

## Adult Baricitinib (Olumiant®) Non-Formulary Criteria

**Background:** Baricitinib (Olumiant®) is a Janus Kinase inhibitor, FDA approved for the treatment of rheumatoid arthritis and under EUA for the treatment of severe COVID-19 requiring hospitalization in combination with remdesivir and steroids. In the [COV-BARRIER](#) trial, baricitinib plus standard of care (SOC) for severe COVID-19 pneumonia requiring hospitalization was associated with a 5% ARR in 28-day mortality compared to SOC alone (NNT=20).

**Valid orders must meet the following criteria:**

- ☐ **Confirmed positive COVID-19 with severe disease requiring hospitalization**
- ☐ **Requested by Infectious Diseases, Critical Care or Pulmonary consultant(s)**
- ☐ **Severity Score (SS)  $\geq 2$  on SOC (steroids + remdesivir [RDV]) for  $\geq 24$  hours AND with  $\geq 1$  elevated marker of inflammation (LDH, CRP, D-dimer, ferritin)**
  - Ordering provider may initiate immediately if SS = 3 (*tocilizumab is preferred over baricitinib for SS  $\geq 4$* )
- ☐ **Is NOT pregnant/breastfeeding and has no known hypersensitivity reactions to baricitinib**
- ☐ **GFR is  $\geq 15$  mL/min; absolute lymphocyte count (ALC)  $> 200$  cells/uL, absolute neutrophil count (ANC)  $> 500$  cells/uL; AST/ALT  $< 5\times$  ULN**

**If all criteria are NOT met** – contact the provider to notify them of the criteria that are not met and recommend revisiting in 24-48 hours and/or repeating relevant labs to follow the trend as necessary. After discussing with the provider, discontinue the order.

**If all criteria are met** – proceed with baricitinib order entry/verification in MedManager. ***\*Default duration now 14 days – no need to further adjust\****

### Pharmacy Requirements:

- **Pharmacists must contact the ordering provider under the following circumstances:**
  - Ordered by providers other than ID/CC/Pulm consultants
  - SS  $< 2$  OR SS = 2 without receipt of RDV and steroids for  $\geq 24$  hours AND/OR no present elevated (above ULN) markers of inflammation
  - Any of the following: GFR  $< 15$  mL/min; ALC  $< 200$  cells/uL; ANC  $< 500$  cells/uL; AST/ALT  $> 5\times$  ULN (*soft stop, no clear contraindication for LFTs*)
  - Missing labs necessary for assessment and/or dose adjustments required based on GFR and table 1
  - Concurrent (or recent within 30 days) use of tocilizumab (NIH/IDSA/AdventHealth do not recommend coadministration)
  - Active roflumilast order – recommend discontinuation of roflumilast | Re-ordered after 14 days of therapy
- **Pharmacists are recommended, but not required, to contact the ordering provider under the following circumstances:**
  - Suspected bacterial infection (use with active *Mycobacterium tuberculosis* is not recommended in the package insert)
  - No VTE prophylaxis – baricitinib may increase rates of VTE and heparin/enoxaparin prophylaxis is recommended unless contraindicated
  - No record of negative PPD or QuantiFERON (for rule out TB)
- **Interventions pertaining to baricitinib must be documented within TheraDoc when communication to an ordering provider occurs**

**Table 1. Dosing, order entry, and monitoring of Baricitinib**

Drug	Dosing	Order Entry	Monitoring	Adverse Effects	Notes
Baricitinib ( 2 mg per tablet) ( \$150 per 4 mg dose)	GFR $>60$ : 4 mg daily GFR 30-60: 2 mg daily GFR 15-30: 1 mg daily	Non-formulary pathway <b>**Max of 14 total days**</b>	CBC, CMP initially and q2-3 days	Infection, thrombosis, hematologic toxicity, hepatotoxicity, TB infection	Oral only – may be dispersed in water for admin via g-tube.

*Severity Score Summary: 0 = room air; 1 = requiring supplemental O<sub>2</sub>; 2 = 1 + ↑ respiratory symptoms; 3 = HFNC or NIV; 4+ = IMV or 3+ progressive disease*

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