TO: YNHHS MEDICAL STAFF
FROM: YNHHS COVID 19 TREATMENT TEAM
YNHHS ANTIMICROBIAL STEWARDSHIP COMMITTEE
SUBJECT: Review of Emergency Use Authorization (EUA) for Baricitinib
DATE: NOVEMBER 25, 2020

Situation:

Background:
The baricitinib EUA was granted based on data from a recent double-blind, placebo-randomized controlled trial (ACTT-2) from which the FDA concluded the known and potential benefits of baricitinib in combination with remdesivir outweighed the known and potential risks for the treatment of COVID-19.

The primary endpoint of the ACTT-2 trial revealed that baricitinib, in combination with remdesivir, reduced the time to recovery by 1 day within 29 days after initiating treatment compared to patients who received a placebo with remdesivir (7 vs. 8 days respectively, p=0.047; 95% CI 1.00-1.1).

However, the mortality rate by day 29 was 4.7% (24/515) baricitinib + remdesivir versus 7.1% (37/518) for placebo + remdesivir (p NS; 95% CI -5.8%. 0.5%).

While ACTT-2 was already underway, data from the RECOVERY trial revealed a mortality benefit for dexamethasone therapy in moderate to severe COVID-19 that in turn has guided our current COVID-19 treatment algorithm.

The safety and efficacy of baricitinib in combination with dexamethasone, the only medication shown to have an effect on mortality for COVID-19, has not been established though an increased risk of infection could be possible. Additionally, baricitinib has a risk for thrombosis which dexamethasone does not have.

Assessment:
Based on current information, the YNHHS COVID-19 Treatment Team met to review the data behind the FDA’s EUA for baricitinib.

Recommendations:
Given the data that is currently available, it is recommended to not make changes to the YNHHS COVID-19 Adult Treatment Algorithm at this time. Dexamethasone will continue to be recommended with remdesivir as the therapy for COVID-19 inpatients who have a RA O2 sat of ≤ 95% and require supplemental oxygen.

Baricitinib will not be added to the YNHHS COVID-19 Adult Treatment Guideline at this time. As additional data become available, the use baricitinib may be re-evaluated as we have done with all of our COVID-19 therapies to date.
References:
