Commonly Asked Questions for mAbs in General

How long post-antibody treatment must a person wait before they can receive a vaccine (and what to consider about that)?
Because monoclonal antibodies may diminish the efficacy of COVID-19 vaccines and there is minimal risk of re-infection for up to 90 days after testing positive for COVID-19, the CDC recommends that administration of the COVID-19 vaccine be delayed for 90 days after receiving treatment for COVID-19 with monoclonal antibody products.

What happens when someone tests positive after receiving the first vaccine dose (when applicable)? Can they receive treatment with the mAbs or is there a time period they must wait?
There is a current lack of evidence regarding this scenario, however if a patient does test positive and meets criteria for receiving monoclonal antibody therapy, at this time it would be appropriate to administer treatment. However, the CDC currently recommends to wait 90 days after monoclonal antibody treatment to receive the second dose of the vaccine due to potential interference and evidence for lack of re-infection within 90 days of testing positive for COVID.

What happens when someone tests positive after the second dose of vaccine (when applicable)? Can they receive treatment with the mAbs or is there a time period they must wait?
There is currently a lack of evidence regarding this scenario, at this time it would be appropriate to administer treatment with mAbs if the patient meets criteria. This recommendation may change as more information becomes available.

What are the storage and administration requirements for the available mAb treatments?

*Casirivimab/Imdevimab Injection*
Administer as an IV infusion over > 60 minutes immediately after dilution. Allow to warm to room temperature for ~30 minutes if refrigerated. Use a PVC, polyethylene-lined PVC, or polyurethane infusion set with a 0.2 µg polyethersulfone (PES) filter. Flush infusion line with NS after completion of infusion.

Store intact vials at 2 - 8°C (36 - 46°F, refrigerator temperature); do not freeze, shake, or expose to direct light.

Diluted infusions are stable for up to:
- 36 hours at 2 - 8°C (36-46°F, refrigerator temperature); allow to warm to room temperature for 30 minutes before infusing.
- 4 hours at 20 - 25°C (68 - 77°F, room temperature)

*Bamlanivimab (and etesevimab)*
Administer as an IV infusion, immediately after dilution, at a rate of <310 ml/hr via PVC or polyethylene-lined PVC infusion set with 0.2 or 0.22 µg in-line or add-on polyethersulfone (PES) filter. Flush infusion line with NS after completion of infusion.

Store intact vials at 2 - 8°C (36 - 46°F, refrigerator temperature); do not freeze, shake, or expose to direct light.

Diluted infusions are stable for up to:
- 24 hours at 2 - 8°C (36-46°F, refrigerator temperature); allow to warm to room temperature for 30 minutes before infusing.
- 7 hours at 20 - 25°C (68 - 77°F, room temperature) including infusion time.
Bamlanivimab (and etesevimab) FAQs

Who qualifies for treatment with bamlanivimab?
Bamlanivimab was granted EUA for non-hospitalized patients who test positive for COVID-19 and who are at high risk for developing severe disease, which includes patients over the age of 65. Here is a complete list of those considered high risk.

When should bamlanivimab be administered?
This medication should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset.

What data exists that shows benefit of treatment with bamlanivimab?
Data from the BLAZE-1 trial showed efficacy of bamlanivimab which contributed to its EUA approval. Patients with mild to moderate COVID-19 treated with bamlanivimab within 3 days of a positive test were less likely to visit the emergency room or be hospitalized within 28 days vs placebo (3% vs 10%). More data will be available as the BLAZE-1 trial continues, as well as other ongoing clinical trials.

What data exists that shows the benefits of treatment with both bamlanivimab and etesevimab?
Results from phase 2 and phase 3 of the BLAZE-1 trial showed a 70% reduction in hospitalizations for patients treated with the combination of bamlanivimab and etesevimab compared to placebo, and there were also no deaths in the treatment group vs 10 in the placebo group.

Is it better to use bamlanivimab alone or in combination with etesevimab?
There are currently no studies evaluating the efficacy of bamlanivimab vs the combination of bamlanivimab and etesevimab. Both monotherapy and dual therapy have shown significant improvement vs placebo, however there is no evidence to suggest superiority of either monotherapy or combination therapy.

Are there any drug interactions to be aware of?
There have been no reported drug interactions. Neither of these medications are metabolized by the CYP450 enzymes or are renally excreted, therefore it is unlikely to have a known drug interaction.

Are there any recommended dose adjustments for geriatric patients, or patients with renal or hepatic impairment?
There were no pharmacokinetic differences noted in the BLAZE-1 trial for patients based on age, and patients over the age of 65 represented 14% of participants in the trial. This medication is not eliminated intact renally and there is no evidence of renal impairment. There is no evidence of PK difference in patients with mild hepatic impairment, but it has not yet been studied in patients with moderate or severe impairment.

Should we flush once the infusion is complete?
Yes, it is recommended per the manufacturer to flush with 0.9% sodium chloride to ensure delivery of full dose.
Casirivimab and imdevimab FAQs

What is an Emergency Use Authorization (EUA) and what are the mandatory requirements when using casirivimab and imdevimab?

In case of an emergency, when there are no other adequate and available alternative options, the FDA commissioner, under section 564 of the Federal Food, Drug, and Cosmetic Act, may allow unapproved medical products be used to diagnose, treat, or prevent a serious or life-threatening disease or condition.

As part of the EUA, all health care providers must:

- Communicate to the patient or caregiver the information noted in the “Fact Sheet for Patients, Parents and Caregivers” as age appropriate, prior to receiving the infusion and document in the patient’s medical record that the patient/caregiver has been:
  - Given the “Fact Sheet for Patients, Parents and Caregivers”
  - Informed of any alternative treatment options
  - Informed that casirivimab/imdevimab is an unapproved drug that is authorized for use under the EUA by the FDA
- Report to the FDA all serious adverse events and medication errors potentially related to casirivimab/imdevimab within 7 calendar days of the event via the MedWatch reporting system. More information about how to report these events and a complete list of qualifying serious adverse events can be found on the Regeneron REGEN-COV Fact Sheet for Health Care Providers.

When are casirivimab/imdevimab mAbs approved for use based on the EUA issued by the FDA?

Casirivimab and imdevimab are approved for use, in combination, to treat adults and children ≥ 12 years old, weighing >40 kg, who have mild-moderate symptoms of COVID-19, confirmed by viral direct SARS-CoV-2 viral testing AND are at risk of progressing to severe COVID-19.

Are there limitations for use of casirivimab/imdevimab mAb?

Yes, casirivimab/imdevimab are NOT authorized for use in patients who:

- Are hospitalized
- Require oxygen therapy due to COVID-19 or have a need for chronic oxygen therapy and require an increase in baseline oxygen flow due to COVID-19
- Require mechanical ventilation

Should casirivimab/imdevimab be dose-adjusted in the patients with renal and hepatic impairment?

Neither casirivimab or imdevimab is renally eliminated and should not be affected by renal impairment or ESRD. Additionally, dialysis is not expected to impact the pharmacokinetic profile of either medication. The effects of hepatic impairment are not known at this time.

Should patients continue to self-isolate after receiving treatment with casirivimab/imdevimab?

Yes. After receiving treatment, patients should continue to self-isolate and use infection control measures which include wearing a mask, frequent handwashing, disinfecting “high-touch” surfaces, and social distancing based on CDC guidelines and recommendations.

Are there any dose adjustments required when using casirivimab/imdevimab in older adults?

There are currently no dosing adjustments recommended for older adults, however the pharmacokinetic differences in patients ≥65 years old have not yet been studied. Of the 799 participants included in the published data of the randomized control trial, 7% were 65 years or older and 2% were at least 75 years old.

References: