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Connecting Care: Outpatient Treatment of COVID-19 With Neutralizing Monoclonal Antibodies

Announcer:
Welcome to CME on ReachMD. This activity titled, “Connecting Care: Outpatient Treatment of COVID-19 with Neutralizing Monoclonal Antibodies” is provided by Forefront Collaborative and AKH and supported by an educational grant from Lilly. This replay of a live broadcast focuses on how we can overcome challenges in the treatment of COVID-19.

Since the presentation-recording, the Assistant Secretary for Preparedness and Response (ASPR) paused all distribution of bamlanivimab+etesevimab and etesevimab alone (to pair with existing bamlanivimab supply). Two additional changes of note: dosing of casirivimab+imdevimab decreased to 600 mg of each compound; EUA criterion pertaining to BMI was reduced to 25.

Here’s your moderator, Dr. Jennifer Caudle.

Dr. Caudle:
Hello, I’m Dr. Jennifer Caudle and I’d like to welcome Dr. Andrew D. Badley and Dr. Chad Worz to the program. They are joining me to discuss the outpatient treatment of COVID-19, specifically the use of neutralizing monoclonal antibodies. Welcome to the program, Dr. Badley and Dr. Worz.

Dr. Badley:
Thank you very much.

Dr. Worz:
Thank you.

Dr. Caudle:
Of course. For everyone out there, please note that our disclosures are available to you on the event page and are listed on the slide, as well. You’ll have the chance to claim credit by completing an evaluation after participating in the course and to submit questions during the presentation, which is actually going to be a very important part of this presentation we’d ask you to type them into the chat control panel on the left side throughout the program or in your comment box through Facebook Live. We will try to answer as many questions as we can during the time allotted. We’ll also be asking you questions throughout the presentation, so please take out your phone and text “ReachMD” to 22333, that’s “ReachMD” to 22333. When we get to each question, you will respond with the letter that corresponds with your answer in that same text chain. Once again, it’s “ReachMD” to 22333. And alternatively, you can respond via your computer at OEV.com and you’ll enter “ReachMD” there, as well. So, let’s begin. You know, Dr. Badley, we’re gonna start with you. For the past year, we’ve been, all of us have been walking around in fear of COVID-19 and honestly, for good reason. We know that the majority of patients diagnosed with the disease are either asymptomatic or have a relatively mild case, which is good, but it’s still very frightening. And there’s a lot of misinformation out there about what to do when you’re actually diagnosed. So, I’d first like to ask you, you know, what are some of the key things healthcare professionals need to know when treating patients outside of the hospital setting?

Dr. Badley:
So, thank you, Dr. Caudle and, and thank you to the audience for joining, today. That’s a great question and why don’t we begin to address that by going through a case series, so, can we put up the first slide, please? So, this is a case of a 69-year-old woman who

presented after testing positive for SARS-CoV-2. Her initial symptoms were cough, pleuritic chest pain, post-tussive vomiting that worsened on the day of her diagnosis. She also reports a little bit of loss of appetite. Her past medical history is notable for type 2 diabetes, COPD, iron-deficiency anemia and hypertension. She was evaluated in the emergency room where her white count was 3.1, D-Dimer was slightly elevated at 564, she had a mild transaminitis and her chest x-ray was normal. Physical exam was unremarkable, and vitals were notable for being hemodynamically stable, afebrile and oxygen saturations of 95% on room air. Next slide. So, here's the first question: what is the best evidenced approach to management of this particular patient? The options are A) observe and monitor symptoms, B) give zinc and vitamin D or both, C) prescribe hydroxychloroquine, D) admit to the hospital and prescribe remdesivir, or E) administer anti-spike monoclonal antibodies as an outpatient. We'll give you a few moments to register your responses. Well, it looks like some of the audience would like to prescribe zinc or vitamin D and some of the audience would like to administer anti-spike monoclonal antibodies. So, let's look into this a little bit more. Next slide, please. So, one of the options was observation. And what we now know about SARS-CoV-2 infection is that mortality from an infection increases as a function of age, with those ages greater than 65 having the highest mortality rate. We also know that diabetes increases mortality rate, as well, whether it's type 1 or type 2 diabetes. So, in this case, for this patient who is 69 and has type 2 diabetes, observation would be associated with an increased chance of death, so that's not a good answer. Next. Another option is zinc and vitamin D. there are biologic reasons why these may play a role but there's no definitive evidence, yet, of either their safety or therapeutic efficacy. Clinical trials are ongoing with 45 for zinc and 70 for vitamin D.

Dr. Caudle:
So, you know, that's a really interesting point, Dr. Badley, I'm gonna jump in really quickly, there. There's a lot of sort of, talk about zinc and vitamin D so, just to clarify, are you saying that people shouldn't take vitamin D or zinc?

Dr. Badley:
Well, great question. Zinc and vitamin D are likely safe, but in terms of their ability to effectively treat or, in fact, prevent SARS-CoV-2 infection and COVID disease, there's no definitive evidence, to date. So, we would not recommend that. Next slide, please.

Dr. Caudle:
OK.

Dr. Badley:
Another option was hydroxychloroquine, there's a lot of hype about hydroxychloroquine early in the epidemic with some test tube studies suggesting an effect. However, when these have been tested in in-vivo models, there's no effect from hydroxychloroquine and on the basis of those studies as well as some relatively small, some controlled, some uncontrolled trials, the leading treatment recommendation groups such as the Infectious Disease Society of America and the FDA, both argue against the use of hydroxychloroquine for treatment of COVID-19. Next slide, please. Remdesivir is an anti-viral, it has been shown in the ACTT-1 trial to have benefit for treating COVID disease. This was for hospitalized patients who had sats of less than 94% on room air or required supplemental oxygen and in these patients, time to hospital dismissal was shorter and symptom improvement was faster. On the basis of this, the FDA issued a EUA and now a full approval for this drug. However, the indications for using this drug are hospitalized patients, saturations of less than 95% on room air or requiring supplement oxygen or ECMO. So, because this patient has none of those criteria, this would not be an appropriate therapy. Next slide. Finally, there's neutralizing monoclonal antibodies. The premise of these antibodies is that they bind with high-affinity to the spike-protein expressed on the surface of the SARS-CoV-2 virus. Because the spike-protein is now covered up by the monoclonal antibodies, the spike-protein cannot bind to the ace-receptor and therefore, the virus cannot bind to the cell leading to internalization, fusion and viral replication. So, next slide, please. On the basis of this discussion, let's review the case again and vote again. Options were: Observe and monitor, give zinc and vitamin D or both, prescribe hydrox- hydroxychloroquine, admit and prescribe remdesivir or finally, anti-spike monoclonal antibodies as an outpatient. Please vote.

Dr. Caudle:
And once again, we encourage you to take a second to answer this polling question as you did the one prior, on your screen. We'll take a moment as the questions fill the screen and go ahead and register your votes and we will then have Dr. Badley talk us through what the best answer is.

Dr. Badley:
Well, I think the majority of the votes are in, now; 20% of the audience recommends observe and monitor symptoms, I would not agree with that because of the chance of increased mortality associated with age greater than 65 and type 2 diabetes. Nobody voted for zinc and vitamin D and that's appropriate because there's insufficient evidence. Nobody voted for hydroxychloroquine, also that's appropriate because of lack of evidence. Admit and prescribe remdesivir would not be recommended because the patient isn't sick enough to require hospitalization and the majority of the audience now voted for anti-spike monoclonal antibodies, which I believe is the correct answer.

Dr. Caudle:
Excellent. For those of you who are just joining us, by the way, this is ReachMD. I'm your host, Dr. Jennifer Caudle and joining me to talk about neutralizing monoclonal antibody treatment for COVID-19 are Drs. Badley and Dr. Worz. I wanna encourage our viewers to submit questions for them. We will have a question and answer period at the end. So, Dr. Worz, we're gonna jump to you, right now, for a moment. You know, there's no question that those in nursing homes have been disproportionately affected by the pandemic. Which is why they're first line first in line for vaccines, yet we know this is a medically fragile population and they will continue to be on the frontlines of the pandemic. So what options are available to them?

Dr. Worz:
Certainly, we're gonna talk about the monoclonal antibody treatments that Dr. Badley had introduced and look at the Emergency Use Authorizations for those products I think what we'll, what we'll explore is where they're appropriate for people that are in community settings and not just skilled nursing facilities but also assisted living, and those older adults that are living in the community. But first, let's get a sense of where everybody is in terms of their own practice, where they see themselves as it relates to these monoclonal antibodies. So, if we move to the next slide, we have a question, and the question is: which of the following statements regarding neutralizing monoclonal antibodies for treatment of COVID-19, such as bamlanivimab, casiriv- ivimab, and imdevimab, best apply to your practice? Are you A) someone that identifies patients with COVID-19 who would benefit from neutralizing monoana- antibody therapy, are you B) someone that prescribes neutralizing monoclonal antibodies, are you C) administering neutralizing monoclonal antibodies, are you D) someone that's never utilized these products in the treatment of COVID-19, are you E) planning to utilize these monoclonal antibodies in the treatment of COVID-19 or are you F) needing to learn more about neutralizing monoclonal antibodies? I'll give everybody a second to respond. OK, looks like about half of you need to learn more and we're gonna go through some of those characteristics about learning more about where to use these. Some of you are comfortable identifying and, and certainly some of you plan to utilize these products for patients that test positive for COVID-19. Next slide. Now if we go into this case, this is a long-term care case. It's a 78-year-old man who tested positive for SARS-CoV-2 in 120 bed skilled nursing facility yesterday. He was transferred to the facility's COVID unit and placed in isolation. He's currently asymptomatic. If we look at his past medical history, he's got Alzheimer's dementia, congestive heart failure, hypercholesterolemia and hypertension. I think the take-home message for this particular case is that this really represents everyone in a skilled nursing home setting. They are individuals that are older, they have multiple comorbidities and certainly they represent as Dr. Caudle mentioned, a high burden as it relates to COVID-19. Next slide. If we look at this a little closer as many of you know, about 1% of America's population lives in long-term care facilities, but that environment's accounted for almost 37% of all COVID-19 deaths in the United States. It's representative of a million cases and over 130,000 deaths, overall for those older adults in those skilled nursing facilities. Next slide. If we expand out and just look at mortality in people older than, in, older than 65, and look at a CDC analysis of more than 114,000 COVID-19-associated deaths, between the months of May of 2020 and August of 2020, 78% of those individuals who died were over the age of 65.

Dr. Caudle:
You know, just jumping in there, really quickly, Dr. Worz you know, someone might ask, given that patients in long-term care facilities have such a high risk of hospitalization and even death from COVID-19, you know, one might wonder is it even worth trying to treat them on an outpatient basis or should they immediately be hospitalized? What are your thoughts about this?

Dr. Worz:
Well, certainly every patient's different and we have to make an assessment of what path they're on in terms of their infection with COVID-19 but for most patients that test positive, especially in environments where we're doing routine testing and we're monitoring closely, like those in skilled nursing facilities and in, in assisted living facilities they may not have progressed to the point that they're at risk. I think Dr. Badley's case does a good job of identifying a community-dwelling individual that, that isn't at risk of going to the hospital. So, these products, these monoclonal antibodies represent an opportunity to treat patients before their disease progresses and, and keep them from moving on to that hospital setting, which ultimately is, is the best for anybody that's that's tested positive for COVID-19. So, if you look closely at these Emergency Use Authorization criteria you'll look at how they identify high-risk patients. And I think the one that stands out is that anybody over the age of 65 is considered high-risk and would qualify for the use of these monoclonal antibodies. If you look closer at that EUA, you'll see that people are authorized to receive this after a positive test with one of these criteria but without symptoms; they don't have to have an- evolved any symptoms, yet. In fact, the earlier we start the monoclonal antibody treatments, the better that patient's course is. So, if we look at some of these other criteria that, just on their own, qualify an individual for receiving these monoclonal antibodies, you'll see that someone with a body mass index greater than 35 qualifies, someone with chronic kidney disease, diabetes as Dr. Badley has suggested, both type 1 and type 2, those that have immuno-suppressive disease and those that currently receive immuno-suppressive treatments would all qualify in the community if they test positive for COVID-19.

Dr. Caudle:
You know, how and this is a question I think a lot of people might be wondering is, how would you actually administer these drugs to a nursing home population? How's that actually done?

Dr. Worz:
Well, these medications are IV medications, so they're intravenous and they require a 60 minute infusion, followed by a 60 minute period of post-infusion monitoring. So, because of the fact that they are a little bit more sophisticated as a, a drug that with a delivery system of IV, they have to be administered in settings where healthcare providers have access to medications to treat infusion reactions such as anaphylaxis and the ability to activate EMS or emergency medical systems, if necessary. Certainly skilled nursing homes qualify, they have qualified nurses, they're used to handling IV medications, they have the necessary supplies to deal with emergency and there are a number of assisted living facilities that would also qualify with experienced nursing and, and capable staff to manage these medications. But these medications could also be administered by companies that specialize in infusion medications and can deliver those medications even in a home setting. And in those situations, you have companies providing end-to-end services, where they're acquiring the product, it's being prescribed by the physician or the nurse practitioner and the, the pharmacy itself comes to the person's house with nursing staff and all the necessary supplies to be able to administer the drug. But that's how we would get it out to people that need it in the community. Next slide. There are 3 programs currently that are directed by the Department of Health and Human Services to, to allocate federal allocations of these products. One is a long-term care pharmacy program where long-term care pharmacies can get access to product and be able to provide it to those nursing facilities or assisted living facilities that are capable. That program is managed through the American Society of Consultant Pharmacists and information on it can be found at www.ASCP.com. There's also a program managed by the National Home Infusion Association, their website is www.NHIA.org and they provide medications to home infusion pharmacies that can also access individuals in assisted living but also at their homes and out in the community. There's a third program that actually works with pharmacies that provide medications to correctional facilities, so really trying to get at those community settings, especially those congruity care settings, where these medications can have the biggest impact. Next slide.

Dr. Caudle:
That's very, that's very, very helpful information, very useful and, and tangible information for our viewers and listeners, as well. I appreciate that. As a reminder to everyone out there, we encourage you to submit your questions for the faculty. Remember, to submit your questions during the presentation, you can type them into the chat control panel on the left hand side throughout the program or in your comment box through Facebook Live. Once again, we'll try to answer as many questions as we can during the time allotted. So, now, Dr. Badley, let's come back to you for a little bit. Throughout this program, we've heard about the use of the neutralizing monoclonal antibodies as outpatient treatment for high-risk patients with COVID-19, but what is the evidence behind their use? You know, how safe and efficacious are they?

Dr. Badley:
Well, I'll do my best to try to answer that. Let's, let's begin with another question. So, can we start with the first slide? So, this is to the audience: did you review the pre-read provided to everybody before the broadcast? So, it looks like roughly half/half; half the population, half the audience did review, roughly half did not, so I think that's an opportunity to go through some of the data. Next slide, please. So, the pathogenesis of SARS-CoV-2 infection and COVID disease follows the ACE2 receptor expression profiles. So, when the virus first comes in contact with a patient, a future patient, the virus enters often through the nasopharynx and the virus binds to those cells which express the ACE2 receptor. At that period, it's mostly viral replication only and the patient is asymptomatic. Subsequently, the virus spreads and infect other organ systems that express the ACE2 receptor, such as the GI and the oropharynx and, and the respiratory system. During that phase, inflammation begins, and patients can get sicker and have more systemic symptoms. Finally, it can progress and this can cause complications like ARDS and renal failure and at this stage, it's mostly an inflammatory process with a minor degree of viral replication. Next slide, please.

Dr. Caudle:
And Dr. Badley, I'm, I'm glad you're moving on to this next slide because I had a question, you know, if you could go through PAPs, where in the viral replication lifestyle -cycle that monoclonal antibodies actually act, that would be, that would be very helpful.

Dr. Badley:
Perfect. I'll do my best. So, the spike-monoclonal antibodies, they target the spike protein, which is present on the surface of the SARS-CoV-2 virus. When these monoclonal anti-s-bodies bind to the spike protein, that makes the spike protein inaccessible to interact with the ACE2 receptor, which, as we just mentioned drives the pathogenesis. Because it can't bind to that ACE2 receptor, the virus cannot enter the cell and enter the subsequent steps of viral replication. Now, before we had these monoclonal antibodies, we had some correlative evidence that antibodies can do some good. There were a large number of studies and observational cohorts looking at

convalescent plasma and in one of those studies, if you gave high-titer plasma, meaning plasma contained lots of antibodies the proportion of patients who went on to have COVID pneumonia was 16% whereas if they received placebo, it was 31%. Similarly, in another study where you did unscreened plasma, meaning you didn't measure how much antibody was present, there was no effect. Altogether, arguing that the presence of ACE of SARS-CoV-2 specific antibody has a therapeutic effect. Similarly, correlative evidence is that in patients who have COVID disease and recover rapidly, their recovery is coincident with the onset of a neutralizing antibody response. Next slide, please. So, the first monoclonal antibody we're gonna talk about is called "bamlanivimab" and bamlanivimab is a Lilly product and they completed a trial where ¾ of the patients received bamlanivimab in 3 different dosing cohorts and ¼ of the patients received a placebo. The baseline characteristics of these patients is shown in this chart and are basically identical. Next slide, please. Here you can see the results from that trial. In the patients who received placebo, the rate of hospitalization was 6.3%. In those patients who received the monoclonal antibodies, the rate of hospitalization was between 1 and 2%. If you took everybody who received the monoclonal antibody together that was 1.6%. Shown in the right graph, is a composite symptom score and you can see that those who received the monoclonal antibody had a quicker improvement in symptoms. Now, bamlanivimab and every other therapy is moving very, very quickly and today, we had another report of some outcomes from bamlanivimab. So, in this trial, bamlanivimab was coupled with another antibody called etesevimab which is also put together by Lilly, and they gave the two-antibody cocktail, roughly 1,000 patients, half received the antibody, half did not. The group that received the antibody, there were 11 cases of hospitalization or death; in the group that received placebo, there were 36 cases of hospitalization or death resulting in a 70% reduction in those composite outcomes.

Dr. Caudle:
Hmm. Very helpful information. And, you know, a lot of good data that you're presenting to us. Can you tell us, maybe, a little bit about what this means for patient care and, you know, how can our healthcare practitioners who are listening think about how they might convey this to patients who might be worried about trying a new drug that has Emergency Use Authorization?

Dr. Badley:
Well, so, we're now becoming aware and every day we get more data like we did today, that, that the preponderance of the evidence suggests that these monoclonal antibodies are effective in preventing hospitalization, improving symptoms and in this last study I just mentioned reducing death and the availability of that data should help to teach both healthcare providers and patients of the therapeutic effect. So, so I think the preponderance of the evidence suggests that we should move that forward. Next slide, please. The next trial we're gonna talk about is another dual-antibody combination; this time made by Regeneron. And the antibodies are called casirivimab and imdevimab. And in this trial, roughly 300 patients were enrolled, a third got placebo, a third got low-dose antibody cocktail and a third got high-dose antibody cocktail. Next slide, please. The baseline characteristics of these patients as shown in this pretty busy graph, chart, and you'll see that the baseline characteristics are identical between groups. Next slide. Here are the results and what you can see is that the outcome they used here was a medically-attended visit and what that means is patients went to the hospital, went to the emergency room or had a outpatient visit for ongoing symptoms. If you looked at all patients, together, those patients who received the cocktail had a absolute reduction of 3 in that composite outcome score. If you looked at the subset of patients who had no antibodies prior to recei- no natural antibodies prior to receiving the cocktail that reduction in composite score ranged between 8 and 10, so again this shows that there is therapeutic effect to administering these antibodies. Next slide, please. In that study, they also measured virus. This time they measured virus in the nasopharynx and what's shown on this slide is in those patients who had very high levels of, of virus in their nasopharynx when they were administered the Regeneron cocktail, the amount of virus dropped precipitously.

Dr. Caudle:
Now, Dr. Badley, I want to jump in and ask you, you know, there are 2 therapies, both neutralizing monoclonal antibodies with and EUA for the outpatient treatment of COVID, so how should clinicians decide which one to use?

Dr. Badley:
Great question. And on the basis of what we know today, there are no distinguishing features between one of the antibody therapies and the other. And there are no head-to-head trials to support that one is superior to the other. So, what I tell my patients and I advise others is, what should be administered is whatever you can get your hands on. Next slide.

Dr. Caudle:
Right.

Dr. Badley:
So, the EUA that you mentioned did come out and essentially, the Emergency Use criteria for administration of these antibodies are identical. Essentially, they consist of those who are at high-risk and that is defined as greater than 65 years of age, BMI of greater than 35, chronic kidney disease immunosuppression, either on the basis of natural immunosuppression or iatrogenic immunosuppression or diabetes. There are conditions whereby if you're 55 to 65, you can also be administered these and they're listed here and if you're

young and you have these other risk factors then you can also be prescribed these therapies. Next slide, please. Now, what I've just told you is very, very promising, but, but as Dr. Caudle alluded to they might not be used as often as they should be used. And this has high the lay press and here's a couple of articles talking about it. And so why are these therapies underused? And there's a few ideas and we'll, we'll try to go through them. So, next slide, please.

Dr. Caudle:
Yeah.

Dr. Badley:
I think the biggest reason for the challenge to administer these antibodies is that places that normally give infusions to patients are full with, otherwise, sick patients, often cancer patients or immunosuppressed hosts. And hospital systems and infusion centers don't want to bring known COVID cases into those infusion centers and potentially infect those who are there. There can also be a challenge for healthcare systems to identify individuals who are at risk for progression. There can also be difficulty in identifying patients within the therapeutic window; these drugs should be administered within 10 days of a positive diagnosis. They require incremental staffing to administer the drugs and lots of hospitals are experiencing staffing shortages. Up until very recently, there was relatively limited evidence of a therapeutic effect that improved today, and I expect we'll see more data moving forward. And then there are logistic challenges such as transporting a patient from where they live to places that can infuse these therapies.

Dr. Caudle:
Mmmhmm. Yeah, I'm really glad that you went through some of those potential limitations and factors because they definitely are real. And I guess, you know, Dr. Badley, sort of, building on that, what can physicians, nurse practitioners, nurses, other healthcare providers do, what can we do to ensure more patients who meet the EUA criteria actually receive treatment?

Dr. Badley:
That is on the top of everybody's minds, and, and possible solutions are as follows. So, 1) hospital centers and infusion centers and outpatient clinics have, and I expect will continue to develop dedicated COVID-specific infusion centers. By that I mean that the only patients who are treated in those treatment centers have COVID and are receiving these antibodies. As Dr. Worz alluded to earlier, there are commercial entities that will act as mobile units to travel to the patient to give the infusions at home, a variety of health systems are doing similarly and also there commercial infusion centers that are being stood up to, to administer these, these therapies.

Dr. Caudle:
That's excellent. Very, very useful information. You know, Dr. Worz, I'm gonna bring you back into the conversation. Would love to know from the pharmacy side, you know, what can pharmacists do to support appropriate COVID patients in getting this treatment?

Dr. Worz:
Well, I think that they can do what, what would be best of all the disciplines which is to get more educated on where the product is, where they can access it and also be able to communicate it to the prescribers that work in their communities to the nursing homes that they service to the assisted living centers that they service so that everybody's on the same page about what these products are, how they're administered, howe they're acquired and how they can get in and be used for patients that have tested positive for COVID-19. I mean, this is, as Dr. Badley had described, this is a, a game-changing therapy option. It's in good supply it's a government-covered product both products are government-covered at this point, so it's a really a question of getting it having it on hand at the pharmacies and having it in the infusion centers and then also getting the word out to the clinicians that it's available and they can start prescribing it for their patients and getting it administered.

Dr. Caudle:
Excellent points. Excellent points. This was a, a really wonderful conversation. We're going to now move into our Q&A section of the program. That's definitely gonna be exciting and important as I've been mentioning throughout the program. So, we're gonna jump right in we've got a few questions from you all, very excited that you've sent questions to us. Dr. Worz you're the first person that's, sort of, in the hot seat, shall we say. For the question this is someone who's writing in saying "I work in primary care clinic, which serves seniors. Where do we order the monoclonal antibodies?". Great question.

Dr. Worz:
It's a great question. So I talked about the one site, the National Home Infusion Association site. It's NIH, it's NHIA.org on that site, they have a locator for home infusion pharmacies that are participating in their program. They have it by the name of the home infusion pharmacies, they also have it by a map, so that you can locate in your particular area, pharmacies that are participating. And that would be my first step, if I'm a primary care physician or I'm working as a pharmacist in a primary care setting I would look for those pharmacies that are part of that program that have access to the medication and start there in terms of getting the patients connected to

those pharmacies.

Dr. Caudle:
Excellent. Very excellent. Let's move on to our next question. This one is for Dr. Badley our, our listener viewer says, or rather asks, "Is there a time limit when you can send…", excuse me, "Is there a time limit when you can and cannot administer the antibody infusion?". That's a really good question.

Dr. Badley:
Ues, so, so it's approved for use within the first 10 days from diagnosis. You also have to meet the inclusion criteria, which we talked about and it's approved for outpatient use. So, if you are sick enough to require hospitalization, for whatever reason it's not available as a prescription in the inpatient setting. There are studies of it in the inpatient setting and your site may or may not be involved in, in, those inpatient studies.

Dr. Caudle:
Excellent. Thank you very much, Dr. Badley. Let's move back to you, Dr. Worz. The next question is geared towards you or rather just to you our viewer says, "What is the cost of these medications and does insurance cover them?".

Dr. Worz:
So, that's a, that's a great question and you'd be surprised how often we get this question, but the, the product has been purchased by the government. So, similar to the way we've administered or, or dealt with the vaccine issue, the government has made an investment in these products, so they are available, they are paid for, there is no pure cost to the medication, so the patient doesn't have anything to pay. There is reimbursement for the administration of the product, it's paid for through Medicare and pharmacies and, and home infusion centers and, and other center that are administering the vaccine have the ability to, to get reimbursed for administering the product, but the product itself has no cost.

Dr. Caudle:
Mmm. Very, that's a very good question and very interesting, important answer. The next question goes to Dr. Badley "Do these monoclonal antibodies work well with the UK, Brazil and South African variance of COVID-19?"

Dr. Badley:
Wonderfully topical question and I'm asked that question, literally, daily. And the answer is, possibly going to change rapidly, so, on the basis of what we know today these, these antibodies do work against the UK variant and the South African variant. The bamlanivimab, the Lilly product has a several-fold reduction in activity against the South African variant. I suspect that's the reason that they're now testing an antibody cocktail of the two drugs bamlanivimab and etesevimab because two antibodies are more difficult to become resistant to than, than one, obviously. There's no data today that I'm aware of about the Brazil variant, but if I were to guess, I think it's going to still cover, but lots of people are, are investigating and testing that and we'll hear updates in upcoming days to weeks.

Dr. Caudle:
That's excellent. That's a really great way to round out our discussion on neutralizing monoclonal antibodies for the treatment of COVID-19. I'd really like to thank my colleagues Dr. Badley and Dr. Worz for helping us better understand the key roles for physicians, nurses, pharmacists in this challenging topic. Dr. Badley and Dr. Worz, it was wonderful speaking with you, today.

Dr. Badley:
Thank you and thank you to the audience.

Dr. Caudle:
Of course, and I agree, our audience was wonderful. Excellent questions. For everyone out there, just please note that another presentation on this topic will take place on February 17th. We welcome you to join us at that time, as well please register and join us again. And to those listening to this course, please proceed to claim credit by completing the evaluation through ReachMD. Also, through ReachMD you can get a PDF of the slides, including explanations to the pre- and post-test questions. Thank you all so much for joining us.

Announcer:
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