HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series
Session #6— Patient/Provider Outreach
Wednesday, February 3, 2021 (12-1 PM ET)
Q&A

Date	Question	Answers		
3-Feb	Please comment on the smaller volume for BAMLAN doses given in less than 60 minutes in regard to side effects and hypersensitivity reactions. THANK YOU!	Live answered.		
3-Feb	Last week's WebEx mentioned about SpO2 measurement parameters from FDA for administering bamlanivimab. I can't find where this is documented; could you tell me where to look for this please?	The EUA does not indicate a specific oxygen parameter. Patients requiring oxygen or patients on baseline oxygen requiring increased amounts are excluded (this would require the clinician/ site protocols to determine the SpO2 cutoff).	Please see "FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB" https://www.fda.gov/media/143603/download.	Additional information: This is where the sp02 parameters are documented for "mild" and "moderate" COVID https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/.
3-Feb	Public, and even physician knowledge about these products and their potential ability to reduce the burden on hospitals is not widely known. While the companies bear some of the responsibility of increasing awareness of these problems, are there any efforts on the part of the federal or state/county governments for raising awareness?	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 targeted outreach efforts.	Please see the Social Media Toolkits at https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx.	Combat COVID Website at http://combatCOVID.hhs.gov.

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3-Feb	We now have a few patients who received first vaccine dose, then within a few days, diagnosed with COVID-19 and then received Bamlanivimab. How will the infusion of the mAb affect the efficacy of the first dose of vaccine, and when Should the second vaccine be given? Should both doses of vaccine be repeated after 90 days?	Please see CDC guidance for latest on vaccine and mAb timing considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Specifically, the "Persons with a current or prior history of SARS-CoV-2 infection" and "Persons who previously received passive antibody therapy" sections.	Probably will not be studied. I will recommend waiting 90 days for second dose of vaccine, vs. starting vaccination all over.	
3-Feb	Is the data published regarding the shorting infusion times?	You can find helpful study information about Bamlanivimab infusion times in the following article: **Dose Preparation and Administration**: https://www.lillymedical.com/en-us/answers/bamlanivimab-dose-preparation-and-administration-121566?hcpToken=A12DSa08bhrd123gg8&channel=GCC.	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 on similar rates of infusion-related reactions at all concentrations evaluated.	
3-Feb	Did the BLAZE 2 study include any exposed patients that have already had the vaccine? If exposed patients in a nursing home already have had the series would we even need to consider a monoclonal?	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:	A COVID-19 patient who has received vaccine but later tests positive would be eligible as per the EUA. However, treatment decision is a discussion between the patient and provider.	

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		https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.		
3-Feb	There has been some "chatter" on the IDSA provider blogs about delayed (7-8 days) infusion reactions - arthralgias, joint swelling, rash. Has this been reported/ seen?	Please see clinical trial results for Bamlanivimab: Overview of Treatment Emergent Adverse Effects with Bamlanivimab Alone.		
3-Feb	Can you provide details about the additional/updated warnings and reactions that you mentioned?	Please see Fact Sheet for Health Care Providers on Bamlanivimab. At the top, it highlights the recent changes and where in the document to find more information. https://www.fda.gov/media/143603/download.		
3-Feb	Our SNFs are fairly hesitant with IVP meds used to treat infusion reactions. Do you anecdotally anticipate infusion reactions increasing with faster infusion and lower volume (not necessarily anaphylaxis)?	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 on similar rates of infusion-related reactions at all concentrations evaluated.	You can find helpful study information about Bamlanivimab: Dose Preparation and Administration at https://www.lillymedical.com/en-us/answers/bamlanivimab-dose-preparation-and-administration-121566?hcpToken=A12DSa08bhrd123gg8&channel=GCC.	

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3-Feb	What about the subcutaneous route for Regen cocktail that they are using for post-exposure prophylaxis?	For information on ongoing studies for the SubQ. route of administration, visit https://clinicaltrials.gov/ct2/show/NCT04452318?term=casirivimab+and+imdevimab%2C+subcutaneous&draw=2&rank=1 and https://clinicaltrials.gov/ct2/show/NCT04666441?term=casirivimab+and+imdevimab%2C+subcutaneous&draw=2&rank=2.	Casirivimab and imdevimab are not authorized for the prevention of COVID-19. Clinical trials remain ongoing to study casirivimab and imdevimab for treatment and prevention of COVID-19. Go to https://clinicaltrials.gov.	
3-Feb	Is there any consideration being given to changing the EUA eligibility criteria? Short of that, wow do we manage expectations around the more "arbitrary" cutoffs (e.g. An 18-year-old with single ventricle physiology? A BMI of 34.4 (no joke, I've been there)? Thanks!	Live answered.		

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3-Feb	Some facilities are hesitant to allow infusions to occur onsite. How is HHS helping to educate the long-term care sites?	A helpful resource has been put together, entitled "Planning Considerations for Monoclonal Antibody Administration" and can be found at this link: https://files.asprtracie.hhs.gov/documents/aspr-tracie-covid-19-monoclonal-antibody-therapy-tip-sheet.pdf and you can also find resources from National Infusion Center Association (NICA) helpful (https://infusioncenter.org/infusion_resources/covid-19-antibody-treatment-resource-center/).	A link to the resource library, a compilation of standing orders, training guides, SOPS, etc. can be found at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html.	Through ECHO, we have covered several topics that potentially addresses concerns that continue to come up. You can find the recording and slides to past sessions at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html.
3-Feb	Do the 70% results hold for both dialysis and transplant patients?	If you are referring to data showing treatment with Lilly's neutralizing antibodies reducing the risk of COVID-19 hospitalizations and death by 70 percent, please go to https://investor.lilly.com/news-releases/news-release-details/new-data-show-treatment-lillys-neutralizing-antibodies.	Additional information for patients with comorbidities in the BLAZE-1 trial can be found in the following article (**Bamlanivimab: Common Comorbidities Associated With COVID-19**) at https://www.lillymedical.com/en-us/answers/bamlanivimab-common-comorbidities-associated-with-covid-19-124537?hcpToken=A12DSa08bhrd123gg8&channel=GCC.	

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3-Feb	Question not answered. What if the patient gets the first dose of vaccine shortly AFTER Bamlanivimab, not 90 days? Should the vaccination start over 90 days later? Will second dose 90 days later result in a good antibody response?	Live answered		
3-Feb	Are there recommendations on the timeline between COVID19 vaccination and then giving BAM if positive just a few days after vaccination?	Please see CDC guidance for latest on vaccine and mAb timing considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Specifically, see "Persons with a current or prior history of SARS-CoV-2 infection" and "Persons who previously received passive antibody therapy" sections.		
3-Feb	How comfortable are the panelists to administer 700mg BAMLAN in 50mls over 16 minutes in your centers? (Our experience is with 16 pts as our program is 1 week old).	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 on 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.	

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3-Feb	How about BAM for asymptomatic COVID positive patients, hard to tell if they were within 10 days when they have no symptoms?	The current EUA is for symptomatic patients only. There may be future data and guidance on use in prophylaxis.	Per the EUA, Bamlanivimab is not authorized for use in patients: who are hospitalized due to COVID-19, OR who require oxygen therapy due to COVID-19, OR who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.	
3-Feb	How often should staff be monitoring vitals after the mAb infusion is over?	The EUA indicates patient observation for 60 minutes post infusion. There is no listed requirement for vital signs (most signs of a reaction are visible through observation and subjective report by the patient).	Per the EUA, it states clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete, it doesn't specify how often.	
3-Feb	Can anyone share training recommendations or resources for sites/clinicians looking at doing this, and who currently have no experience with mAbs, IV infusions, recognizing/managing anaphylaxis, etc. (i.e., FQHCs and similar sites)?	Helpful resources for prescribers and infusion providers can be found here: https://infusioncenter.org/infusion_resources/covid-19-antibody-treatment-resource-center/.	A link to the resource library, a compilation of standing orders, training guides, SOPS, etc. can be found at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html.	We also refer you to **Lily Bamlanivimab Playbook** at https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf and the **REGEN-COV EUA Guidebook** at https://www.regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf.
3-Feb	Dr. Bander: How much has a problem been the restrictive EUA (i.e. "Wait, I don't qualify!??")? I've been humbled by how challenge it's been to get (a reliable) BMI for patients that are not established or haven't been seen in years).	It's a big problem at Sinai, we have rejected 50% of patients for being outside windows like time of symptom onset – Overall, though for BMI we don't knit pick as long as it seems plausible.		

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3-Feb	QUES re: your campaigns to prompt mAbs & other coming EUA meds How are these being funded? How Are these funding Orgs & public health authorities helping w messaging ? What are you doing to counter misinformation ? Thx Many evaluations of other interventions incl other vaccinations The US Task force on Community Preventive Services has always pointed to the most successful= multi component interventions! Please comment.	Community organizations have funding and HHS and OWS has supported them. The train the trainer model is best.	With regards to campaigns, you can find a variety of social media tool kits at https://www.phe.gov/emergency/events/COVID19/therapeutics/toolkit/Pages/default.aspx.	
3-Feb	Knowing the EUA prohibits use for patients admitted with COVID, has anyone treated patients admitted for other reasons then tests positive for COVID? For example, surgical patient- absent the surgery they would have been treated for their COVID as an outpatient?	Bamlanivimab may be used in patients hospitalized for reasons other than COVID-19, so long as the terms and conditions of authorization are met. For example, a patient hospitalized for an elective orthopedic procedure who reports mild symptoms of COVID-19, confirmed with positive results of a direct SARS-CoV-2 viral test, may be appropriate for treatment with bamlanivimab if the patient is also at high risk for progressing to severe COVID-19 and/or hospitalization, as detailed		

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		in the Health Care Provider Fact Sheet (https://www.fda.gov/media/143603/download).		
3-Feb	Are the mAbs being studied in South Africa, Brazil variants, etc.?	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.	So far, the data shows they are effective, but more work is underway to study. Certainty a concern and great question!	
3-Feb	Any governmental initiatives to get the testing facilities to start including viral load on PCR tests?	We are not aware of any.		
3-Feb	If one has received the COVID vaccine, but tests positive for COVID, is there a wait time for Monoclonal therapy?	Please see CDC guidance for latest on vaccine and mAb timing considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html, specifically, the "Persons with a current or prior history of SARS-CoV-2 infection" and "Persons who previously received passive antibody therapy" sections.		

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3-Feb	The shorter infusion times are updated in the EUA. Where were these shorter infusion times studied in patients and rates of adverse effects, etc.? My pharmacists cannot find any of this data and for that reason they are reluctant to approve shorter infusion times, instead remaining cautious with the infusion time.	You can find helpful study information about bamlanivimab infusion times in the following article, Dose Preparation and Administration at https://www.lillymedical.com/en-us/answers/bamlanivimab-dose-preparation-and-administration-121566?hcpToken=A12DSa08bhrd123gg8&channel=GCC	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 on similar rates of infusion-related reactions at all concentrations evaluated.	
3-Feb	Curious to organizers - are speakers filing conflict of interest information that is publicly available to the viewers of these sessions ? Thanks.	All COI information is available in the Agenda attached to the announcements sent by Project ECHO.		
3-Feb	Anecdotally, the NIH and IDSA guidance recommending against the routine use of COVID mAbs is often cited as a source of prescriber & patient hesitation. Any insight on whether NIH and/or IDSA might review the [limited] data that has come out since those statements came out in November, and potentially issue updated guidance?	We do not have information on this that we can share at the moment.		

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3-Feb	Any information about outcomes in pregnancy?	For each of the mAbs authorized, there are negative fetal tissue cross-reactivity studies and therefore requiring non-clinical repro tox studies is not anticipated. Although there is not a signal of potential harm, there is no systematic data collection for pregnant women who are treated and the EUA fact sheet label reflects that. FDA is currently working to determine possible areas of growth for pregnancy data collection.		
3-Feb	What is known about the effectiveness of monoclonal antibody therapy in kidney transplant and dialysis patients?	Non-hospital settings including dialysis clinics are safely and successfully administering mAbs across the country.	Per the EUA, the mAbs are authorized in patients who have chronic kidney disease.	
3-Feb	Any experience/ advice on covering costs associated with infusions (not just drug cost). In New Mexico, infusion delivery is primarily via hospitals/ ERs but this creates an automatic barrier to access for uninsured/ underinsured/ undocumented/ highest risk minority populations when facing costs of ER visit/ infusion center costs.	Anyone can get regardless of status. HHS has CPT code for infusion and there is a block grant being worked on.	Dear … generously shared the link to the HRSA info about uninsured/underinsured patients: https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions.	

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3-Feb	We have been trying to get set up to infuse monoclonal antibodies on an outpatient basis as a rural FQHC but our delay has been due to our outpatient nurses not feeling comfortable doing infusion care. Is there any guidance for nurses to make them more comfortable with this? Outpatient nurses are different than infusion clinic nurses or ER nurses.	We would be happy to talk and share resources we have on this. Next week will be a detailed presentation by Refuah on the nuts and bolts for FQHC, they use regular RN.	A helpful resource has been put together, entitled "Planning Considerations for Monoclonal Antibody Administration" and can be found at this link: https://files.asprtracie.hhs.gov/documents/aspr-tracie-covid-19-monoclonal-antibody-therapy-tip-sheet.pdf and you can find resources from National Infusion Center Association (NICA) helpful (https://infusioncenter.org/infusion_resources/covid-19-antibody-treatment-resource-center/).	A link to the resource library, a compilation of standing orders, training guides, SOPS, etc. can be found at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html We also refer you to **Lily Bamlanivimab Playbook** at https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf and the **REGEN-COV EUA Guidebook** at https://www.regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf.
3-Feb	I believe I heard a Dr. Chuk mention a clinical trial for subcutaneous administration of the mAbs. If yes, can you elaborate on the findings to date?	We are not aware of data being published yet but for SubQ clinical trial information, visit https://clinicaltrials.gov/ct2/show/NCT04452318?term=casirivimab+and+imdevimab%2C+subcutaneous&draw=2&rank=1 and https://clinicaltrials.gov/ct2/show/NCT04666441?term=casirivimab+and+imdevimab%2C+subcutaneous&draw=2&rank=2.		

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3-Feb	Have any of the panelists had experience incorporating mAb referrals/information into contact tracing programs?	Pima County, through their CI/CT contractor Maximus, is providing verbal MAB information as well as specific infusion clinic information during initial case investigation and our contact tracing program. This information is shared based on a verbal script that was developed and integrated into the case investigation and contact tracing process. We have been providing this resource information since the TMC clinic opened earlier this year. The original population that was targeted was 65+ . This has been recently updated to include serious co-morbidities and all adult populations that are included in mAb guidelines. To date we have received very positive feedback from our participants that this resource has been very helpful and a benefit in their treatment options.		
3-Feb	For those involved in clinical trials Are there some efforts as things unfold to design studies as comparative effectiveness trials? Has PCORI considered funding these types of more in-depth studies?	See the following article (Bamlanivimab: Ongoing Clinical Trials for the Treatment or Prevention of COVID-19) at https://www.lillymedical.com/en-us/answers/bamlanivimab-ongoing-clinical-trials-for-the-treatment-or-prevention-of-covid-19-	Information on ongoing COVID related clinical trials can be found at https://clinicaltrials.gov/ct2/results?recrs=&cond=&term=COVID&cntry=&state=&city=&dist=.	

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		120894?hcpToken=A12DSa08bhrd123gg8&channel=GCC.		
3-Feb	What was the name of the document from Duke Margolis center? Was it something in addition to the December mAb report? Thanks.	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.	Also, see Duke Margolis - Recommendations and Promising Practices for Providers: https://healthpolicy.duke.edu/projects/recommendations-and-promising-practices-providers.	
3-Feb	Thanks. Partially answered. I guess we don't have data on the effect of giving bamlanivimab on a recent vaccine dose, so no clear answer.	Correct, we just don't have adequate data on this situation at present, particularly given that national long-term care vaccine roll-out is only roughly 6 weeks old at this point.		

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3-Feb	Where in the Fact sheet says about the o2 sat threshold?	The O2 threshold is not listed in the Fact Sheet or the FDA Letter. We did an extensive search for "saturation" and "sp02". The Lilly site has the following listed as an exclusion criterion in their trial: "Oxygen saturation (SpO2) ≤93% on room air at sea level or ratio of arterial oxygen partial pressure (PaO2 in millimeters of mercury) to fractional inspired oxygen (FiO2) <300, respiratory rate greater ≥30 per minute, heart rate ≥125 per minute". Most oxygen protocols indicate starting oxygen for an SpO2 <90 or 92%, which may be why this is not called out in the EUA. The 93% that is being mentioned is coming from the initial clinical trial exclusion criteria (and not mandated by the EUA).	Additional information: This is where the sp02 parameters are documented for "mild" and "moderate" COVID https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/	
3-Feb	This is an ongoing debate for us too since last week Dr. … said 90% and another doctor said they stick to the EUA of 93%	The EUA definitely doesn't indicate 93% so you could provide the info that it is patients requiring oxygen based on facility protocol/clinical assessment.		

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3-Feb	To clarify: If mAb is administered after the first immunization, do you delay the second dose due to mAb/acute infection? If the second dose is delayed for the 90 days, is the individual considered adequately administered even though the duration between immunizations will be greater than recommended?	Please see CDC guidance for latest on vaccine and mAb timing considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Specifically, the "Persons with a current or prior history of SARS-CoV-2 infection" and "Persons who previously received passive antibody therapy" sections.		

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3-Feb	Question for those who are already doing the infusion - Please comment on the Infusion site workforce- MD, NP, RN . what is RN/patient ratio that is considered safe ? Thanks	At The Wright Center for Community Health, we have integrated the infusion activities in a repurposed auditorium environment within a larger primary care clinic so that on site, able to respond physician supervision is always available, in addition to full medical supplies and an AED because of the rare risk of anaphylaxis. Our direct medical staffing for the infusions in an RN with a ratio of 4 patients to 1 RN. We bring the patients in at 15-minute intervals to get infusions started, run 1-hour infusions and observe the patient for another hour. We did find that offering infusions only a few days a week created moral dilemmas for our providers and did not meet the needs of sick patients, so essentially now we have at least one RN committed staffing for infusions every weekday. All providers have been educated on the workflow as we would ad hoc also organize such services even on the weekend if a patient was sick enough. One additional insight is that the RN:patient 1:4 ratio was notably very stressed when we treated patients in a memory disorder unit where they	You may find information on infusion staffing plan in the mAb-Outpatient Administration Play book at https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_1Feb2021.pdf	

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		had challenged insight, some behavior problems, and more agitation than the general population we have been treating and that RN actually had geriatric senior mental health experience. I share this just to emphasize that context is very important for optimizing the RN:Patient ratio for safety.		

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3-Feb	If I have a colleague who would like to be invited to this, can I forward the meeting, or can I get this invite sent to her?	Your colleague can register for the series at https://echo.zoom.us/webinar/register/WN_nJLmp2xaT-yNBHe-0Pfspw		