EMERGENCY USE AUTHORIZATION OF BAMLANIVIMAB

The FDA has issued Emergency Use Authorization (EUA) to permit emergency use of this monoclonal antibody for the treatment of mild to moderate COVID-19 in patients >12 and weighing more than 40kg who are at risk for progressing to severe illness and/or hospitalization.

Mechanism of Action
Monoclonal antibodies directly neutralize COVID-19 virus and are intended to prevent progression of disease, and are most likely to be effective when given early.

Why?
Early studies show potential to reduce subsequent hospitalization and reduce viral load when compared to placebo.

When?
The medication should be given as soon as possible after symptom onset/positive test, and within 10 days of symptom onset.

EXCLUSION CRITERIA
- Patients hospitalized for COVID-19
- Patients who require oxygen therapy for COVID-19 (or for those on chronic oxygen, those who require increase from baseline oxygen use)

There may be worse clinical outcomes if used in the above patient population

INCLUSION CRITERIA
Positive COVID-19 PCR Test AND Weight >40kg AND within 10 days of symptom onset AND ANY ONE OF THE FOLLOWING:
- BMI >= 35
- Age >= 65

*These are the current criteria based on which high risk groups are likely to receive the most benefit, in consideration of very limited resource, and are subject to change and you will be updated with any adjustments to criteria

PROCESS
1. Once you have a patient that you feel may meet use criteria, use dotphrase .BAM for review of inclusion/exclusion criteria, discuss with patient necessary risks, benefits and alternatives. Complete mandatory components of dot phrase to ensure qualification.
2. Provide patient with “Fact Sheet for Patients, Parents and Caregivers”
3. Order medication typing “Bamlanivimab” in the order entry. There is only one order option with correct dosing and administration instructions defaulted.
   a. Dosage is 700mg IV infusion over 60 minutes
   b. No need for specialized dosing (i.e renal or hepatic)
4. Patient needs to be observed an additional hour after infusion for any adverse events*
5. Patients should be instructed to continue CDC-guided isolation precautions upon discharge
*What do I need to watch for? What if there is a serious adverse event?*

Potential known reactions include:

1. **Hypersensitivity, Anaphylaxis**
   There is a potential for serious hypersensitivity reaction, including anaphylaxis. If this occurs, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.

2. **Infusion-related reactions**
   Signs and symptoms of infusion related reactions may include: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness. If this occurs, slow down and consider discontinuing the infusion and initiate appropriate medications and/or supportive therapy.

Because of limited clinical data, serious and unexpected adverse events may occur that have not been previously reported with bamlanivumab use.

Healthcare providers are responsible for **mandatory reporting** of any and all medication errors and **ALL SERIOUS ADVERSE EVENTS** at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) (Select “Report a Problem”, then “Health Professional” FDA Form 3500)

Provide a copy of the completed form to Eli Lilly and Company:

a. Fax: 1-317-277-0853  
b. E-mail: mailindata_gsmtindy@lilly.com  
c. OR call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.