

**HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series**  
**Session #9— Equity and Underserved Populations**  
**Wednesday, February 24, 2021 (12-1 PM ET)**  
 Q&A Packet

Date	Question	Answer(s)		
24-Feb	<p>How effective have monoclonal antibodies been in treating kidney transplant recipients infected by COVID-19?</p> <p>In general? In African Americans?</p> <p>What data is available to share with my colleagues?</p>	<p>We do not specifically have data on kidney transplant patients who have received mAb treatment, however, the EUA lists patients currently receiving immunosuppressive treatment as one of the eligibility criteria.</p>	<p>For the clinical trial summary on Bamlanivimab: Common Comorbidities Associated with COVID-19, go to <a href="https://www.lillymedical.com/en-us/answers/bamlanivimab-common-comorbidities-associated-with-covid-19-124537?hcpToken=A12DSa08bhrd123gg8&amp;channel=GCC">https://www.lillymedical.com/en-us/answers/bamlanivimab-common-comorbidities-associated-with-covid-19-124537?hcpToken=A12DSa08bhrd123gg8&amp;channel=GCC</a></p>	
24-Feb	<p>Is this treatment covered by Medicare/Medicaid?</p>	<p>Live answered</p>	<p>The drug is free at this point-- provided by the US government. The infusion is also reimbursed. Medicare set the payment at \$309. Providers will also receive this rate when administering to uninsured individuals.</p>	<p>This may be helpful: <a href="https://healthpolicy.duke.edu/publications/covid-19-mono-clonal-antibodies-paying-administration-and-better-evidence">https://healthpolicy.duke.edu/publications/covid-19-mono-clonal-antibodies-paying-administration-and-better-evidence</a>.</p>

24-Feb	One of the big challenges w/ promoting and building awareness of the availability and value of mAb treatment has been the message getting lost in the midst of the primary focus on vaccine access and administration. We do need to create more awareness and work w/ trusted voices from churches and other community-based organizations.	This is a great point. Community collaboration and community connections are the way to get to people. Working with churches, YMCA, Boys and Girls Clubs are an excellent suggestion. Thank you		
24-Feb	There is a treatment location, but it is not convenient to most of our community members. At this stage in vaccine distribution do you think it is too late to begin to advocate and outreach for local treatment locations?	Live answered.	For an infusion center locator, go to <a href="https://infusioncenter.org/find-an-infusion-center/">https://infusioncenter.org/find-an-infusion-center/</a>	
24-Feb	The biggest barrier for getting more FQHCs and other practice locations to provide mAb treatment is not a product ordering issue but rather limitations in space and staff. We also looked at mobile sites but found we were competing w/ limited resources that were already being mobilized for vaccine clinics.	Thank you for sharing this insight with us.		

24-Feb	We just implemented in SC a web- based mAb screening and referral tool that can be used on mobile and desktop devises at any point of care including community testing sites, free clinics or other patient care settings.	Thank you for sharing information on the innovative things that you are doing.		
24-Feb	How do I get more information on the work w/ FQHCs through the National Minority Quality Forum?	You can reach <a href="mailto:kpurnell@nmqf.org">kpurnell@nmqf.org</a> for additional information. Please indicate if you would like to receive regular updates about the work, and we will add your email to the listserv.		
24-Feb	I would like to know from the FQHC infusion sites- did you open your infusion site to the community physicians? What's your workflow and do you require the patients to see your providers in order to be scheduled for the infusion or the community physicians refer the patients directly to the Infusion nurses? Is there a risk in the organization if the patient had an unexpected severe adverse reaction? Thanks	We share with you helpful resources from several facility types which include standing orders, order sets, protocols, SOPs, etc. at <a href="https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html">https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html</a> , 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.	
24-Feb	Do you think we should be sequencing patients as they receive treatment? Any thoughts on variants involved with mAbs?	Coram (CVS) has a pilot that does home infusion. SPEED program also uses home infusion companies to administer mAbs where the patients are, but only in LTC setting. No private home infusion through that program.		

24-Feb	Has any group developed Home Infusion Monoclonal therapy? If so, are there different protocols, guidelines, or risk reduction protocols in place?	Live answered	Challenge with home infusion is that the payment is site specific and the \$309 rate does not cover the cost of providing an infusion in home setting. Without a payment adjustment, we are unlikely to see home infusion providers be willing and able to administer.	Sorry, payment is site neutral.
24-Feb	Was hoping for 'magic bullets' to decrease inequities in monoclonals.....other than community and community engagement, each with education.... IS there anything else?	There really are no magic bullets, beyond a plan, collaboration, and perseverance.	We refer you to <a href="https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/CDC-Strategy.pdf">https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/CDC-Strategy.pdf</a>	
24-Feb	Can you please go into detail into how the outpatient infusion was set up at the FQHC?	We worked with our local nursing school to help do training for our nurses and they helped support us getting started. We have a very strong nursing department which was very important to being able to do this. Once we got it started it has continued to run smoothly.		
24-Feb	Does anyone on this panel know of expanding access to essential workers, frontline healthcare workers, or more patients with other types of risk-criteria that are not currently addressed in the FDA guidelines? It appears the scarcity factor (for mAbs) is not quite the issue it was when the initial	We do not have information beyond the eligibility criteria that is outlined in the FDA issued EUA		

	restrictions/criteria were set forth.			
24-Feb	CORAM does home infusions	Thank you for clarifying this.		
24-Feb	Do you think we should be sequencing patients as they receive treatment? Any thoughts on variants involved with mAbs?	<p>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.</p> <p>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.</p> <p>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</p>		

		authorized under emergency use. We will update our stakeholders with any new recommendations.		
24-Feb	..., and other panelists with a shortage of health workers, have you looked at asking Team Rubicon to help with staffing up some of the health centers you mentioned? just an idea since they have volunteer medical teams that work internationally but have been used nationally for the COVID crisis especially on the Navajo nation.	Thank you for sharing this information with us.		
24-Feb	How are you handling the 1-hour post-treatment monitoring in pop up and drive through infusion sites?	We monitor people in their cars, we have a canopy that the cars drive under and there is a work station for the nurses out there as well. The nurses monitor them throughout the infusion and then after for 1 hour in their car. Our volume has not been very high, the most we have done in 1 day is 5 so this has not been an issue with space for us.		
24-Feb	Yes please. Additionally, did you encounter any insurance issues in those who have IPA or commercial insurance with your provider seeing them and the infusion procedure charge?	We have not had any issues that I am aware of with this. We do accept some commercial insurance and are credentialed providers in those networks. However, the majority of our care is Medicaid, uninsured and Medicare. We have the provider do a visit the day of the visit and bill for that and it has not been an issue as far as I know.		

24-Feb	I know someone aged 57 and uninsured, who got mAb for COVID, and then a bill for \$6,700. What suggestions do you have for helping her navigate this charge?	Happy to connect with you after the call on this issue. There are a few questions that we will need to have answered such as, was the infusion in the hospital or at an infusion site etc. My email is part of the packet for the group.		
24-Feb	If you can share the workflow, I really appreciate it. Thanks	Can you send me an e-mail and I can share?	A link to the resource library, a compilation of standing orders, training guides, SOPS, workflows, etc., can be found at <a href="https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html">https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html</a>	
24-Feb	Some locations developed very good videos to help educate patients. These have been used to decrease patient hesitancy.	Thank you for sharing.		
24-Feb	Once you receive the MAB, do you still need to get the Vaccine?	Please see CDC guidance for latest on vaccine and mAb timing considerations: <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html">https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</a> . Specifically, the "Persons who previously received passive antibody therapy" section.		

24-Feb	What is considered early for monoclonal treatment?	Per the three different EUAs, it indicates that the mAbs should be administered within 10 days of symptom onset, please see <a href="https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf">https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf</a> , <a href="http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf">http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf</a> and <a href="https://www.fda.gov/media/143603/download">https://www.fda.gov/media/143603/download</a>		
24-Feb	Like other investigational agents, it may be possible to apply for individual compassionate use.	Thank you for your comment, for further information on how to request for compassionate use through the FDA, please go to <a href="https://www.fda.gov/news-events/public-health-focus/expanded-access">https://www.fda.gov/news-events/public-health-focus/expanded-access</a> .		
24-Feb	Any updates on decreasing the post-infusion monitor time?	We do not have information beyond the 1-hour observation time that is listed in the EUAs.		
24-Feb	Community and community organization engagement....			
24-Feb	<a href="https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma">https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma</a> .	Thank you for sharing this link.		

24-Feb	Thank you! Looking for the information about contacts. Can you post it?			
24-Feb	Can ... please elaborate on doctor's writing prescriptions. Will that allow the treatment even if the patient doesn't meet the technical EUA high risk factors?	The FDA maintains the authority to make a decision on revising the eligibility criteria based on emerging date. To find out how to submit a compassionate use request for a patient who does not meet the EUA eligibility criteria, go to <a href="https://www.fda.gov/news-events/public-health-focus/expanded-access">https://www.fda.gov/news-events/public-health-focus/expanded-access</a> .		
24-Feb	In response to ...s question: "There is a treatment location, but it is not convenient to most of our community members. At this stage in vaccine distribution do you think it is too late to begin to advocate and outreach for local treatment locations?" We created a local treatment locator ( <a href="https://hitesite.org/monoclonalantibody">https://hitesite.org/monoclonalantibody</a> ) as we also find the HHS locator not as helpful for patients/community providers. The directory was created through outreach to our member institutions to understand their processes.	Thank you for sharing this resource.		