HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series
Session #4—A Healthcare System's Approach
Wednesday, January 13, 2020 (12-1 PM ET)
Questions and Answers Packet

Date	Question	Answer(s)		
13-Jan	We've received many questions about whether Bamlanivimab is appropriate for SNF patients who test positive but are initially asymptomatic. Are COVID positive asymptomatic patients appropriate for Bamlanivimab administration?	The EUA excludes asymptomatic patients - but if these patients then develop symptoms, they may be appropriate candidates.		
13-Jan	Will Dr. Gandhi's slides be made available and can they be shared?	The slides were linked in the announcement that went out from Project ECHO yesterday. You can also find them on our website by the end of the week: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html	Yes, Dr. Gandhi's slides were included in yesterday's session announcement. The slides will also eventually be posted to the ECHO COVID-19 Outpatient Tx Mini-Series Site. All previous sessions and resources are archived on this site at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html	
13-Jan	Our ER doctor received the 1st dose of Moderna vaccine Monday. Tuesday he was feverish and tested positive for positive for Covid. He wants to know if receiving the bamlanivimab today will "blunt" effect of his vaccine?	We have recently dealt with similar scenarios here at UCSD! We decided to give mAbs to several high-risk healthcare workers who developed infection after receiving dose#1 of vaccine, because we felt that trying to prevent disease progression to more severe symptoms outweighs any longer-term theoretical risk that giving the mAbs could blunt the effect of the first dose of vaccine.		

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13-Jan	Hello Dr. Horton…so would that be ANY symptoms, no matter how mild?	Yes - any symptoms could be considered mild COVID.		
13-Jan	Should race and ethnicity be added to explicit eligibility criteria for receiving mAb treatment?	While these criteria for eligibility can be considered, my greater concern is the demographics of the populations that actually have access (availability, offered by the treating physician, affordability) to monoclonal antibodies. Certainly, monoclonal antibodies may mitigate the need for hospitalization, this reduction in healthcare costs and use of hospital resources may be for naught if the hurdles to access are not overcome.	We included race and ethnicity in our scoring system to prioritize patient eligibility- we developed this protocol with consultation by our Ethics. Many of the other UCs included race/ethnicity in their criteria.	
13-Jan	I had not previously heard/read that asymptomatic patients are excluded under the EUA (though I do see the EUA indicates treatment for mild/moderate symptoms). Are any panelists aware of any written guidance regarding mAbs for asymptomatic patients? I worry about high-risk patients missing the window of optimal mAb effectiveness (early in the disease course) if they have to wait for symptoms to develop.	We only have data on symptomatic patients at the moment.		

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13-Jan	Are trialist beginning to look at other end points related to reduction of lung injury, recovery time, long term sequalae? On outpatient, this is the huge implication of people out of work for weeks and some with ongoing lung disease (to just skim the surface of a deep topic)	I think this is a critical point. We definitely need longer term data on outcomes in people who've received different interventions, including antibodies.		
13-Jan	Does monoclonal antibody administration inhibit the natural or native antibody development? If so, does that show any clinically significant implications?	That is a good question. Don't have all the data yet to answer the question but further information is expected.		
13-Jan	If someone worsens after receiving a mAb and is still COVID PCR positive, can/should that patient be treated with Remdesivir?	We have gone ahead and given Remdesivir to a patient who worsened despite mAb therapy and was hospitalized (UCSD).		
13-Jan	What are your thoughts on administering a mAb to a patient who had Moderna vaccine 7 days ago and now has tested positive for COVID-19?	We have been in this position and weighed risks and benefits - ultimately, we have given MAbs to two patients who had received the vaccine in the previous week - both have done well clinically.		
13-Jan	Any consideration of IM formulations of mAb? In pipeline?	Yes, e.g. AZD4227 https://clinicaltrials.gov/ct2/show/NCT04625972		
13-Jan	Can you comment on the DEA/CDC recommendation(s) on vaccination after monoclonal antibody therapy?	We plan to wait 90 days after antibody therapy before giving vaccine. I think that's reasonable because risk of reinfection is low within first 90 days after COVID.		

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13-Jan	If a facility has access to rapid combined IgM IgG testing, would you still infuse patients who have antibodies? Would the mAb infusion provide much benefit if antibodies are already present?	The EUA does not include presence of antibodies as a contraindication for infusion or discuss antibody.		
13-Jan	Can point of care antigen test be used to identify high risk patients early, or is a PCR required?	Per the EUAs, PCR test is not required. Rapid antigen tests can actually help get patients treated as soon as possible after symptom onset.	Testing. Therefore, from a clinical standpoint I don't think we can comment on what the impact for a person with natural antibodies would be.	
13-Jan	The time line makes this challenging from an outpatient standpoint. Has anyone seen the availability of MAB therapy push labs to expedite tests on patients who have this as a treatment option?	We have not specifically asked to expedite tests for these patients - I'm not sure if our lab would be able to do so. We've been lucky at UCSD in that most of our PCR tests return within about 24 hours for symptomatic patients. But this is getting more challenging and turnaround has increased as numbers increase! But I certainly think that if there is a way for a lab to give these high-risk patient's test priority, it would be helpful.		

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13-Jan	In our tiny hospital (17 beds in the hospital) we have only one site to treat which is the ER. Luckily despite the high rates in CA we are doing ok so have in fused about 23 patients so far. We have found many difficulties with the timing as we have only 3 rooms appropriate for COVID patients so need to "Schedule" an ER visit for these patients. If the ER is busy with other COVID or other ER patients we have to delay the infusion. Any thoughts on how to do this well?	One suggestion would be to look at ED utilization rates by time of day. If there is a clear pattern, consider offering patients ED slots during times of day when ED has the most capacity. This could be the graveyard shift, but if the goal is to treat patients sooner rather than later, that might be amenable to patients.	Agree with first answer, looking at slower time periods to schedule the infusion. Additionally, looking at nontraditional resources to support the infusion team such as paramedics.	
13-Jan	Hearing that the monoclonals are hard to get at some of the worst hit areas (i.e., LA), what would be the obstacles with requesting/applying for these antibodies?	I think the issue is not necessarily the supply of medications themselves - but the infrastructure needed to screen and administer these medications in a timely manner (in a location where healthcare workers and resources are already utilized and likely prioritized for patients who are hospitalized with COVID).		

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13-Jan	Question about symptoms: If the patient did have symptoms when scheduled for mAb infusion but they had completely resolved at the time they present for infusion; would they still be a candidate for BAM? Since COVID has a variable course, is it appropriate to give the infusion, given symptoms could resume/worsen and patient did have mild/moderate symptoms through course of disease with positive test?	This likely means the patient has cleared the infection on their own. We are hearing from the field that most patients who have completely resolved symptoms by the time of mAb scheduled infusion are refusing the infusion and then doing okay. If patient still wants the infusion, it is okay to give per EUA since they have history of mild/moderate symptoms.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	The EUA indicates patients with mild to moderate COVID are eligible. If a patient has met the eligibility criteria and has been referred, they can still receive the infusion. Patients certainly can "opt out" of the infusion but improvement in symptoms is not a contraindication to administration in a previously eligible patient.
13-Jan	Patients are deferred if they require oxygen, but is that regardless if the oxygen requirement was in place prior to CoVID?	Live answered	Patients are ineligible for the mAbs if they develop a new O2 requirement related to COVID-19. See EUA and Fact Sheet for Health Care Providers for more details. https://www.fda.gov/media/143603/download	
13-Jan	What are your thoughts on utilizing rapid testing to determine a patient's eligibility as we have noticed patients falling out of the 10-day window while we are waiting for PCR results?	That was my concern during the outbreak at my facility as well. I did utilize rapid testing to test residents daily. I also submitted PCR testing for residents, and it was of some value. On one occasion the rapid test was returning a negative result, but the PCR test came back positive. I did however prioritize rapid testing to get results in real time.	In our system, if the testing reagents are available, we try to offer rapid testing to the higher risk patients even if they do not meet criteria for admission. Sadly, this is usually not the case as the reagents to run the rapid test is, more often than not, in limited supply.	
13-Jan	Is there any data / concerns that mAb therapy will lessen one's own passive immunity?	Unclear question as mAbs are passive immunity. There is a theoretical concern		

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		regarding active immunity, but no clinical data that I am aware of.		
13-Jan	Please comment specifically on the inclusion of age 55 with comorbidities. What does the data say about benefit in this population?	These patients were included in the analysis of high-risk patients for the data submitted to FDA to support the EUA.		
13-Jan	What is the web address for replaying this presentation?	Please go to: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html		
13-Jan	This question was raised with our state dept of health ID team and remains unresolved. Any additional advisement would be appreciated. If patient did have symptoms when scheduled for mAb infusion but symptoms resolved at the time they present for infusion, would they be a candidate for BAM since COVID has a variable course and patient has had qualifying symptoms during course, but are asymptomatic at time of presentation for infusion?	This likely means the patient has cleared the infection on their own. We are hearing from the field that most patients who have completely resolved symptoms by the time of mAb scheduled infusion are refusing the infusion and then doing okay. If patient still wants the infusion, it is okay to give per EUA since they have history of mild/moderate symptoms.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	The EUA indicates patients with mild to moderate COVID are eligible. If a patient has met the eligibility criteria and has been referred, they can still receive the infusion. Patients certainly can "opt out" of the infusion but improvement in symptoms is not a contraindication to administration in a previously eligible patient.
13-Jan	The EUA for monoclonal antibodies states that patients must be COVID-19 positive through direct viral testing. Is a positive rapid antigen test qualify as direct viral testing, or	Rapid antigen testing qualifies as direct viral testing. PCR testing is not necessary.		

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	is a positive PCR test or other molecular test necessary?			
13-Jan	Will these slides be available to share with the other nurses in the company that I work for?	Hello - The slides were linked in the announcement that went out from Project ECHO yesterday. You can also find them on our website by the end of the week: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html		
13-Jan	What reimbursement is available for giving the mAb infusion? Is cost covered by Cares act? How about for the uninsured?	CMS has established a mAb administration reimbursement rate for Medicare (national average of $309.60) in all healthcare settings. See links and infographic for more details. For uninsured, there is a HRSA COVID-19 uninsured fund. https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf https://www.hrsa.gov/CovidUninsuredClaim		

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13-Jan	I can't copy some of the Q+As for future reference, can they be made available somehow? Thx!	Q&A transcripts for all sessions will be posted to the ECHO website. Give 1-2 weeks after each session for us to get all the questions fully answered. https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html		
13-Jan	Could someone address role of mAb treatment for COVID + patients in the ED setting and patients in hospital or long-term care settings who develop lab confirmed COVID and otherwise are eligible for mAb treatment?	Long-term care patients are eligible for treatment with mAbs, as long as they meet EUA requirements. Hospitalized patients may be eligible IF they are not being hospitalized for COVID-19 and otherwise meet the EUA requirements for treatment with mAbs.		
13-Jan	One final question (and thanks): Any experiences or insights around borderline patients? The 45 year-old diabetic with BMI 34.5 and the patient with left hypoplastic heart and Fontan repair who is 19 years old not 17 years old. This creates some frustration for concerned providers and patients.	Currently, EUA does not cover these patients.		

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13-Jan	Were race/ethnicity criteria based on statistical risk of more severe illness or limited access to care or both? Can you share your scoring system (since it has been vetted, at least within your system)?	Here is the UCSD Health Criteria scoring for prioritization (Apologies at the copy/paste into Zoom formatting is messy) **Point Criteria** 3 q >65 years-old 3 q BMI >35 2 q >55 years old with cardiovascular disease or HTN or chronic lung disease 2 q Diabetes Mellitus 2 q Chronic Kidney Disease 2 q Immunosuppressed status* 1 q Higher risk race/ethnicity (ie. Black, Native American, Hispanic/Latino) 1 q Patient-facing healthcare worker		
13-Jan	Why are you using a lottery system? There is plenty of supply. Currently, the supply of MABs is not limited.	We don't use a lottery system - but I will say that the big challenge for us and I think every medical center is not primarily the amount of MAb available, but the resources required to infuse them. We are utilizing one of our infusion centers, and initially only were able to infuse 3 patients a day with staffing shortages, but. now are up to 6 patients. But again - that staffing, and facility resources have been the rate-limiting resource for us.		
13-Jan	Is there any discussion on the federal level HHS to expand distribution for home infusion use?	mAbs are available for home infusion use and some home-infusion companies are providing this service.		

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13-Jan	Thanks for your answer Lucy. How about his second dose of Moderna in 28 days? Do we put a hold on that if he received the bamlanivimab? Or do we go ahead and give it?	The second dose should be held - the CDC guidance is to wait at least 90 days after monoclonal administration to give vaccine. This guidance doesn't specify whether to resume with 2nd dose at this point versus restarting the series with 1st dose though.		
13-Jan	How long after the infusion can a patient receive a COVID vaccine? Had heard 45 days?	CDC guidance is to wait 90 days		
13-Jan	Our small facility has very limited access to rapid testing and so far, is not using any of our 18 tests a week for possible monoclonal ab use. Most of our tests take 3-4 days to return. This delays identification of patients who might benefit. Do you think it is valuable to try to do rapid tests to improve early treatment with BAM?	I would attempt to reach out to local and state resources to obtain more rapid testing kits, but I most definitely found it valuable to do the antigen testing especially if the turnaround time is 3-4 days.	Rapid testing is the best avenue to improve early treatment with BAM. In our system, the testing reagents to perform rapid testing are frequently limited in supply. As such, we try to prioritize performing the rapid test on the patients at the highest risk of deterioration based upon their co-morbidities and clinical presentation.	
13-Jan	Dr. Lennes, does MGB approach offering to treatment to pregnant and lactating pts?	Yes, we have treated a few pregnant patients and lactating patients.		

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13-Jan	Thank you for this presentation. Would you be aware of 'real-world' outcomes from mAb use? We're seeing a higher % of patients needing subsequent care than was reported in the trials and we're presuming that's because we're treating sicker patients. However, without a placebo group we don't have a comparison group. Have you looked at your outcomes?	We have treated about 100 patients at UCSD at this time. We do require that symptoms started within the last 5 days prior to infusion, so are infusing patients early. But only one of our patients has required hospitalization for worsening COVID-19 at this time. So, so far, despite how high-risk our patients are, we've done fairly well.		
13-Jan	Would you share your materials on training for shared decision making?	Yes, happy to share.		
13-Jan	What is the recommendation for nursing home patients on hospice care? And those with a do not hospitalize order?	Encourage shared decision making with provider and patient/caregiver.		
13-Jan	I see that molecular tests, either RT-PCR or Antigen testing, is recommended to confirm COVID-19 prior to administration. The BinaxNOW Antigen test may have a positive predictive value as low 57% if a population prevalence is only 5%. Do you feel that a particular level for PPV should be required prior to initiating a decision to administer monoclonal antibodies?	That makes sense but hard to enforce in practice. In communities with low prevalence, informed clinicians will hopefully order the PCR tests.		

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13-Jan	The CDC guidelines are pretty open to giving vaccine once the acute illness has passed versus the 90 day period. Especially, to not lose the patient to follow-up when administered in a hospital. Is the 2nd dose administration after 14-day quarantine period still a valid approach?	For latest CDC guidance, please review: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	CDC guidance on discontinuing isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions: • At least 10 days* have passed since symptom onset and • At least 24 hours have passed since resolution of fever without the use of fever-reducing medications and • Other symptoms have improved. *A limited number of persons with severe illness may produce replication-competent virus beyond 10 days, that may warrant extending duration of isolation for up to 20 days after symptom onset. Consider consultation with infection control experts. See Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance). CDC guidance for vaccine after COVID-19 infection is as below: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html Vaccination of persons with known current SARS-CoV-2 infection should	

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			be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, while vaccine supply remains limited, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection, and therefore the need for vaccination, may increase with time following initial infection. For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.	

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13-Jan	For Dr. Lennes: how sharable is your EHR build (especially if EPIC) and your shared decision-making pathway? (editorially: EHR builds are a barrier in lower resource organizations - smoothing or partnering with the big companies to build would be helpful in this period of rapid knowledge acquisition).	Happy to share any details that could be helpful. I believe that we can't easily export it, but happy to connect you to the people who built the system for specifications that may be helpful. Don't hesitate to email me if you'd like more info.	Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:	
13-Jan	Is the CVS pathway home infusion company providing MABs to SNFs, nursing homes, and or in the patient's home?	They are doing home infusions, but they will go to congregate settings and we have used them for dormitory administrations, so it does not have to be a single-family home.		
13-Jan	How is CORAM getting MAB drug for Home Infusion use?	The state is supplying the drug and a grant program is covering the costs of infusion.		
13-Jan	Home infusion? We have to have the patient for 1 hour post transfusion for reaction observation. How do you do that at home infusion?	The infusion nurse does the observation in the home.		
13-Jan	Has anyone with experience using mAbs seen any significant adverse effects including severe allergic reactions?	I administered 38 doses of medication and had minimal to no side effects. 2 patients had a slight drop in blood pressure, but no intervention was required. If anything, ensure that the patient is resting comfortable in bed when you administer. Other than that, no side effects or adverse reactions.	A limited number of persons with severe illness may produce replication-competent virus beyond 10 days, that may warrant extending duration of isolation for up to 20 days after symptom onset. Consider consultation with infection control experts. See Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19	

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			in Healthcare Settings (Interim Guidance).	
13-Jan	How is the CVS home infusion company monitoring for infusion and or allergic reactions (especially if providing in the home)?	The home infusion companies observe with the same parameters as the in-person infusion. They have a protocol for follow up phone calls as well. We have developed a protocol for PCPs to call after the CVS infusion to check on patients as well.	CDC guidance for vaccine after COVID-19 infection is as below: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	
13-Jan	Did MGB have concern about the medical and medicolegal risk of home administration with the possibility of reaction to infusion? How did you assess the risk: benefit comparison in home infusion care?	The data for reaction is low. The home infusion company nurses are equipped with a kit of as needed infusion reaction meds. When we consider displacing cancer or medical infusion patients, we deemed it a reasonable choice. And reduction in exposures.	Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.	
13-Jan	Please comment on the practice of some centers charging patient (uninsured or insurance deductible or other cost sharing) infusion fee up to $300.	We do not charge any fees to patients.	While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, while vaccine supply remains limited, persons with recent documented	

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			acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection, and therefore the need for vaccination, may increase with time following initial infection.	
13-Jan	A very practical question de signing a consent. We insist on a multiply signed consent form which means the patient must handle the paper and then we have to deal with a "contaminated" piece of paper. How do you get around this? We do not have an electronic method.	We do not sign a consent form. We document the shared decision making visit and document the assent of the patient.	For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.	
13-Jan	What were the patient responses and outcomes in the LTC?	A link to the ECHO session entitled "Update on Critical Access Challenges and Successes can be found at: https://www.youtube.com/watch?v=HQVb7nLIIz8&feature=youtu.be	On Jan 21, Lilly put out a news release on this topic: https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-prevented https://www.usatoday.com/story/news/health/2021/01/21/monoclonal-antibody-treatment-eli-lilly-found-reduce-covid-risk-bamlanivimab/4242415001/	Overall, the response was positive. I did not observe any significant side effects as a result of the treatment. The residents that received the treatment had a shorter recovery time, less severe progression of illness, and were sent to the acute setting much less then those who did not receive the treatment.
13-Jan	'@LucyHorton Thank you for sharing your scoring system.	If we have more eligible candidates then spots available on a given day, we will rank according to scoring system		

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	How did you use it? Was there a scoring threshold?			
13-Jan	Do you keep a waiting list of patients who didn't "win" the lottery but want to be considered in case others decline?	Yes, we do. We always fill all the spots. We try not to say that there are lottery 'winners'. Rather the lottery gives us a prioritization list.		
13-Jan	Can infusion admin costs be reimbursed through federal programs similar to testing costs?	Yes, CMS has developed a reimbursement rate for mAb administration. See links for more details. https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf		
13-Jan	How did the residents do who received BAM?	The residents did very well. They had a shorter recovery time, less severe progression of illness (e.g. pneumonia did not occur or was minimal, O2 needed less often), and they rarely had to be sent to the acute setting compared to those that did not receive the treatment. I would also like to mention that the IV fluids alone were very helpful. Many of the patients perked up quite a bit after receiving and having a		

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		line started facilitated further treatment for dehydration as well.		
13-Jan	Seeing post-COVID syndrome. Can ECHO address in future series.	Laurie, ECHO and partners are currently planning and seeking support for a long-COVID ECHO.	Dear Laurie, Thank you for this important question! As Christian notes, we are hoping to address this important topic of post-COVID syndrome in the future.	
13-Jan	If done in the outpatient setting - any suggestions on cleaning and disinfecting? set up for multiple patients at time?	We have a dedicated subsection of our infusion center with private patient rooms- only one patient per room unless members of the same household in which case there can be two patients simultaneously. Patients are met by staff outside the facility and escorted directly to the infusion room to minimize any contact with other patients and staff in the health center.	Monoclonal Antibody Infusion Center Model: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Monoclonal-Antibody-Infusion-Center-Model-508.pdf	
13-Jan	Do you use a consent form for patients before starting? and if anyone has a copy of the form they use would they be willing to share?	At the long-term care facility, I work at we contacted the family and received verbal consent and then documented it in their chart. Also, patients that are their own responsible party were asked and it was documented in their chart.		

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13-Jan	'@LucyHorton, a follow-on question. If a patient has been unable to get mAb on the first day because they ranked below another person, would they go to the top of the rank list the following day (if more mAb were available and the patient was still an eligible candidate…not become too ill or too long since symptom onset)? Or do they enter the rank list exactly as the day(s) before?	We don't have specific guidance for this scenario, but they would keep their same risk score.		
13-Jan	Reactions to mAb in San Antonio experience?	Live answered	No significant reaction as a result of the treatment were observed. There were 2 patients that had a slight drop in blood pressure, but no intervention was required. If anything, I would recommend that the patient rest comfortably in bed while the treatment is being administered.	
13-Jan	Will these questions and answers be archived for later viewing? There is great information in here.	Hi, Harry! Yes, we will be sharing the Q&A on the website in a few days.		
13-Jan	Should our consent forms include notification that one will likely have to delay vaccination for 90 days after infusion? Do you tell folks this?	I tell patients that this is the recommendation but not a hard contraindication; I document this advice in their chart, but we don't include it in the consent		

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13-Jan	What were the outcomes of the residents treated with mAbs? Did any require hospitalization after the infusion? Did any experience any infusion-related reactions?	None of the patients required hospitalization after the infusion, and there were minimal to no reactions. The only notable side effect was a slight drop in blood pressure for 2 residents during the infusion, but there was no need for intervention.		
13-Jan	Was this for a skilled facility or Assisted Living facility	Skilled nursing facility		
13-Jan	Was this for a skilled facility or Assisted Living?	Skilled nursing facility		
13-Jan	In patients who have had the first vaccine and then test positive, is there any difference in treatment with monoclonal antibodies for these patients? When can patients who get the treatment get vaccinated following treatment? If they tested positive after the first vaccine, do they need to wait 90 days and then begin the vaccine treatments over starting with the first dose?	Guidance from CDC is to wait at least 90 days after monoclonal administration before vaccination but does not specify whether to restart the series or just proceed to second dose. We are tentatively planning to restart with first dose for such scenarios.	CDC recommends waiting 90 day after monoclonal administration before vaccination, this includes 1st and 2nd doses. They do not recommend restarting the series.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.
13-Jan	Any information on prophylaxis with Antibody therapy?	On Jan 21, Lilly put out a news release on this topic: https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-prevented https://www.usatoday.com/story/news/health/2021/01/21/monoclonal-antibody-treatment-eli-lilly-found-reduce-covid-risk-bamlanivimab/4242415001/		

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13-Jan	What is the data that led to recommendation that a patient receiving monoclonal antibodies wait 90 days before having COVID vaccination?	Taken from CDC website: 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. More information: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	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.	
13-Jan	Can you elaborate about the At Home option? I thought the ED needed to be collocated?	mAbs are available for home infusion use and some home-infusion companies are providing this service.		

Date	Question	Answer(s)		
13-Jan	With patients that have received the first COVID vaccine, and they develop COVID before getting the second vaccine. What are the thoughts of the patient receiving a monoclonal antibody infusion?	For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells. Please see CDC guidelines for more information: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	
13-Jan	CDC states patients may wait 90 days for vaccine after COVID infection. Only need to wait 10 days if asymptomatic or mild symptoms, correct? Sorry accidently placed in chat.	See latest on CDC recommendations here: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		
13-Jan	If someone got one COVID vaccine and developed COVID before the 2nd dose and otherwise qualified for monoclonal antibody would you advise giving it?	For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	

Date	Question	Answer(s)		
13-Jan	To Justin- of 38 residents, what was your success rate?	We had 2 patients that did end up expiring. The other patients completely recovered.		
13-Jan	We gave mAb to a surgeon who was 64, met criteria, fairly ill but no O2 requirement, and had just received 1st vaccine dose 3 weeks before. He had great improvement over the next 24 - 48 hours.			
13-Jan	Is anyone else giving mAb in your ED? Any pushback from staff or administration?	We use plenty in our ED		
13-Jan	How about the use of monoclonals after the first or second dose of the COVID vaccine? Or does it make any difference?	For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	
13-Jan	So if they have been previously vaccinated but then test positive, they do not need to be considered for therapy?	For individuals who develop COVID-19 following vaccination with a COVID-19 mRNA vaccine, it is reasonable to administer monoclonal antibodies at least two days following the vaccination. The rationale is that the immune response to the vaccine has been initiated by then and the S protein antigen expressed by the mRNA vaccine has largely disappeared from the surface of cells.	Patient would be eligible as per the EUA. Treatment decision is a discussion between the patient and provider.	

Date	Question	Answer(s)		
13-Jan	Have any of the panelists had direct experience with Casirivimab/imdevimab rather than Bamlanivimab? Any observations or gestalt about it if you have?	C/I has more complicated storage, package labeling, and administration instructions. Otherwise, we are hearing similar safety and efficacy for both products.		