HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series

Session #10— *Partnering with Urgent Care Centers to Increase Access and Utilization of COVID mAbs*

Wednesday, March 10, 2021 (12-1 PM ET)

Q&A Packet

Date	Question	Answer(s)		
10-Mar	Have/can patients receive Bamlanivimab after they have received a COVID-19 vaccination?	Patients who test positive for COVID-19 after receiving vaccination are not precluded from receiving treatment with the COVID-19 mAbs if they meet the criteria outlined in the EUA.	Updated link: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html	For the latest information, please see the CDC "Interim Clinical Considerations for Use of COVID-19 Vaccines" found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.
10-Mar	Do we have to finish our bamlanivimab stock first before using Regeneron mAb?	Live answered	You may use any product you have available.	For your awareness, the United State Government (USG) is evaluating recommendations for use of bamlanivimab in regions where the SARS-CoV2 mutation L452R found in B.1.429/B.1.427 lineages (a.k.a. 20C/CAL.20C) is circulating in high numbers given concerns that the clinical activity of bamlanivimab is impacted by this variant. ASPR will limit distribution to these regions of the country by stopping direct ordering for bamlanivimab while evaluations are ongoing. Currently, this action will only affect the states of California, Arizona, and Nevada.

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				The other two authorized products, bamlanivimab + etesevimab and casirivimab + imdevimab, do not appear to be affected and will continue to be available for direct ordering in these states. ASPR is working with the CDC, NIH, and FDA on any recommendations for treatment and will continue to work closely with these agencies on surveillance of this and other variants that may impact the use of the monoclonal antibodies authorized under emergency use. We will update our stakeholders with any new recommendations.
10-Mar	If a patient gets worse with COVID symptom after bamlanivimab infusion, can we assume he/she has the variant COVID?	Live answered	There are a portion of patients who present for mAb infusion but develop worsening symptoms and require hospitalization. This was the case prior to variants being an issue, so based on the data it would not be unexpected regardless of variant status.	

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10-Mar	and if so, can we still give Regeneron mAb (as a second mAb infusion?)	Live answered	There are a portion of patients who present for mAb infusion but develop worsening symptoms and require hospitalization. This was the case prior to variants being an issue, so based on the data it would not be unexpected regardless of variant status.	
10-Mar	What are the fastest rates your facilities are running the BAM? The EUA states can run over 16 minutes. Has anyone seen any poor outcomes from running this more quickly?	Live answered		
10-Mar	Is there any contraindication to administering mAb in a patient who developed COVID within a week after getting a COVID vaccination?	Patients who test positive for COVID-19 after receiving vaccination are not precluded from receiving treatment with the COVID-19 mAbs if they meet the criteria outlined in the EUA.	For the latest information, please see the CDC "Interim Clinical Considerations for Use of COVID-19 Vaccines" found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.	Updated link: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html
10-Mar	Would you be willing to share some of those playbook resources?	Live answered		
10-Mar	Have MCAs relegated infusions of convalescent plasma to medical history?	Live answered		

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10-Mar	This link does not work - (page can't be found)	Please try this link: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html	Updated link: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html	
10-Mar	Hi, any updates on BAM/ETE cocktail? Is it being distributed yet?	Yes, all three products are available for direct ordering. Direct ordering information can be found at https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/direct-order-process-covid19-mAb.aspx, and to place an order go to https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8.		
10-Mar	What is your average infusion time in urgent care setting?	We are using 16-minute infusion and no issues to date.		
10-Mar	What eligibility criteria are you using?	We do not have any recommendations beyond the eligibility criteria that is outlined in the COVID Monoclonal Antibodies EUAs, please visit https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.		
10-Mar	I know rapid infusion is approved for BAM, but are you currently doing more rapid infusion with Regeneron as well?	At CMG we are using the Lilly mono product only. No experience with Regeneron product.		

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10-Mar	The EUA for BAM states that the IV tubing for BAM need to be PE and/or PVC lined. Is everyone using this type of tubing? The recent facility I toured was not…is this absolutely necessary?	You don't need a non-PVC IV bag or infusion set. The conventional normal saline bag and tubing are fine. For BAM, a filter is strongly recommended but not required.		
10-Mar	Can you share the training videos or other resources related to your training process?	Unfortunately, we cannot share training material as it is made for in-house use only.	Tool for creating the video is "My Absorb".	
10-Mar	Can you share codes for billing and compensation from CIGNA insurance for the entire procedure, I santibody supply to be paid up front by the private urgent care, cost per vial/dose	I would be happy to find the correct person to connect with you on your question. Please provide contact information and I will share with appropriate enterprise colleague. you may send to…		
10-Mar	Can you speak on approximate percentage of patients receiving MABs who are successful in avoiding severe dz/hospitalization from COVID?	Our experience shows that only a small number of patients who received the infusion developed worsening of symptoms and none of those patients required hospitalization. The majority of our patients receiving this therapy are older than 60 years of age.		
10-Mar	There is no info on monoclonal antibodies in the above links - only updates on vaccines	Apologies. It looks like CDC recently updated their website and no longer explicitly addresses recommendations on infusing mAbs after vaccine. From our perspective, the recommendation that patients		

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		can receive mAbs following vaccine remains true.		
10-Mar	How many infusions have you completed and what percentage of patients turn down the mAb option?	We have completed roughly 40 infusions. I am not sure what percentage of the eligible patients turn down the mAb therapy. That would be an interesting metric to trach though.	Through end of February, • 78 eligible patients • 49 opted for infusion	As of Wed 3/10, we had done 578 infusions across our 11 hospital sites. Cannot quantify the amount of patients who turn the option down.
10-Mar	Curious to know what the utilization of mAbs looks like nationally? Is that data available through claims data? Can you provide a link to this?	This had been reported at a state level not the individual facility level. Additionally, there are some distributors which receive the product and then further distribute it which we would likely not have visibility on. With regards to claims data, we have not looked at claims data and there is probably a bit of a delay in the processing of claims data. We have been working off of facilities self-reporting.		
10-Mar	Could any member comment on the challenge of unfunded patients? If the system is "traditional" bill insurance vs. "discount" for unfunded, etc. there tends to be a lot of challenge to work through this	HRSA has an FAQ on this, see link: https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions. It's under the "funding and other resources" section.	https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions.	

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	in a timely way. Some patients simply walk away.			
10-Mar	My Absorb	Thank you for sharing this information.		
10-Mar	Can we see that video?	Unfortunately, we cannot share training material as it is made for in-house use only.		
10-Mar	Now that the NIH advisory panel has given a thumbs up to the new Lilly mAb cocktail but not the other 2 mAb products available, how are you looking at decisions re: which of the products to use going forward (including how to factor in the effectiveness of the dual mAb products w/ the viral variants)?	The United States Government is evaluating recommendations for use of bamlanivimab in regions where the SARS-CoV2 mutation L452R found in B.1.429/B.1.427 lineages (a.k.a. 20C/CAL.20C) is circulating in high numbers given concerns that the clinical activity of bamlanivimab is impacted by this variant. ASPR will limit distribution to these regions of the country by stopping direct ordering for bamlanivimab while evaluations are ongoing. Currently, this action will only affect the states of California, Arizona, and Nevada. The other two authorized products, bamlanivimab + etesevimab and casirivimab + imdevimab, do not appear to be affected and will continue to be available for direct ordering in these states.		

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		ASPR is working with the CDC, NIH, and FDA on any recommendations for treatment and will continue to work closely with these agencies on surveillance of this and other variants that may impact the use of the monoclonal antibodies authorized under emergency use. We will update our stakeholders with any new recommendations.		
10-Mar	Can you share the mix of demographics you have treated with the antibodies and any interesting findings based on the demographics?	Treated Urgent Care Patients - Race/Ethnicity American Indian or Alaska Native: 1 Asian: 2 Black or African American: 4 Declined: 9 Other: 7 White: 26 Total: 49		
10-Mar	Sorry, that was intended to be a question - My Absorb? Name for the training/LMS platform?			
10-Mar	Do you have standing orders for non-life-threatening reactions/side effects? What do you include?	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**".	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.	

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10-Mar	What kind of reimbursements are you seeing per infusion visit	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.		
10-Mar	For the patients you are treating in the urgent care setting, are there any plans to track patient outcomes post-treatment including any progression of illness or hospitalizations?	We follow up with the patients 24-48 hours after the infusion, mainly just to check in and see how they are doing. We are not currently tracking post-treatment outcomes, however, like I mentioned during the Q and A session, I do feel there would be some use to tracking that. We may implement long term tracking at some point in the future.	We follow through within 72 hours of treatment with patients to monitor progress, symptoms. Currently, no long-term tracking of patients.	
10-Mar	Is in-person care still down? If no, at what point would you say it rebounded and is utilization same as pre-COVID as far as infusions?	Inpatient admissions have returned to pre-COVID numbers. We believe infusions are helpful for patients beyond limiting utilization and saving resources for the health system. We are planning to increase availability of infusions over the next few weeks.		
10-Mar	With regard to IV tubing, we are using Paclitaxel tubing which meets recommended	You don't need a non-PVC IV bag or infusion set used for paclitaxel, as it is not stipulated in the EUA. The		

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	criteria - again curious to whether this is absolutely necessary as it is much more expensive...	conventional normal saline bag and tubing are fine.		
10-Mar	The Baxter tubing that includes the 0.22-micron filter is PVC tubing - can be	You don't need a non-PVC IV bag or infusion set, as it is not stipulated for use in the EUAs. The conventional normal saline bag and tubing are fine.		
10-Mar	How can you bill for follow up visit within 24hr? CMS does not reimburse tele visit unless 7 days later.	A nurse calls to check on the patient. This is not a billable visit.		
10-Mar	Can we give Regeneron mAb infusion, if patient gets worse symptoms after Bamlanivimab infusion, suggesting variant form of COVID that is not covered by Bamlanivimab?	We don't have guidance on this particular question at this time.	There are a portion of patients who present for mAb infusion but develop worsening symptoms and require hospitalization. This was the case prior to variants being an issue, so based on the data it would not be unexpected regardless of variant status.	
10-Mar	Are there any educational videos to share with our patients to address their concerns/side effects/outcomes prior to infusion?	We are not aware of any educational videos, but we refer you to the Patient Fact Sheets for the various EUA, https://www.fda.gov/media/145803/download, https://www.fda.gov/media/145612/download and		

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		https://www.fda.gov/media/143604/download		
10-Mar	In SC, we created a web-based patient careening and referral app that can be accessed from any point of care and includes referral contact information for all of our treatment sites across the state. It is built on a REDCap database platform.	Thank you for sharing this information.		
10-Mar	Is anyone billing "hospitals without walls"? If so how and what is required?	This link provides background on "Hospitals Without Walls", which was a CMS initiative: https://www.cms.gov/files/document/covid-hospitals.pdf.		

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10-Mar	Would Project ECHO speaker/clinicians from the past few months who are sharing information about their infusion experience be willing to share their patient follow-up / outcomes data with each other (and hopefully publicly, as part of the resource library on the website)? Follow-up and outcomes data collection/reporting is not required by the EUAs but since individuals are clearly doing it voluntarily, this could be a very valuable source of shared information. To date, nearly 1 million patient courses have been allocated, with 760,000+ "delivered" (I assume that means delivered to the site, not the patient?) - https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/allocation.aspx so far we are getting only anecdotal information on reactions and outcomes after several months of this being done. Seems like a huge	Thanks for the recommendation! You make a very good point and we can further discuss with HHS/ASPR.	Please send me direct communication and we can work off-line to try to address your question.	

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	missed opportunity, and it is really time to get moving on this.			

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10-Mar	So is there statutory or contractual consequences for making a "clinical judgement" for "Borderline" patients who fail to qualify by EUA and whom we document a clinical reason?	When the COVID mAbs are ordered, the person ordering attest and certify that (i) their organization will use the ordered therapy only as authorized pursuant to the therapy's applicable Emergency Use Authorization, (ii) their organization (or provider if an LOA is provided) will adhere to the administration requirements of the Emergency Use letter of authorization.	Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. For more information, please go to https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices.	

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10-Mar	Although a positive test is required, the 10 days begin from the symptom date according to the EUA. We find that the sooner they get it, the better it works. Patients who tested positive and received the infusion within 24-48 hours of onset of symptoms, recovered extremely well and quick. We have infused almost 100 patients so far with fantastic results.	Thank you for the comment.		
10-Mar	Repeating my question- Are all facilities using PE or PVC lined IV tubing for BAM?	You don't need a non-PVC IV bag or infusion set, as it is not stipulated for use in the EUAs. The conventional normal saline bag and tubing are fine.		

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10-Mar	My understanding is that allocation of mAbs is tracked publicly (see https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/allocation.aspx). Utilization data reporting is required by EUA "Healthcare facilities and providers must report therapeutics information and utilization data through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services" -- is this data public?	This had been reported at a state level not the individual facility level. Additionally, there are some distributors which receive the product and then further distribute it which we would likely not have visibility on		