

**HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series**  
**Session #1— Monoclonal Antibodies**  
**Wednesday, December 9, 2020 (12-1 PM ET)**  
**Q&A**

Date	Question	Answer(s)	
9-Dec	I want to understand whether COV-19 antigen testing positive would be enough for a high-risk patient to receive a monoclonal antibody or does a COV-19 NAA PCR need confirm this prior to being considered for monoclonal antibody.	I believe a positive antigen test is sufficient. We have had some issues with false negatives, but not false positives. We are using the Abbott Binax for this purpose	Correct - ANY test is fine.
9-Dec	Is convalescent plasma an intervention that can be used on an outpatient basis?	No, its EUA covers inpatient care only. HOWEVER, it could be used in patients who are being treated in situations such as hospitals without walls, Alternate Care Sites, and the like - that is, locations that are outside the hospital but are “inpatient.”	
9-Dec	Has there been receiving payment for Bamlanivimab for non-Medicare payers?	We anticipate it’ll be available under Medicaid programs and private insurers (this has begun to happen but should be confirmed at locations). Also, the HRSA uninsured patient fund may be used for patients being treated with these outpatient antibodies. <a href="https://www.hrsa.gov/CovidUninsuredClaim">https://www.hrsa.gov/CovidUninsuredClaim</a>	

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9-Dec	Can these therapeutics be administered in the home health setting?	<p>Yes. Home infusion services should be able to provide it. A pilot is ongoing now. More information on pilot: <a href="https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx">https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx</a> and <a href="https://www.nhia.org/news/bam-pilot-program/state-resources/">https://www.nhia.org/news/bam-pilot-program/state-resources/</a></p>	Home infusion providers have not been receiving allocations from the state to offer home infusion on a broad basis. We have identified only a handful of instances where hospitals have provided product to their home infusion affiliate. (NHIA)
9-Dec	Given extensive infusion times, are hospitals using infusion centers in lieu of EDs, despite concerns about proximity of immunocompromised patients? If seen as appropriate to use these facilities, what barriers, cleaning practices should be used?	Yes - we have seen a great variety of locations used. Infusion centers can certainly be used. This possibility may be very useful in rural areas. There are no special instructions for cleaning other than the standard COVID-19 recommendations.	
9-Dec	Barriers to care and access: It is taking at least 48 if not 72 to 96 hours to get PCR results back in most areas which might be the time to symptoms for these patients high risk patients. I hear many areas cannot get bamlanivimab.	Thank you. To address both issues: (1) PCR availability DOES vary - however, under the EUA any COVID-19 test is qualifying for treatment; so that means a rapid antigen test is sufficient. Also, re: availability - states are allocating to sites within their states, and the overall supply has been a total of 260,000 patient courses of bamlanivimab and ~77,000 patient courses of casirivimab/imdevimab. Please email <a href="mailto:asprstakeholder@hhs.gov">asprstakeholder@hhs.gov</a> if you are experiencing shortage and would like further info.	

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9-Dec	Can mAb be used for patients with renal issues?	Live answered.	<p>Bamlanivimab and Casirivimab/Imdevimab are not eliminated intact in the urine, thus renal impairment is not expected to affect the exposure of bamlanivimab. For more information, see Fact Sheets for Health Care Providers:</p> <p><a href="https://www.fda.gov/media/143603/download">https://www.fda.gov/media/143603/download</a></p> <p><a href="https://www.fda.gov/media/143892/download">https://www.fda.gov/media/143892/download</a></p>
9-Dec	Are patients who are physically in the hospital, but are under observation and not admitted, eligible for these?	We have specifically confirmed this question with CMS, and the answer is YES: a patient in observation status (and therefore not an inpatient) may receive the medications, and infusion would be reimbursable, even if physically the patient is in the ER, or another part of the facility.	
9-Dec	Can these be administered in nursing homes?	Yes, they can be administered in nursing homes. They do not require any special monitoring equipment, full crash cart, or even an IV pump. But they do require routine monitoring and access to medication in the event of a reaction. Like diphenhydramine and epinephrine, which SNFs should have on their e-kits.	YES - absolutely, and the infusion charge is reimbursable under Medicare. We think that nursing home use holds a great deal of promise to keep patients out of the hospital.

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9-Dec	<p>In randomized trials, which Pharma trials and drugs tested were comrade to synthetic controls?</p> <p>In order to conduct these quickly &amp; please discuss the downsides of touch new trial practices?</p>	<p>This disease is so pleomorphic and the SOC evolving so fast that it is hard to use anything other than concurrently randomized.</p>	
9-Dec	<p>I see Sickle Cell Disease is on the listing of High-risk criteria for those aged 12-17 who are symptomatic. What about the adult population? Also, is there any data on those with Sickle Cell Trait as being at any greater risk?</p>	<p>Yes - we have noted that someone with sickle cell qualifies (for example) if someone is 17 but this not once, they turn 18. We've let FDA know about this issue, so they are aware.</p>	
9-Dec	<p>Are administrations to patients in a SNF/ALF billable to the Medicare vaccination program if the patient only has Medicaid as a payer source?</p>	<p>Thank you for the question. We will share this with our CMS colleagues.</p>	<p>Medicare cannot pay claims for Medicaid beneficiaries who are not dual eligible. See links below for more reimbursement information:  <a href="https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf">https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf</a>   <a href="https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf">https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf</a></p>

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9-Dec	Dr. Steinberg: do you have details you can share about the ongoing home infusion pilot? Thanks.	Dr. Wong can give you additional details as this is moving through Operation Warp Speed.	<p>Please see below links for more information about home infusion Pilot:  <a href="https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/default.aspx">https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/default.aspx</a></p> <p><a href="https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx">https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx</a></p> <p><a href="https://www.nhia.org/news/bam-pilot-program/">https://www.nhia.org/news/bam-pilot-program/</a></p>
9-Dec	I have a patient who is a physician, got Lilly Monoclonal on Thr 2 weeks ago tomorrow She was due for vaccine on 12/17.  Can she get it?	I don't know of a contraindication. She will have likely mounted her own immune response. Might want to wait a month or so but there are no recommendations on this.	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.

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9-Dec	Can you provide any information on cost and commercial insurance reimbursement?	The cost of the medication is zero for the administering facility - it's been procured by the US government for use in the whole country. Commercial reimbursement will vary, but the Medicare reimbursement for the infusion is ~\$310. There are other parts of the patient journey that are billable (initial visit, etc., including Telemedicine-based care).	The mAbs have been purchased by the USG and are available at no cost to facilities/providers. CMS has established reimbursement for administration costs, which is approximately \$310. <a href="https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf">https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf</a>
9-Dec	Can you send the criteria for use?	<a href="https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-eua/">https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-eua/</a>	The Criteria for use are the same for both products. See Fact Sheets for Health Care Providers for both products below. Bamlanivimab: <a href="https://www.fda.gov/media/143603/download">https://www.fda.gov/media/143603/download</a> Casirivimab/Imdevimab: <a href="https://www.fda.gov/media/143892/download">https://www.fda.gov/media/143892/download</a>
9-Dec	Do you anticipate these antibodies being delivered in a home care setting at this point? What might be some of the complications of such in home delivery of biologics?	Difficult for home infusion; First, it is about a two-three-hour process. One-hour infusion and one hour of observation. If you include travel to/from home, you can only treat 2 -3 patients in 8 hours	Yes. Best with people experienced in home infusions. There can be infusion reactions. Drug storage conditions are not onerous. jw
9-Dec	As a home care nurse, we would do this in our homes for our high-risk pts even though time wise it wouldn't be money making for us on that visit to improve our pt outcomes if we could get it.	That sounds exciting! Please email <a href="mailto:asprstakeholder@hhs.gov">asprstakeholder@hhs.gov</a> and we can get you connected.	

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9-Dec	Are sites that have set up infusion centers receiving referrals from testing centers or are referrals primarily through the ER or PMDs?	We have a central site for infusion. We accept referrals from multiple sources	
9-Dec	Please discuss post marketing adverse events surveillance for uses of mAbs, including is if the CDC Vaccine Data Link project is currently developing monitoring among participating HMOs in the Datalink? As I understand it, the Pharma companies are continuing long term follow-up of trials (for how long)?	Under the EUA the companies are in charge of collecting adverse events and there are instructions for practitioners to submit adverse event reports. This is not really marketing and no, Vaccine Data Link will not be involved, they are doing the vaccines.	
9-Dec	Thank you. Who might be payor source for delivery of services if these were done in home care? For Medicare, I understand it would be provided under Part B, but what about for non-Medicare beneficiaries.	We anticipate it'll be available under Medicaid programs and private insurers (this has begun to happen but should be confirmed at locations).	
9-Dec	Okay, thank you. Any comment on sickle cell trait creating greater risk?	Mechanistically not high risk but don't know anything about actual use. jw	I'm sorry but I don't know if sickle cell trait is a risk or not - others may know.
9-Dec	More in support of home health administration: No exposure to or of others in a clinic, only one healthcare provider is interacting with the patient.	Agree that home infusion is ideal	
9-Dec	In my non-medical center federal prison setting, we utilized the dental operatories that were not being utilized and a separate team to administer this medication.	Very creative! jw	
9-Dec	In the home health setting, is there a certain gauge needle the therapeutics should be infused with?	No, this would be dependent on patient clinical assessment for vascular access placement.	

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9-Dec	How soon after the infusion do the GI side effects occur?	We do not currently have field data on the GI side effects. (12/21/20)	
9-Dec	Thx for the correction on vaccine Data link... Am well versed in this having worked for the CDC	live answered	
9-Dec	Re "post availability" adverse event surveillance. Dr W said "Janet Woodcock M.D. "Operation Warp Speed": Under the EUA the companies are in charge of collecting adverse events and there are instructions for practitioners to submit adverse event reports. This is not really marketing." My question is how often and what processes are used by the FDA to monitor these efforts by Pharma...? Thx	Prescribing healthcare providers and/or designee are responsible for mandatory reporting of all medication errors and serious adverse events to FDA MedWatch. See Fact Sheets for Health Care Providers for more information. <a href="https://www.fda.gov/media/143603/download">https://www.fda.gov/media/143603/download</a> <a href="https://www.fda.gov/media/143892/download">https://www.fda.gov/media/143892/download</a>	
9-Dec	What about IV Vitamin C administration while we have IV access, is this a consideration at all?	<a href="https://www.covid19treatmentguidelines.nih.gov/adjunctive-therapy/vitamin-c/">https://www.covid19treatmentguidelines.nih.gov/adjunctive-therapy/vitamin-c/</a>	
9-Dec	Is the therapy available in the US territories...?	Absolutely! We have distributed to all parts of the US, including territories, and including the Pacific Territories.	



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9-Dec	<p>Nursing home staffing is a major barrier to administering bamlanivimab due to the monitoring requirements. Are there any models out there that have found a solution to this barrier?</p> <p>Thanks, This has been very informative and helpful.</p>	<p>Ideally, in-house SNF staff would be the ones to hang and monitor. But it's true that staffing can be problematic. Possible solutions could include having a home infusion service come into the SNF to do the infusion, having outside staffing support for this (through public health or through registries), or having the SNF dispensing pharmacy supply the staff. I don't specifically know of models using these currently, but I suspect in the next few weeks we will see some spring up.</p>	
9-Dec	<p>Any difference adverse event rates or post infusion side effects in pediatric pts as opposed to adult?</p>	<p>At this point we don't have data on pediatric vs adult reaction rates. (12/21/20)</p>	
9-Dec	<p>Do any of the SDoH carry more "weight" than others?</p>	<p><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7234789/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7234789/</a></p>	
9-Dec	<p>Appreciate hearing from our rural Kentucky colleagues. The question is about equitable access and how these PHA s are distributed especially to communities of color and others suffering the largest impacts for various reasons. Or will this be a 'haves" and have nots scenario? How is equity in distribution assured? Thx</p>	<p><a href="https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx">https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx</a></p>	<p><a href="https://www.nationalacademies.org/event/12-16-2020/workshop-on-allocation-of-covid-19-mono-clonal-antibody-therapies-and-other-novel-therapeutics?utm_source=HMD+Email+List&amp;utm_campaign=4035f8c4e7-EMAIL_CAMPAIGN_2020_04_22_04_18_COPY_01&amp;utm_medium=email&amp;utm_term=0_211686812e-4035f8c4e7-180705570&amp;mc_cid=4035f8c4e7&amp;mc_eid=a5d67b1bf7">https://www.nationalacademies.org/event/12-16-2020/workshop-on-allocation-of-covid-19-mono-clonal-antibody-therapies-and-other-novel-therapeutics?utm_source=HMD+Email+List&amp;utm_campaign=4035f8c4e7-EMAIL_CAMPAIGN_2020_04_22_04_18_COPY_01&amp;utm_medium=email&amp;utm_term=0_211686812e-4035f8c4e7-180705570&amp;mc_cid=4035f8c4e7&amp;mc_eid=a5d67b1bf7</a></p>

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9-Dec	Is there any consideration to providing therapeutics at home given by home health agencies? Some will be able to this easily. Others may choose not to. Who pays for the medication and related infusion supplies?	Home health agencies will most likely partner with an infusion pharmacy to provide the drug and administration supplies. Most are not equipped with facilities to store and dispense the drug directly. When provided at home, the administration payment must cover both pharmacy and nursing costs, as well as supplies for administration.	<a href="https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf">https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf</a>  <a href="https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf">https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf</a>
9-Dec	We are a closed door LTC pharmacy in NC that services ~30 homes and we have the opposite problem of getting the medication but are unable to meet the necessary monitoring requirements due to staffing difficulties during these times.	It is a real problem in facilities that are hit hard. We need to consider solutions to the staffing issues.	
9-Dec	Do you have any examples of administering this in the home? If so, how are anaphylaxis kits handled?	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.	

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9-Dec	<p>Are there any SNF models that have found a way to overcome the staffing problem?</p> <p>Thank you very much, this is very helpful.</p>	<p>Some facilities have had their own LTC dispensing pharmacies provide staffing to assist with monitoring. Some facilities have been able to obtain additional staff from registries or from local or state health departments. I believe there are some home infusion services coming into SNFs in some areas to provide the monitoring. And most facilities have been able to incorporate it into their existing staffing. Sometimes they will have a single staff person monitor multiple residents who are receiving the infusion. But for some facilities, staffing issues have continued to pose an impediment to their residents' being able to receive the monoclonals.</p>	<p>Home infusion &amp; link, EMS. Some NH are using MS staff to assist with admin and monitoring.</p>
9-Dec	<p>How long is the efficacy in terms of expiration date</p>	<p><a href="#">Bamlanivimab Baseball Card</a></p>	<p><a href="#">Casirivimab + Imdevimab Baseball Cards</a></p>
9-Dec	<p>Are there any known Home Health agencies that have administered this in the home?</p>	<p>Several hospital-based home infusion providers have administered bam at home.</p>	