Baricitinib Executive Summary

March 12, 2021

Indication for Use:

- Baricitinib is a FDA-approved drug for rheumatoid arthritis (RA) and has been recently authorized by the FDA (November 19, 2020) for emergency use for the treatment of confirmed or suspected COVID-19.
- Permits use of baricitinib in combination with remdesivir (without dexamethasone) for the treatment of suspected or confirmed COVID-19 in:
    - Hospitalized adults and pediatric patients 2 years of age or older AND
    - Requiring supplemental oxygen, mechanical ventilation, or ECMO
    - Patient cannot be receiving dexamethasone concurrently

Mechanism of Action:

- Baricitinib is a selective inhibitor of Janus kinase (JAK) that reduces cellular activation and inflammation
    - Most commonly used to treat RA

Clinical Evidence Review:

- Clinical evidence was reviewed by a team of RRH medical and pharmacy providers
- Baricitinib plus remdesivir was superior to remdesivir alone in reducing recovery time and accelerating improvement in patients with COVID-19, notably among those receiving high-flow oxygen or noninvasive ventilation

Safety:

- Patient Fact Sheet must be reviewed prior to receiving Baricitinib. Providers must document in the EMR that the patients received the fact sheet, were informed of alternatives, and were informed that baricitinib is for investigational use in COVID-19 patients.
- Most common adverse reactions include: upper respiratory tract infection, nausea, herpes simplex, herpes zoster, and venous thrombosis.
- All serious ADEs must be reported to Lilly and FDA MedWatch within 7 days (see provider EUA fact sheet for instructions)

Emergency Use Authorization Restrictions:

- For inpatient use on suspected or confirmed COVID-19 positive patients as outlined in indication for use above
- Patient must have an eGFR, aminotransferases, and CBC with differential evaluated prior to first administration
- ***Exclusion Criteria***
    - Receiving dexamethasone
    - Not requiring oxygen

- Under the age of 2 years

RRH Guidelines for Use:

- **Allow for use in the inpatient setting**
  - **Target date by March 26, 2021**
- **Requiring high-flow O2 or BiPAP/CPAP**
- **Receive in combination with remdesivir**
- **Patient should not be on dexamethasone concomitantly**

Should we use this medication at RRH?	Yes
Who can prescribe?	• **Restricted to Pulmonary and Infectious Disease Providers** • Providers must review EUA Provider Fact Sheet
Who can receive?	Given small allocation, limit initial use to: • Inpatient suspected or confirmed COVID-19 positive adult and pediatric patients ages 2 years and older AND • Requiring supplemental oxygen, mechanical ventilation, or ECMO
How is it ordered?	**Inpatient Pulmonary or Infectious Disease Providers will order in CareConnect®**
Is this reimbursable?	**No; included in DRG ($156 per day)**
Where will they receive?	All eligible inpatients at RRH
How will medication be provided?	Inpatient Pharmacy: **One bottle kept at RGH.** Will distribute across the system as needed.

Administration & Monitoring Instructions	• Dose
	  ○ Adult and peds patients ≥ 9 years
	  ▪ 4 mg PO/NG once daily
	  ○ Peds patients 2-8 years
	  ▪ 2 mg PO/NG once daily
	  ○ eGFR < 15mL/min not recommended
	• Duration
	  ○ Total of 14 days or until hospital discharge, whichever comes first
	• Monitoring
	  ○ CBC with differential
	  ○ Basic metabolic panel
	  ○ Liver enzymes (ALT or AST)
	  ○ Signs and symptoms of infection
	  ○ eGFR