Provider Workflow for Baricitinib (Olumiant) for the Treatment of COVID-19 In Adults

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of baricitinib for treatment of coronavirus disease 2019 (COVID-19). Baricitinib is FDA-approved for treatment of rheumatoid arthritis, however, it is not approved for the treatment of COVID-19. To support CMH's providers ordering these medications and satisfy FDA requirements, providers should follow the workflow outline below.

Patient Candidate for Baricitinib Therapy

See Inclusion/Exclusion Criteria Checklist

Step 1: Contact ID Provider for Approval

Use is restricted to ID approval

Step 2. Complete Patient's Inclusion / Exclusion Checklist

Step 3. Review medication information consistent with the FDA "Fact Sheet for Patients, Parents and Care Givers" with patient / care giver. A written copy must also be provided**.**

Step 4. Obtain patient / care givers' written consent to receive drug

Using CMH drug specific Consent form

Step 5. Documentation in patient medical record

Documentation that (Dot phrase is available: /Baricitinib_treat_covid)

- The FDA "Fact Sheet for Patients, Parents and Care Givers" has been reviewed and copy provided
- Patient / care giver was informed of alternatives to receiving Baricitinib
- Patient / care giver was Informed that Baricitinib is an approved drug that is authorized for the unapproved use of the treatment of COVID-19 under this Emergency Use Authorization

Complete drug order

Step 6. Pharmacy notification

- **Fax copy of the completed Inclusion / Exclusion Criteria Checklist and signed consent to Pharmacy. (FAX 795-5675)**

Step 7. Monitor the patient for adverse events.

- Monitor ALT, AST, ANC, ALC, hemoglobin, eGFR, signs and symptoms of infection (prior to, during, and after therapy), new onset abdominal symptoms, signs of thrombosis

Step 8. Prescribing Physician is responsible for reporting all potentially medication error or adverse event to the FDA and Eli Lilly and Company within 7 days

- Clinical Research Coordinators will assist with follow-up documentation and FDA submissions regarding patient reactions, etc.

Baricitinib (Olumiant) for the Treatment of COVID-19 in Adults. Inclusion/Exclusion Criteria Checklist

Apply Patient Sticker Here

(Fax to Pharmacy: 795-5675)

Date:	Ordering Provider:
Patient Name/FIN (if no sticker):	Hospital: CMMC RH BH

Inclusion criteria (Check all that Apply) Must meet all Criteria:

☐	Confirmed COVID-19 via laboratory testing in Hospitalized adult or pediatric patient (2 years of age and older) (per EUA)	☐	≥1 elevated inflammatory marker **CRP, D-dimer, LDH, ferritin***
☐	Requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. (per EUA) **Not well studied in patients who are already requiring invasive mechanical ventilation or ECMO at baseline, for these patients recommend use of Actemra (tocilizumab) if available****	☐	Not recommended for patients with known active tuberculosis
		☐	Not receiving concurrent Actemra (tocilizumab) therapy
☐	ID provider approved use	☐	Able to take medication enterally/ no absorption issues (This is an oral medication)
☐	Exhibiting rapid respiratory decompensation due to COVID-19		
☐	Laboratory parameters: Patients must have an eGFR, aminotransferases, and CBC with differential determined prior to first administration to determine treatment suitability and dose. (Use not recommended with eGFR < 15 mL/min/1.73 m2 or dialysis. Please note there are dose adjustments required based upon eGFR. There is limited information regarding use in patients with COVID-19 and any of the following: ALC <200 cells/uL, ANC < 1000 cells/uL, and Hemoglobin <8 g/dL)		

If all the above Inclusion Criteria are met, Evaluate the following Warnings and Precautions for Risk vs Benefit

☐	**Serious Infection:** There is limited information regarding use of baricitinib in patients with COVID-19 and concomitant active serious infections. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic / recurrent infections (per EUA)	☐	Immunosuppression: consider avoiding use in patients who are significantly immunosuppressed, particularly in those with recent use of other biologic immunomodulating drugs
☐	**Thrombosis:** Serious venous thrombosis, including pulmonary embolism have been observed in COVID-19 patients treated with baricitinib and is a known adverse drug reaction. In hospitalized patients with COVID-19, prophylaxis for VTE is recommended unless contraindicated (per EUA)	☐	Malignancies: Lymphoma and other malignancies have been observed in patients treated with baricitinib for treatment of Rheumatoid arthritis. Risk when used for treatment of COVID-19 unknown
☐	**hepatic impairment:** Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk. (per EUA)	☐	Cardiovascular related events: increased risk of serious heart-related events such as heart attack or stroke when used in treatment of rheumatoid arthritis. Risk when used for treatment of COVID-19 unknown
☐	Gastrointestinal (GI) perforation: Events of GI perforation have been reported in clinical studies with baricitinib for treatment of rheumatoid arthritis, although the role of JAK inhibition in these events is not known. Risk when used for treatment of COVID-19 unknown.		

- The FDA "Fact Sheet for Patients, Parents and Care Givers" has been reviewed and copy provided to patient/care giver
- Patient / care giver was informed of alternatives to receiving Baricitinib
- Patient / care giver was Informed that Baricitinib is an approved drug that is authorized for the unapproved use of the treatment of COVID-19 under this Emergency Use Authorization

Provider Name: _____ Provider Signature: _____ Date:_____

V1 9.22.21