**"
   - Provide this document to the patient or their caregiver prior to the patient receiving baricitinib
     - **English Version** / **Spanish Version**

b. Chart Documentation Requirement
   - Use smartphrase **".EUABARICITINIB"** which will document the following:
     - The EUA fact sheet has been given to the patient
     - The patient or caregiver has been informed of alternatives to receiving baricitinib
     - The patient or caregiver has been informed that baricitinib is not FDA approved for COVID-19, but is authorized for use under the EUA

c. Medication errors and serious adverse events considered to be potentially related to baricitinib must be reported within 7 days from onset of event through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. In addition, this must also be reported to Lilly at: 1-855-LillyC19 (1-855-545-5921). Please also provide a copy of all FDA MedWatch forms to: Eli Lilly and Company, Global Patient Safety fax at 1-317-277-0853 or via e-mail at mailindata_gsmtindy@lilly.com

d. Additional information can be found in the EUA's Fact Sheet for Healthcare Providers and/or FAQ

6. **Ordering EUA Baricitinib**
   a. Baricitinib for COVID-19 must be entered as a non-formulary request
   b. Prefilled non-formulary order for baricitinib can be ordered in Epic by searching "baricitinib"
   c. Please refer to the section on **Dosing and Monitoring** when entering the order

7. **Pharmacist Role in Non-formulary Review**
   a. Decentral pharmacist will page the appropriate on-call pharmacist when a non-formulary request is entered
      - Weekdays (0700 – 1700): Infectious Diseases Pharmacist
      - Weekdays (1700 – 0700): Weekend/Afterhours Pharmacist
      - Weekends or Holidays (24h): Weekend/Afterhours Pharmacist
   b. The on-call pharmacist will review the request and follow up with the ordering provider as needed
   c. If approved, the on-call pharmacist will write a chart note detailing the outcome of their review
   d. If approved, decentral pharmacist will process the non-formulary order and schedule administration

Please direct additional questions to members of the Antimicrobial Stewardship Team:

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