| Date | Question | Answer(s) | |
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| 6-Jan | What is the guidance for MAb treatment after someone has had COVID vaccine, yet has now tested positive and meets other criteria? | Live answered | |
| 6-Jan | I have a doctor who wanted to give BAM in addition to Remdesivir for a patient who was inpatient and very high risk. Sick enough for high flow oxygen, weighs over 400lbs, many co-morbidities; can you speak to using both BAM and RDV at the same time? | Not indicated in inpatients. | |
| 6-Jan | Why the mismatch of supply and demand in the midst of the current surge? | Skepticism and logistical challenges. | |
| 6-Jan | Has any data been collected based on the time of symptom onset and infusion date - related to patient outcome? In essence, if patient receives the antibody within 2 days of symptom onset vs 9 days are the outcomes better. | This is likely but not proven. Certainly, when patient get sick enough to be hospitalized benefit is less. | |
| 6-Jan | That's quite surprising. Our tracking data reflects over 50 percent of doses allocated to Arkansas have been utilized. We have regular webinars/conference calls with facilities to encourage use. We have also developed flyers and a webpage to direct patients and referring physicians to facilities. | 50% use is much better than Michigan. Well done. This is tough. We need to continue to do our best at making the info widely available. No single approach to making this happen. | |

| Date | Question | Answer(s) | |
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| 6-Jan | I work as a COVID-19 case investigator in Alaska and we recommend monoclonal antibodies to those who qualify, and Alaska seems to really have it together in that regard. On a personal note, my brother in law is sick with COVID in Vermont and I have done everything I can to try to get the treatment for him including finding the place for him to go. However, his doctor says it is experimental and doesn't recommend it. How to change this view? | Perhaps try local hospitals? | For others trying to locate mAbs, checkout the Therapeutics Distribution Locator Tool: https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations |
| 6-Jan | 1.) What, if any, is the known potential tissue damage from infiltration and extravasation? Many administering in the outpatient setting may not be proficient at IV insertion/ therapy?<br><br>2.) Will cardiac monitoring be necessary during infusion (3 lead EKG)? | Live answered | |
| 6-Jan | The MAbs are contraindicated in hospitalized patients, are they being given to hospitalized patients? | Hopefully not outside of studies | mAbs are not authorized for use in patients who are hospitalized due to COVID-19. |
| 6-Jan | If someone receives the Moderna or Pfizer vaccine, are they still a candidate for the monoclonal antibody if they test positive? | Current CDC guidance is that prior receipt of mRNA COVID-19 vaccine should not affect treatment decisions in persons who are subsequently infected. | CDC guidance is that receipt of vaccine should not affect treatment decisions, including use of monoclonal antibodies, in persons who subsequently are infected with SARS-CoV-2. |
| 6-Jan | Most uptake has been from Infectious disease physicians. Is there any effort underway to educate other physicians about how to identify patients and prescribe? | Yes, the COVID-19 Response Therapeutics team is working on this, as are the companies. | |

| Date | Question | Answer(s) | |
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| 6-Jan | Provider skepticism? | Me too, at first. This is a challenging clinical decision. Normally, we wouldn't even be having this discussion but because of the magnitude of the public health emergency we think it is a reasonable therapy considering the decent safety profile. | |
| 6-Jan | Offering to any pregnant pts? If so, any agreed to receive? | At physician discretion. | |
| 6-Jan | High risk patients that choose to remain at home, candidates for MAb infusion; prescribers requesting if this can be given as a Home Infusion therapy. Any input from the team on national interest relating to this and is there any push to make MAb available for Home Infusion use? | Yes - HHS has established a Special Projects for Equitable and Efficient Distribution (SPEED) program to improve access in non-hospital settings. There is a bamlanivimab pilot program established with the National Home Infusion Association: https://www.nhia.org/news/bam-pilot-program/ | Link to SPEED website: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx |
| 6-Jan | If a patient received first dose of vaccine, but tests positive for COVID a few days later, then receives the mAb treatment, do they get second dose of vaccine 90 days after mAb or do they start the two dose vaccines series again in 90 days? | This is a challenging question, and currently there are no substantial data about the efficacy of mRNA COVID-19 vaccines following mAbs. Right now, CDC guidance is to give a 2nd dose at least 90 days after receipt of mAb in this scenario (don't start the series over again). Guidance will be updated as additional data are available. I think this will be discussed some more in the Q&A today. | |

| Date | Question | Answer(s) | |
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| 6-Jan | Like most antivirals, most effective when given early (e.g., Tamiflu). One of the challenges as I see it, is getting mAb into COVID patients 'early' in the course of their disease. Most start with flu like symptoms, don't rush to see the doctor or go to the hospital, and therefore often it is usually in the 5 - 10 day post sx course of the disease when a patient will seek care. At that time, the mAb less effective. And yet most people with COVID will recover. Seems like the challenge is how do we get the right patients in 'early' and not those who most likely will recover on their own? | Absolutely. Most of the current trials were done in all comers, thus not high hospitalization rate. Link with testing of high-risk people most helpful or in nursing homes, and so forth | |
| 6-Jan | Is there a difference in when a patient should receive the COVID vaccine after they received bamlanivimab versus casirivimab/imdevimab considering the very different half-lives? | If they were treated, presumably they were infected and current (without data) recommendation is wait 90 days. | |
| 6-Jan | Several facilities are having positive cases but are choosing not to treat with mAb stating the residents are asymptomatic. Is there any data supporting not to treat if resident is not symptomatic? | We only have data on symptomatic patients at the moment. | |
| 6-Jan | To rephrase - do you recommend cardiac monitoring during the infusion and/or post-infusion observation period to monitor for adverse reactions? | Cardiac monitoring not required, just vital signs | We've had paramedics come into facilities to start IVs and the RNs run the infusion. We have not been made aware of infiltration yet. We do not recommend ECG monitoring during infusions but simply full vitals every 30 minutes, or more often as needed. |

| Date | Question | Answer(s) | |
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| 6-Jan | NYAC Infusions has a dedicated facility for COVID infusions. Please let me know how and where we can order. | If NYAC is a Federally Qualified Health Center (FQHC), HHS/Operation Warp Speed (OWS) can directly provide you mAbs separate from the state-based mAb allocation system. You can contact me at david.wong@hhs.gov, if you qualify for the direct SPEED allocation system (i.e., FQHCs, dialysis, correctional, LTCFs). | |
| 6-Jan | Could you please describe the experience of using monoclonal antibodies in the home? Was a special team sent? How was it decided that home was a safe environment? | Home infusion services are doing this now. They do home infusions for other agents, so are experienced. There are some infusion reactions, some are serious. | Patients are pre-assessed for history of infusion rate reactions to mAbS, and allergy status to other products. Patients must live in a 911 service area. Nurses carry an extensive list of medications and supplies that can be used to stabilize patients and administer emergency meds in case of a reaction. To date, no serious infusion rate reactions have been reported (i.e., No use of epi).<br><br>Home infusion nurses are specially trained in managing infusion rate reactions and routinely provide biologics in the home setting. |
| 6-Jan | Is there any data to suggest widespread underutilization or is Michigan an outlier? | OWS data shows widespread underutilization across much of the country. | |
| 6-Jan | Hello, Sarah. Could you send me the link? I could not find it so I could share this information with our physicians. | https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html<br><br>Guidance about timing of 2nd dose if person develops COVID-19 after 1st dose should be added within the next couple of hours. | |
| 6-Jan | How long is the infusion and what type of monitoring is required? | One hour infusion plus one hour post, monitoring. No EKG monitoring, just vitals. Need ability to deal with infusion reactions. | |

| Date | Question | Answer(s) | |
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| 6-Jan | Will slides be sent out? | The slides and the recording of today's session will be shared via the website: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html | |
| 6-Jan | Will the MI case study/data be made available for pilots to use in educating facilities and physicians about the benefits of mAbs? | You are welcome to share our data from the slides, we will be completing a report in the next few days which will be publicly available. | |
| 6-Jan | How do we get more information on how to get this medication for FQHC? | Thanks! Please contact me directly at david.wong@hhs.gov. We can provide background materials about the mAbs, reimbursement, etc., and also set up a call with your team. Through the SPEED program, HHS/Operation Warp Speed can directly allocate mAbs to FQHCs (and/or partnering hospitals or community infusions centers) separate from the state-based mAb allocation system. | |
| 6-Jan | How does an FQHC get started? Who do they contact? | Work with your local healthcare system to find the best option. This could be sending patients to an infusion clinic in the community, home care infusions, paramedics, or doing on site infusions with your staff. | Separate from the state-based allocation, HHS/Operation Warp Speed can also directly allocate mAbs to FQHCs and/or their partnering hospitals or community infusion centers. For more information about SPEED, please contact me at david.wong@hhs.gov. |

| Date | Question | Answer(s) | |
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| 6-Jan | Dr. Ramers, I'm at a rural FQHC and we're trying to get an allocation of mAb to infuse outpatient in our COVID clinic. How are your FQHCs handling the mixing process for the drug, especially with the combination mAb? And were you able to get allocated doses directly from your state health department, or did you acquire them through a different pathway? | Our physicians and nurses mix right at the bedside. Not too complicated after studying the materials in the playbooks. We were allocated doses from our county which came through the state but are thinking of engaging directly with SPEED to access more doses. | For information about direct allocation to FQHCs, please contact: david.wong@hhs.gov. |
| 6-Jan | Are there any recommendations regarding when patients can get the vaccine if they receive a dose of monoclonal antibodies? | If they get a monoclonal, that currently means they have been infected, and there is a current recommendation to wait 90 days till vaccination after infection. No data available. | |
| 6-Jan | Any advice or thoughts on how to/whether to attempt to increase uptake in those populations who feel well enough and therefore don't feel it is worth overcoming their skepticism about taking this therapy? As mentioned by others, most effective when given early, so I could envision the risks being worth the benefits even though symptoms may initially be mild. | Yes, this is one of the problems. Maybe explain their risk factors for progression? | |
| 6-Jan | Clarification: SPEED program with NHIA does not include home infusion of mAbs, only LTC. | Thank you - I appreciate the correction. | |
| 6-Jan | Participating in NHIA pilot program - NHIA directive to use Bam mAb supply strictly for SNF/LTC; has this been opened up for Home Infusion patient use? | Apologies - ... with NHIA corrected the information I shared. Some health systems have explored providing infusions through their own home infusion programs. I have not seen outcomes data on these examples, though. | |
| 6-Jan | Is there a time frame between patients who receive IV Bam versus Vaccines? | Suggested that vaccination be 90 days after infection. | |

| Date | Question | Answer(s) | |
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| 6-Jan | So, you cannot receive mAb and the COVID vaccine? | Yes. Current recommendations are to defer the vaccine for 90 days after mAb therapy based on lack of info with both novel treatments. | |
| 6-Jan | What do you think of the Infectious Disease Society of America guidelines which recommend against the routine use of bamlanivimab in ambulatory patients with COVID 19. The guidelines note that in patients at increased risk, bamlanivimab is a reasonable treatment option if, after informed decision -making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events. | Live answered. | |
| 6-Jan | There is a recommendation for follow-up post mAb in 1 week or so. Is there any specific clinical items we are looking to evaluate? Can this be performed virtually? | Yes, I believe so. These are human IgG so don't expect late problems. | |
| 6-Jan | Need for supplemental oxygen is a contraindication for BAM therapy. We have the ability to provide supplemental oxygen in our long-term facilities. Do you recommend using BAM in patients that only need low flow oxygen by nasal cannula/mask and can maintain good oxygen saturation? | The issue is: do monoclonal increase the hyper-inflammatory state and thus could cause worsening? No benefit seen in hospitalized patients, but data are early. | |
| 6-Jan | What is the cost and how is insurance coverage for both the drug as well as administration related fees? | Drug is free. Administration covered by CMS at $310. | Billing codes are available on the CMS website. Private insurance reimbursement will vary and depends on contracts. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies |

| Date | Question | Answer(s) | |
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| 6-Jan | Does anyone have experience using Primatene mist [epinephrine] rather than parenteral epinephrine for allergic reactions? | I have used this in the past for the respiratory symptoms. | |
| 6-Jan | Any info on people that are newly immunized and tested positive for COVID shortly after immunization ... and ... received mAb | Not yet. | |
| 6-Jan | Is there a guidance document that will provide COVID-19 medications or mAb reaction treatment for prehospital personnel? In the home or congregate living setting this guidance would be incredibly helpful. | We have tool kit on PALTC website. | See pages 130-133 for sample eligibility checklist and infusion orders: https://cdn.ymaws.com/www.ascp.com/resource/resmgr/docs/mab/fulldocument2.pdf |
| 6-Jan | Should patients who were on oxygen prior to contracting COVID be considered for mAb therapy? | Yes. The oxygen with mAb is simply a marker for severity of COVID-19. | |
| 6-Jan | Aren't you giving mAb for symptoms of COVID? | Patients must be symptomatic but also have the risk factors and meet other criteria. | |
| 6-Jan | Has anyone seen issues with capacity and needing to prioritize patients (how do you do that?)? We haven't had this problem yet, but we're anticipating it and trying to design a workflow for that. | Live answered. | Capacity can be a challenge for sure, especially in LTCs. These facilities provide the Fact Sheet for patients (required) to surrogate decision makers. Because of the high supply, we haven't needed to prioritize use based on capacity. |
| 6-Jan | Can the speaker provide slides or attachments to summarize her presentation? I'm especially interested in the comparison of hospitalization esteem mAb recipients and non-recipients. | No slides are available at this time. | |
| 6-Jan | There is plenty of drug to be provided for home care patients; is there a push to have HHS make the drug available for home use for participants of the NHIA Pilot program? | mAbs are available for home care patients and some home infusion providers are administering them to individuals at home. | |

| Date | Question | Answer(s) | |
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| 6-Jan | The vaccine is not given for symptoms, correct?? Why would people forgo mAb to wait for the vaccine? | They are hesitant to defer the vaccine for 90 days as the data for efficacy and safety is very convincing on vaccine.<br>So mild to moderate sx patient may want to take the risk and rather choose to get the vaccine. | |
| 6-Jan | What is the current number needed to treat to prevent one hospitalization? | Based on the Michigan Data with a hospitalization rate of 5% and using placebo hospitalization rates reported in the studies of 9 to 15% (but with very wide confidence intervals) we find NNT of 15-20. It's hard because in the 2 trials they combined admission with ED visit instead of just admission. But a NNT of 20 considering the effort needed would seem to still be very beneficial in reducing impact on healthcare system. | |
| 6-Jan | Can you clarify the vaccine administration plan? Are we still deferring it by 90 days from COVID infection? | Patients can receive vaccine once they are non-contagious.<br>90 day with mAb. | |
| 6-Jan | Can anyone who participated in the ACIP tell me if state psychiatric hospitals (long stay psychiatric rehabilitation) were included in the 900,000 "other residential care" beds included in phase 1A RBreen MD? | They generally did not include state psychiatric hospitals or rehabilitation facilities, unless a state flagged them as serving individuals aged 65 years or older. | |
| 6-Jan | How long after mAb infusion can a patient expect to have some ongoing protection from another COVID infection? | We don't know, should get some answers soon from ongoing trials | |

| Date | Question | Answer(s) | |
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| 6-Jan | Patients on dialysis - can this be given during the dialysis treatment, and if so at what point? Is it dialyzable? Do you have to pre-treat with Tylenol or other medications prior to giving? At what rate should the infusion be given? | There is no hard data on the interaction between mAbs and dialysis membranes. In discussions with nephrologists and dialysis centers, the safest thing is to administer the mAbs post-dialysis. Dialysis centers are eligible for direct mAb allocation from HHS/Operation Warp Speed through the SPEED program. Pre-treatment is not required per EUA, but we hear some providers are doing that. Infusion should be at least 60 mins and can be given via pump or gravity. | |
| 6-Jan | Re competing hazards: consideration to pre or wrap around treatment with NSAIDs? | There are not directions for premedication in the EUA and we are unaware of literature on the impact of NSAIDs or Leukotriene inhibitors. | |
| 6-Jan | Many nurses working in FQHC/ primary care setting are not regularly starting IVs and infusing medications. What type of training could you recommend? | Some FQHCs are getting hands-on training from local infusion centers. | |
| 6-Jan | Competing hazards: leukotriene inhibitors? | There are not directions for premedication in the EUA and we are unaware of literature on the impact of NSAIDs or Leukotriene inhibitors. | |
| 6-Jan | Will the Q&A conversation/information be included in the archived documents? | Yes, we post fully-answered Q&A documents to the ECHO website. https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html | |

| Date | Question | Answer(s) | |
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| 6-Jan | Is there documentation specifically stating that consent is not needed before treatment of mAb ? | The Bamlanivimab Fact Sheet for Healthcare Providers (pp. 5-6), requires that providers share the Fact Sheet for Patients/Caregivers, review pertinent information, and document in medical record. Formal consent is not required per the EUA. | |
| 6-Jan | Can you talk more specifically about recommended or required follow up and what healthcare providers should do to monitor outcomes after administering mAbs? Is there a source to go to for these recommendations? | I'm not aware of any FDA or manufacturer guidance on post-mAb follow-up beyond the 60-minute post-infusion observation period. I think we are stuck with good clinician judgement, sooner follow-up with more vulnerable patients and PRN for milder severity and lower risk factors. | |
| 6-Jan | What is the reason mAb administration pushes vaccine out to 90 days vs current guidance for COVID positive patients? | If they were treated, presumably they were infected and current (without data) recommendation is wait 90 days. | Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. |
| 6-Jan | Is that any vaccine or just COVID? | My comments were just related to COVID vaccines. Thanks for the opportunity to clarify! | |
| 6-Jan | mAbs are a scarce resource at many institutions. How do you triage patients to their use? | mAb really should not be a scarce resource. The hospital should work with their state health department to increase availability. | |

| Date | Question | Answer(s) | |
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| 6-Jan | Can the ordering provider delegate the process for providing the fact sheet and discussion to nursing or office staff? | Our guidance in Michigan is that the ordering clinician has the ultimate responsibility, but they are delegating to some degree, especially in LTC facilities. Ultimately, it's the doctor's responsibility. | |
| 6-Jan | Thank you for answering, where is the guidance listed on the use of mAbs and vaccine? We are getting a lot of questions, I would want to point them to a source document | https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html | |
| 6-Jan | Are/ will antibody levels be followed in those that have received mAb shortly after vaccination then receive 2nd dose of vaccine to see that levels are equal to those never having received mAb? | Yes, these studies are being set up. | |
| 6-Jan | Any data on combined mAb and steroid use ? | I have not seen data but this is similar to Remdesivir where administration should not be simultaneous given EUA criteria and NIH guidelines. There should not be any interaction issues for administering steroids to patients who received mAbs. | |
| 6-Jan | How do we engage with SPEED? | My understanding is that HHS is reaching out directly to some of the specialty pharmacies and allocating directly to them. Pharmacies, FQHC,s etc. might want to contact their professional associations. | Long-term care pharmacies, and other pharmacies that serve seniors can go through ASCP: https://www.ascp.com/page/mab?_zs=LXU1e1&_zl=51QJ7 |
| 6-Jan | I'm sorry if I missed seeing this somewhere else, but will the recording be available after this session? | Yes. | |

| Date | Question | Answer(s) | |
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| 6-Jan | Dr. Gaur mentioned a "how-to" document regarding staffing, etc. Can you please provide the link to this resource? | I don't have a link but feel free to email me at falesw@michigan.gov and I can share our documentation document used at LTCs. We are seeing commonly 1 RN to 3-4 patients working well. | https://cdn.ymaws.com/www.ascp.com/resource/resmgr/docs/mab/fulldocument2.pdf |
| 6-Jan | Will the slides from Michigan be available? | Yes | |
| 6-Jan | I am not sure if it was answered and I missed it. Since the mRNA is stimulating the generation of the spike protein as a mechanism, will that cause a false positive in the antigen or PCR test? There has been varying information in medical discussions. | We don't think so. | |
| 6-Jan | Are there any protocols you can share? | We have adopted a state emergency protocol for EMS that can be adopted locally, this is available at https://www.michigan.gov/documents/mdhhs/14.13_nCoV_Monoclonal_Antibodies_Final_12.16.2020_711050_7.pdf | |