

HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series
Session #2— Equitable Access
Wednesday, December 16, 2020 (12-1 PM ET)
Q&A

Date	Question	Answer(s)	
16-Dec	Can you address the current CDC recommendation of waiting 90 days after monoclonal antibodies to receive vaccine? Particularly impact on long-term care facility residents. Should they or their families be counseled about this?	The 90-day waiting period seems reasonable, based on half-life and to minimize risk of mAbs interfering with vaccine efficacy. Studies are being done to study mAb-vaccine interactions, but those data will take time.	Currently, there are no data on the safety and efficacy of Pfizer-BioNTech COVID-19 vaccination 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 interference of the antibody treatment with vaccine-induced immune responses.
16-Dec	As an FQHC, we don't usually provide infusion therapy but refer out to infusion centers or local hospitals. That said, we feel that as long as the condition we are treating is within scope, then infusion therapy is covered under our HRSA-approved scope of services. Is this correct? Does it apply to infusion of EUA compounds like monoclonal antibodies, so that are providers are covered under FTCA	live answered	

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16-Dec	Did you already own the equipment?	Some of our facilities own equipment, some do not. Our central pharmacy set up kits to go out to clinics that needed material. We are not sending pumps.	
16-Dec	The challenge is getting access to the medication. The demand is higher than the supply. How can a specialty infusion pharmacy get access to the program to help reduce the load from hospital setting? How can we register to get access to the medication?	Through the SPEED program (Special Projects for Equitable and Efficient Distribution) which was launched this week, HHS/ASPR is directly allocating mAbs to providers/pharmacies serving priority populations (e.g., LTC, FQHCs, correctional facilities, dialysis centers). We are shipping mAbs this week to home infusion pharmacies (for use in LTC facilities) and LTC pharmacies. Does your pharmacy fall in those groups? Other SPEED programs will be launching soon. We are working with partner associations (e.g., National Home Infusion Association; American Society of Consultant Pharmacists) to get the word out.	https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx
16-Dec	Since you have the infusion pumps but find them difficult, are you using the pumps? Or do you sometimes opt for gravity sometimes.	It depends on the clinic. In the BOP some facilities have pumps others do not.	

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16-Dec	Related to my prior question: if our FQHC-based providers don't feel comfortable providing infusion, but HHS has allocated some of the monoclonal antibody to us, can we transfer it to our local hospital partner?	For this scenario, it might work best for your FQHC to access mAbs that have already been allocated by the state to your hospital partner. If we know the hospital is partnering with an FQHC, we can provide additional allotment to your hospital partner through SPEED. One of today's panelists will discuss a similar model to this.	
16-Dec	May we get email with the slides?	It was sent with the announcement via email yesterday. You can also visit the ECHO website in a few days for session presentations and recordings: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html	
16-Dec	Did St. John's have extra staff to repurpose? That seems to be my biggest concern. We are tight on nursing/MA staff and now we're going to start vaccinating too.	We reassigned staff and hired an RN. We're having staffing issues overall as well, but we decided that this was important enough. We reassigned staff from one of the mobiles to accommodate.	
16-Dec	I may have missed this, but how many patients have been treated so far?	I believe Jim mentioned having treated 14 patients in the past week. He just started last week.	
16-Dec	Do you have a nurse screening all patients within your system with a positive COVID test?	Live answered	
16-Dec	How do you plan on handling patient selection once the drug is no longer free?	Live answered	

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16-Dec	These are not included in EUA: Are any sites routinely (1) administering premeds (APAP and diphenhydramine) and (2) other IVF pre and post infusion (other than to have available IV NS readily available should infusion reaction occur)?	BOP is not however we do make sure Epi-Pens, injectable diphenhydramine are on hands just in case.	
16-Dec	You mentioned devices for monitoring - is this during the infusion via zoom or other?	Monitoring is done through telehealth after. For the hour after the infusion, we have an RN observing patients.	
16-Dec	Is there information to give patients weighing risk and benefits taking the vaccine issue into account?	Not yet, we're in the process of developing this with UCLA.	
16-Dec	What the reasons that patients turning down the infusion therapy? Time commitment? Don't think they need it? Something else?	The either haven't heard of it, or they're afraid.	
16-Dec	Do you have a designated area for medication preparation or is it done at bedside?	In BOP it depends on the site, some are in pharmacy, some at bedside.	
16-Dec	Have you been able to treat your staff? If so how has the response been? Are they able to act as community advocates?	We have not treated staff yet since we're still ramping up.	
16-Dec	For Colleen, are you all mixing bamlanivimab in a hazardous IV hood or a regular IV hood?	Regular IV hood	

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16-Dec	Are there SNF protocols from those who have successfully implemented successfully that can be shared?	<p>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 "Resource Library"</p>	
16-Dec	Dr. O'Connor - With staffing being a significant constraint on your program, I'm wondering if you have considered nursing home staff administering the medication. Most SNF's have significant experience with IV infusions.	Live answered.	
16-Dec	How long after the infusion do you plan to actively follow the patients who receive bamlanivimab?	2 weeks.	

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16-Dec	How can we get enrolled into the SPEED program? we are located in CA	<p>Sharing David Wong’s response in the Chat - HHS/Operation Warp Speed to Panelists and Attendees (10:49 AM) mAbs are primarily being distributed through state HDs. Through the Special Projects for Equitable and Efficient Distribution (SPEED) program that HHS/ASPR launched this week, we are directly allocating mAbs to providers/pharmacies that serve priority populations (e.g., FQHCs, LTC, correctional, dialysis). Only the LTC SPEED programs have launched to date. We are coordinating the SPEED programs with partner associations who educate members (and non-members) and identify those who are willing and able to administer mAbs. We are providing small amounts of patient courses to each participating site to first assess their ability to administer it.</p>	<p>https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx</p>
16-Dec	How did you go about acquiring and setting up the IV hood and room at an FQHC? Our FQHC does not have a set up at this time	I was mistaken. I just confirmed that we are not using an IV hood.	
16-Dec	Is mixing at the bedside appropriate considering that this mixture could be considered a medium risk compound and then there may not be pharmacy involvement?	We have pharmacy supervision, but a nurse can mix the compound. It just involves adding the antibody to saline drip.	

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16-Dec	Cost for uninsured?	<p>The HRSA uninsured patient fund may be used for patients being treated with these outpatient antibodies.</p> <p>https://www.hrsa.gov/CovidUninsuredClaim</p>	
16-Dec	Covered by health insurance?	<p>In California it is covered by medi-cal. Uninsured are covered under emergency authorization in medi-cal (name for CA Medicaid) for COVID testing and treatment</p>	
16-Dec	<p>I want to ensure the group is aware that the bamlanivimab mixing instructions have been simplified making the compounding process much cleaner:</p> <p>https://www.fda.gov/media/143603/download</p>		
16-Dec	<p>Provider outreach is huge in the SNF world. I have providers trying to write blanket orders for entire nursing homes “bamlanivimab for all residents who are Covid positive and over 65.” As a pharmacist I can be the gatekeeper but it’s tough to get 100% trust in my clinical recommendations, which are just based on the EUA recommendations.</p>		
16-Dec	<p>Will HHS consider providing bamlanivimab to home infusion providers to administer to patients at home who meet the exclusion and inclusion criteria?</p>	<p>https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx</p> <p>https://www.nhia.org/news/bam-pilot-program/</p>	

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16-Dec	Is SPEED providing the meds directly to the facilities, outside of the state allocation process? Just wanted clarification.	https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx	
16-Dec	What is the cost of the MAB? Who pays? What is the reimbursement and cost for nursing and administration?	https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf	