HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series
Session #7— Achieving Speed and Scale
Wednesday, February 10, 2021 (12-1 PM ET)
Q/A Packet

Date	Question	Answer(s)		
10-Feb	Wondering about side effects/tolerability of the more rapid infusion of bamlanivimab. Is the 16-minute infusion tolerated as well as the slower infusions. Thanks	Unfortunately, I have not had the opportunity to use the rapid infusion in the LTCF/SNF setting yet.		
10-Feb	Do you have any recommendations against premedication with acetaminophen 650mg and cetirizine 10mg x1 1 hour prior to infusion?	Premedications are not routinely recommended.		
10-Feb	We know that FDA issued yesterday EUA for the new combination of IV BAM/Etesevimab and I wonder what's the clinical difference that distinguished the new Combination from IV BAM? When the new combination of the IV BAM and Etesevimab be available for utilization among COVID patient population?	Yes - the FDA issued a new EUA yesterday for the combination of bamlanivimab 700 mg and etesevimab 1400 mg. We expect that both monotherapy and combination bam/etesevimab will be beneficial, and the most effective therapy will be the one that can get to the patient most quickly (much like bamlanivimab vs. casirivimab/imdevimab). The EUA was based on comparing combination therapy to placebo,	As of 3/1/21, bamlanivimab and etesevimab as a combination regimen is now available to be ordered through direct order at https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf	

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		not mono vs. combo therapy. And lastly, the availability of etesevimab has not yet been established.		
10-Feb	With COVID risk allocation calculator - has this been used for pregnant patient yet? We see now a peak of pregnant COVID patient and more of them end up being hospitalized. Would like to learn how to stratify them for risk	No, because pregnant patients are not included in the EUA, we excluded them from the risk calculation.		
10-Feb	Love the mAb squad reference. How do you promote the referral process to practices and practitioners outside the Intermountain system?	We have performed outreach education, developed fliers, presented at department meetings and in-service and included information in weekly email newsletters, all facilitated through our affiliate provider connections. The state website has also been a great source of material as well.		
10-Feb	I recognize this isn't an outcome-focused talk, but -- perhaps for the panel -- are we at least looking at positive endpoints other than hospitalization (like return to work, dyspnea on exertion and other features of the "long COVID") syndrome? (or is this outcome measurement too underdeveloped to utilize for outcomes measurement?). I	Thanks ... We are anxious to learn more about these functional outcomes as well! I didn't share, but we are also observing a decrease in overall mortality in infused patients.		

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	would also like preventing protracted and/or indefinite disability that come through my clinic regularly.			
10-Feb	Do you have MDs, APPs and PAs on your MAB squad team or only MDs?	We have both and an RN. The APP colleagues have been outstanding. It's an eclectic group; among the MDs, we have a dermatologist, gastroenterologist, ID doc, ED doc, several urgent care and several family medicine and internal medicine. It's been very satisfying for them to be directly involved in the COVID response.		
10-Feb	What is your median time from symptom onset to infusion?	We are small NM rural hospital (25 bed critical access) and have completed 20 infusions (BAM) with only 1 minor infusion reaction and only 1 patient whose disease process progressed to hospitalization. New Mexico Dept of Health has gladly shipped us both BAM and Regeneron upon allocation of supply and has given us very sufficient amounts of both. KEY is identifying and treating patients ASAP within a window of 4-5 days from symptom or positive test BEFORE symptoms become moderate to severe.		

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10-Feb	Does anyone know if the antibody gets stuck to the dialysis membrane?	Live answered.		
10-Feb	We have now 7000 high risk patients that have successfully completed treatment w/ infusion reaction rate of 0.2% and a 14-day admission rate of <4%.	Thank you for sharing this experience!! Congratulations! What health system are you with?		
10-Feb	Are those 18? care access points only in Utah?	1 site is in southeastern Idaho; 2 other sites serve border communities in Arizona and Nevada; we are also working with our Intermountain Nevada colleagues as they roll out in the Las Vegas area.		
10-Feb	Any experience with adding a H2 antagonist to the above referenced H1 antagonist?	Premedications are not routinely recommended.		
10-Feb	Have you used both products, and do you see better efficacy for either product?	We are doing comparative effectiveness analysis as we speak and intend to make those early results publicly available as soon as we can to help advance our knowledge.		

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10-Feb	Is there any availability to treatment at home for home bound high risk patients	As part of a pilot program to provide therapy to long term care and skilled nursing facilities. With success outside of hospitals, we hope to move further infusions into the home.	Generally, monoclonal antibodies have been provided at home for more than 20 years and management practices of acute infusion reactions are well developed. Mild and moderate reactions are usually managed through administration of acetaminophen/diphenhydramine and/or slowing (or temporarily stopping) the infusion rate. Severe reactions may require epinephrine, 911, and other supportive measures. See articles published by NHIA at https://www.nhia.org/news/bam-pilot-program/state-resources/.	
10-Feb	Are you using urgent care centers as infusion sites?	We found that urgent care facilities were excellent choices for scaling out quickly because of their wide geographic footprint and their experience with doing infusions and managing possible reactions. They have proven to be an outstanding ally for speed and scale.		

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10-Feb	What had been your experience with the faster infusion rate? Is that something you would recommend to provide more access to our at risk patients? Thanks	The faster rates were approved by FDA because higher doses were given during the clinical trials (equating to the same infusion rate indicated in the new EUA). The decision for faster infusion rates was based similar rates of infusion-related reactions at all concentrations evaluated.	You can find helpful study information about Bamlanivimab infusion times at: Dose Preparation and Administration: https://www.lillymedical.com/en-us/answers/bamlanivimab-dose-preparation-and-administration-121566?hcpToken=A12DSa08bhrd123gg8&channel=GCC.	
10-Feb	Are you aware of any new information on treatment against any of the COVID variants?	Regeneron released a press release on Antibody Cocktail effectiveness against SARS-CoV-2 Variants first Identified in the UK and South Africa, for more information, go to https://investor.regeneron.com/news-releases/news-release-details/regen-covtm-antibody-cocktail-active-against-sars-cov-2-variants.		
10-Feb	What would the typical charge be for the "service and monitoring" of the infusion and is there any difference. Between an ED referral or outpatient office??? Thank you	Charges for infusion services are very similar between infusion centers and urgent care. Of note, insured patients including Medicare have had excellent coverage for these services. We've leveraged CARES act/HRSA reimbursement and a voucher system to ensure that financial concerns are not a barrier to treatment for uninsured populations		

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10-Feb	Are you encountering any issues with staffing for this? if so, how are you managing this?	Many of the "MAb Squad" are working on this program via our HR redeployment program that helps providers whose normal clinical volumes have been decreased by COVID.		
10-Feb	How many infusions have you done?	We are small NM rural hospital (25 bed critical access) and have completed 20 infusions (BAM) with only 1 minor infusion reaction and only 1 patient whose disease process progressed to hospitalization. New Mexico Dept of Health has gladly shipped us both BAM and Regeneron upon allocation of supply and has given us very sufficient amounts of both. KEY is identifying and treating patients ASAP within a window of 4-5 days from symptom or positive test BEFORE symptoms become moderate to severe.		
10-Feb	Can you discuss the efficacy of monoclonals for new strains?	Regeneron released a press release on Antibody Cocktail effectiveness against SARS-CoV-2 Variants first Identified in the UK and South Africa, for more information, go to https://investor.regeneron.com/news-releases/news-release-details/regen-covtm-antibody-cocktail-active-against-sars-cov-2-variants.		

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10-Feb	Would you accept a referral for a pregnant woman that otherwise meet eligibility criteria?	We would probably address this scenario by contacting the manufacturers and initiating a compassionate use eIND since pregnancy falls outside of the studied population.	To find out how physicians can request an emergency IND (eIND), go https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use.	
10-Feb	Can you confirm, did … say NNT=9 in high risk patients? Thanks!	Correct. That is what the Phase III studies showed, and we're seeing a very similar NNT in our real world experience.		
10-Feb	Will allocation of etesevimab (ETE) follow similar channels as other MoAbs and when can health systems expect to get shipments?	Bamlanivimab and etesevimab as a combination regimen is now available to be ordered through direct order at https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf.		
10-Feb	Are there any special pharmacy requirements for obtaining either product?	Pharmacies that currently have bamlanivimab are part of a pilot program through HHS and the National Home Infusion Association. I am unsure of any way to currently receive the product outside of the hospital.	To order the COVID mAbs, you need either a pharmacy license or physician letter of authorization. Pharmacies also need to be able to properly store the medication. Otherwise, there are no restrictions.	
10-Feb	[…]'s talk was really informative I'm wondering how involved state health depts in other states in helping assure that infusion	We're very fortunate to have great engagement at the state level in Utah. The "MAb" committee I referenced is comprised of representatives from		

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	centers or clinics are distributed equitably? It sounds like Utah was very helpful. Also, how? Thx	all healthcare systems in the state, including the rural and critical access hospitals, and we've been able to coordinate strategic geographic access in that group and then report on that to the department of health and state incident command.		
10-Feb	We are small NM rural hospital (25 bed critical access) and have completed 20 infusions (BAM) with only 1 minor inf reaction and only 1 patient whose disease process progressed to hospitalization. New Mexico Dept of Health has gladly shipped us both BAM and Regeneron upon allocation of supply and has given us very sufficient amounts of both. KEY is identifying and treating patients ASAP within a window of 4-5 days from symptom or positive test BEFORE symptoms become moderate to severe.			
10-Feb	Are other clinics using risk stratification for mAb eligibility? What different tools are being used? Are these being monitored & evaluated & recalibrated as more evidence comes to light?	Please see UTAH COVID-19 Risk Score Calculator at Novel Therapeutics | coronavirus (utah.gov)		

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10-Feb	The data I showed was for the state of SC where I serve as the physician lead for this program. Thanks!			
10-Feb	We are an FQHC with an inhouse pharmacy considering starting the process to provide monoclonal antibodies at our center as the center is describing	That's great. Please reach out to the SPEED team at covidtx@hhs.gov. If we can be helpful in getting mAbs to your health center.	You can get the process started through "Direct Ordering". To place an order go to https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf	
10-Feb	Dr ... brings up the issue of equitable access How are others addressing this?	Please see the ECHO session on "Equity and Underserved Populations" that occurred on February 24, please follow this link, https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html		
10-Feb	Was the picture of the waiting room for patients getting the infusion or waiting for test results?	That particular photo was the post infusion monitoring. I think it was a patient and spouse. The camera can cycle through different rooms or show all rooms as once.		
10-Feb	Do you do several infusions in the same room?	No, one infusion per room, we allow the spouse to sit in the room with the patient if they choose. I think that's what you saw in the photo.		

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10-Feb	What proactive precautions have you taken to ensure best practices in patient safety, should the worst-case scenario happen--i.e. severe reaction/anaphylaxis? It's rare, but not nonexistent, and many outpatient staff/settings have no experience with starting IVs, monitoring IV infusions, or recognizing/responding to anaphylaxis.	We share with you helpful resources from several facility types which include standing orders, order sets, protocols, SOPs, etc. at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html, specifically, go to "Resource Library".	I am the director of nursing in our FQHC and we hired our local nursing school to train up our nursing staff which promoted comfort. We also overstaffed initially to provide comfort around support.	
10-Feb	Does this service require a negative pressure room?	Live answered.	No, it does not require a negative pressure room.	
10-Feb	Is anyone collecting/sharing outcomes data, outside of clinical trials?	See Duke Margolis White Paper that provides insight on COVID-19 Monoclonal Antibody Treatments: Using Evolving Evidence to Improve Care in the Pandemic at https://healthpolicy.duke.edu/publications/covid-19-monoclonal-antibody-treatments-using-evolving-evidence-improve-care-pandemic	We also refer you to a previous ECHO session on Monoclonal Antibody Therapy in Michigan: A Preliminary Analysis of the First 1500 Patients". To find this presentation, visit https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html, and click on "Where Are We Now?"	
10-Feb	Did you have any engagement with your Healthcare Coalitions/ Coalition leads when activating these? If so, what did that look like?	For a talk on different types of engagement and partnerships, we refer you an ECHO session on "*Regional Approaches to mAb Administration – Operationalizing Partnerships*", this can be found at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html		

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10-Feb	For Dr …, how did your nurses adapt to this when they are not infusion nurses? We have had trouble with our outpatient nurses being comfortable doing infusions and the thought of dealing with infusion reactions, that has really been our limiting factor for starting monoclonal infusions.	Participation is optional (aka we are not forcing nurses to do this) so those who are inherently risk adverse don't opt in handle. Strong working relationship between nurses and providers with providers always available to jump in to help. Do it when a provider is "around" just in case. In our case a Rapid Response Team already exists who the nurse can call on. We have a clear algorithm for managing infusion reactions which is based on the recent ECHO session on that precise subject. It was great if you haven't watched it check it out!		
	As a nurse myself, I understand your nurses' concerns. Starting IVs, mixing IV drugs, monitoring IV infusions, and recognizing & responding to emergencies such as anaphylaxis are not simple skills, and most outpatient nurses have not had this type of training or experience. I am hoping some panelists can address this question and share the training materials they are using for inexperienced	One thing we've found helpful is to have RN "champions" at each of our infusion sites who take point in training and attend a daily virtual huddle with the mAb squad where we troubleshoot issues and share best practices.	I am the director of nursing in our FQHC and we hired our local nursing school to train up our nursing staff which promoted comfort. We also overstaffed initially to provide comfort around support.	

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	staff, to ensure competence and patient safety.			
10-Feb	So - if you can't measure the direct impact - what about the surrogate impact of lesser effect size?	Good question. We felt like if there was adsorption to the membrane is was likely small and the benefit to some passive immunity likely outweighed the risk of a decrement in dose. Clearly answering this question with more definitive date will be important but our early results are compelling.		
10-Feb	I'm interested in bringing the operations from a clinical setting to a public health setting. Any thoughts/experience on having non-clinical staff screening and referring patients? (i.e. contact tracers/staff test result call centers). Risks in turning what is largely a clinical decision to a pure algorithm? Are there any known examples of infusion centers outside of individual clinical settings?	Thanks! There have been locations in which non-clinical staff (think public health staff, especially in the outreach community) are able to refer in. There are a couple of different ways: such staff could refer to a testing site, from which (+) people go to a treatment center. Or, a referral could happen to a site that has the ability to BOTH test onsite and have onsite monoclonals. And all should bear in mind that rapid testing is an excellent choice for this setting; it doesn't have to be PCR.		

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10-Feb	thank you - do you have specific training protocols/materials?	Yes. if you email me at … I'll connect you with our infusion site leaders who can share the reaction protocol		
10-Feb	Is there any information on using monoclonals in high risk exposed patients for example in nursing homes? Any information on IM use as a prophylaxis similar to palivizumab for RSV bronchiolitis in high risk neonates?	Generally, monoclonal antibodies have been provided at home for more than 20 years and management practices of acute infusion reactions are well developed. Mild and moderate reactions are usually managed through administration of acetaminophen/diphenhydramine and/or slowing (or temporarily stopping) the infusion rate. Severe reactions may require epinephrine, 911, and other supportive measures. See articles published by NHIA at https://www.nhia.org/news/bam-pilot-program/state-resources/.	Regarding IM formulations in the pipeline, please refer to e.g. AZD4227 https://clinicaltrials.gov/ct2/show/NCT04625972	Other COVID-19 related trials can be found at https://clinicaltrials.gov/ct2/results?recrs=&cond=&term=COVID&cntry=&state=&city=&dist=
10-Feb	Regarding mAb treatment use. Are states and the feds keeping a registry of patients provided these therapies just as state and local immunization information systems are doing for tracking COVID-19 vaccinations?	There is not a federal registry of patients who've gotten monoclonals. In the case of vaccine, there is a required second dose.	Operation Warp Speed is funding an effort coordinated by the C19 Healthcare Coalition (MITRE corporation) to create a MAb registry	

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10-Feb	For our SNF residents, we are being more cautious with rate of infusion. We had 2 infusion reactions with a faster rate, so MD began pre-medicating and hasn't hade issues w/ infusion reactions since then. Do you recommend for or against this? Or neutral on this recommendation? Thank you.	Premedications are not routinely recommended.		
10-Feb	Have you a strategy to inform the lay public and primary specialty care physicians to the availability and access to so sites?	Several outreach efforts and stakeholder engagements are ongoing to raise awareness in various settings, one of which is through the SPEED program (https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx). States, Hospital Systems, Professional Organizations are also engaging in several outreach efforts.	We have also developed Social Media Toolkits to be shared across the board, the toolkits can be found at https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx.	Please see the Combat COVID Website at http://combatCOVID.hhs.gov.
10-Feb	Is any targeted marketing being done on the lay side? Church or other community groups? HR departments of industry? YMCA/YWCA (many w/ >65 yr. old active members)	Several outreach efforts and stakeholder engagements are ongoing to raise awareness in various settings.	We have also developed Social Media Toolkits for dissemination in the public, which can be found at https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx	

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10-Feb	Thanks - do you know how we can find out more about how non-clinical staff do the screening? For example - the specific screening tool that might be used? And how much additional screening might be needed at the infusion center?	The tool we use is available on the Utah state coronavirus website and described in a pre-print publication on MedRxiv for those who are interested. It is easy to calculate and includes an appendix with a dictionary of definitions for the various comorbidities. We have a registered nurse who works with our team and independently does a lot of the screening and does it very well. At the infusion sites, the staff are trained to assess vitals and oxygen levels and to escalate concerns about patients whose disease has advanced and may not still qualify to a member of the "MAb squad" on call for that day. The combination of the initial "MAb squad" provider EHR and phone screening and the onsite screening has been successful and has resulted in a number of patients being appropriately triaged to higher levels of evaluation and care in the emergency department and hospital.		
10-Feb	What kind of clinical follow up is necessary? Is it ok to have no	Yes - there is not a requirement for follow up (but it's a good idea).		

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	clinical follow up (i.e. for patients with no primary care provider)			