ASPR TRACIE Webinar Transcript

Closing the COVID-19 Test to Treatment Gap

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Shayne Brannman: On behalf of the US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, I'd like to welcome you to ASPR's Technical Resources Assistance Center and Information Exchange Webinar titled, Closing the COVID-19 Test to Treatment Gap. Next slide. Before we begin, we have a few housekeeping items to note. The webinar is being recorded. To ensure a clear recording, everyone has been muted. However, we encourage you to ask questions throughout the webinar. If you have a question, please type it in the question section of the GoToWebinar console. During the Q&A portion of the webinar, we will ask the questions we receive through the console. Questions we are unable to answer due to time constraints will be followed up directly via email after the webinar. To help you see the presentation better, you can minimize the GoToWebinar console by clicking on the orange arrow. Today's PowerPoint presentation and speaker bios are provided in the handout section of the GoToWebinar console, and will be posted along with this recording of the webinar within 24 hours on ASPR TRACIE.

Next slide. The opinions expressed in this presentation and on the following slides by non-federal government employees are solely those of the presenter and not necessarily those of the US Government. The accuracy or reliability of the information provided is the opinion of the individual organization or presenter represented. Slide four. To meet the nation's health and medical needs, ASPR is focused on three key priorities. One, extend capabilities to respond well and emerge quickly from the COVID-19 pandemic. Two, restore resources and capabilities diminished during the pandemic and third, prepare for future emergencies, whether natural or manmade. Next slide.

My name is Shayne Brannman, and I'm the Director of ASPR TRACIE and I want to welcome new and old friends of ASPR TRACIE. I want to thank you for what you do daily to enhance the preparedness, response and recovery activities of your healthcare entities and communities. Your role is so vital to addressing the daily and arduous challenges being presented. So, your willingness to spend the next 60 minutes with us to further advance your knowledge is noteworthy. I also want to convey my heartfelt thanks to our awesome lineup of panelists and moderator for this webinar. Your willingness to lend your precious time and share your substantive expertise so others might benefit is commendable and genuinely appreciated.

Last, many thanks to the ASPR TRACIE crew for coordinating this session. For our new friends to ASPR TRACIE on the webinar today, this slide depicts the three domains of ASPR TRACIE,

Technical Resources, Assistance Center, and Information Exchange. If you cannot find the resources you are looking for on ASPR TRACIE website, simply email, call or complete an online form and we will respond to your inquiry expeditiously. Next slide. It is now my distinct pleasure to introduce one of ASPR's most hard-working individuals and the moderator for today's webinar, Ms. Cicely Waters, who serves as ASPR's Director for External Affairs. Cicely, over to you now.

Cicely Waters: Thank you so much, Shayne, and thank you to the ASPR TRACIE team for partnering to host this relevant and timely webinar. I am Cicely Waters with the US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response and it's my honor to serve as the moderator for today's webinar. Next slide. Thank you all so much for joining us. As the topics that we will discuss today are truly relevant and I'm sure are topics of conversation across your organizations within your offices and perhaps even within your patients. What we'd like to do today is given that the COVID-19 environment is truly dynamic, we want to make sure that healthcare providers, those within the state and territorial health departments, emergency managers, potential patients have a clear understanding of the current COVID-19 therapeutics environment.

We all know that vaccines remain the primary way to help get us all out of this COVID-19 pandemic, but we do have therapeutics that are available that can help protect Americans across the country and help slow the spread of COVID-19. So we want to highlight what the therapeutics landscape looks like right now and then we also want to focus on some initiatives that can help close that test to treatment gap as many of the therapeutics that will be highlighted today require quick attention for those patients who are eligible and we want to make sure that those who are dialed in that you are aware not only of the therapeutics that are available, but also of some initiatives and best practices that you can help us to employ to one, educate and inform providers and potential patients to help us close that timeframe between when a potential patient tests positive or becomes eligible for these therapeutics, and the time that they receive the treatments.

We do want to have as much time as possible to join in discussion with our expert panel and to answer questions and answers that you may have. Our presenters today will be Dr. Derek Eisnor, who serves as the Federal Lead for the allocation and distribution of the COVID-19 therapeutics. We'll also be joined by Dr. Meg Sullivan, who serves as the Acting Chief Medical Officer for the Office of the Assistant Secretary for Preparedness and Response and then also joining us on our expert panel will be Dr. Michael Anderson, who serves as a Senior Advisor within the Office of the Assistant Secretary for Preparedness and Response. With that, I'd now like to move into the presentations for our program and turn it over to Dr. Derek Eisnor.

Dr. Derek Eisnor: Thank you so much, Cicely and thank you for all the participants for taking time out of your busy schedules to be with us today. I'll take next slide, please. So, looking at a timeline of COVID-19 illness and where our specific therapeutics fit into this, for the purpose of today's discussion, I'm going to focus solely on outpatient therapies, starting with those individuals who are immunocompromised and at very high risk for progression to severe disease. In the setting of an acute COVID infection, there is a pre-exposure prophylaxis product, Evusheld. This product is not indicated for treatment or post-exposure prophylaxis and there is

guidance with both NIH and CDC in terms of helping providers identify these populations. There's also very specific guidance in FDA's EUA on this product and so, again, I would refer you to that for those that have questions in this regard.

One of our current gaps, obviously, is post-exposure prophylaxis due to Omicron and the lack of neutralization of our legacy mAbs, REGEN-COV and BAM-ETE. These are no longer authorized, but I think it's key for planners to certainly, you know, part of our discussion today is really having patients, empowering patients to have information that allows them to rapidly link to assessment and possible treatment where indicated and just reflecting what Cicely mentioned that the treatment window for many of our outpatient therapeutics is quite narrow and again, I think having that information both on the provider side and the patient side, so that individuals really have a clear path in front of them once they have that positive test is really key to making sure that we can maximize use of these therapeutics. On the front of treatment of outpatient mild-to-moderate COVID-19, again, specific to individuals that are at risk for progression to hospitalization and/or severe disease, we have our oral antivirals and that includes Pfizer's Paxlovid and Merck's molnupiravir.

I know we've messaged in the past that supplies have been constrained, but based on our most recent utilization data, we know that there is product on the shelf and that providers again, you know, many of these patients should be identified prior to, you know, in terms of their comorbidities and risk factors, we've certainly foot stomped that vaccination is the foundation of, of our efforts in terms of reducing progression to severe disease, but also understanding that there are individuals with high risk co-morbidities, older individuals that can and will progress to hospitalization, even despite vaccination. So, again, very important, and again particular to the oral anti-viral is a very narrow treatment window of five days from symptom onset.

We also have our monoclonal antibodies, and that also includes the most recently authorized, Lilly's bebtelovimab, as well as GSK/Vir's sotrovimab and again, indicated for those with mild-to-moderate COVID-19, positive test and again, individuals who are at risk for progression to severe disease. I'll also mention FDA's approval of the use of remdesivir, 3-day outpatient infusion for those same at-risk individuals down to age 12, as well as a EUA authorization for pediatric patients down to 3.5 kilograms understanding that there was a huge gap when BAM-ETE was paused due to Omicron in those specific pediatric age groups, so again, just wanted to make those that may have these capabilities to utilize this certainly aware of where we are with remdesivir.

Next slide, please. Looking at the pathway to treatment from a patient's perspective, again, having information prior to illness is key and knowing how to rapidly access assessment and get yourself in front of a prescriber, so understanding that our treatment window with oral anti-viral is five days and then really now down to seven days from symptom onset with our monoclonal antibody products. Key to this working is obviously communication and patients really having that information and knowing where to go so that they can navigate this pathway in a timely fashion to get in front of a provider and have that vital assessment done and prescribing, again, if indicated. This all is predicated on reducing turnaround times and delays wherever possible, understanding that many patients may present a couple of days into their symptom onset and so wherever possible to be able to rapidly not only access tests, but have rapid turnaround times,

and then have the patients know exactly where they're going to go from there to get in front of a provider, and again, prescription if possible.

Next slide, please. So, along this pathway as I've already highlighted that information awareness is key. So patients understand their comorbidities, their current risk, again, despite the presence of whether they're vaccinated or not and really know to be able to rapidly identify their symptoms, to be able to access testing, whether that's at home tests or within their neighborhood, to understand that fast turnaround is key on these tests and to know exactly where to go with a positive test, and to be able to answer questions with a negative test, how to access providers, and really minimize any delays if at all possible on this treatment journey. What our program highlights is, is attempting to identify locations that one may have all of this under one roof in terms of testing, assessment, and, and dispensing, but understanding that this can't be the case in all locations for all patients, but wherever we can minimize these delays.

So I think many of us live in communities where, you know, we have access to rapid testing and then understanding that the time really needs to be minimized from that positive test to accessing a provider to be able to have a in-depth conversation on the risk benefits, what are the current treatment options and then again, link to prescribing and dispensing if that is the provider and the patient's choice. Next slide please. And at this point, it is my pleasure to turn things over to Dr. Meg Sullivan, who is the Acting Chief Medical Officer for ASPR. Meg?

Dr. Sullivan: Thank you so much, Dr. Eisnor, and good afternoon everyone. I am incredibly honored and excited to be here today just to talk a little bit more about the test to treat work that we have been doing and will continue to do to address many of the challenges and issues that Dr. Eisnor has mentioned. Next slide. So just to reinforce a lot of what Dr. Eisnor just said, as we think about our COVID-19 test to treat strategy or initiative or approach, really have three overall goals. The first is to facilitate early diagnosis and rapid linkage to treatment for individuals with COVID-19 who are at high risk for complications, again, to get within that timeframe that Dr. Eisnor just described. The second is to prevent disease progression and transmission through early diagnosis of high-risk individuals, thereby reducing morbidity and mortality caused by COVID-19, again, knowing that we now have effective treatments available in addition to vaccines, and third, to reduce disparities in COVID-19 outcomes through equitable strategies that prioritize access to test and reduce barriers for treatments for high-risk individuals who are disproportionately impacted by COVID.

Next slide. So, as we do or have been focusing on the test to treat efforts, we really aim to address some of the challenges that patients have with obtaining therapeutics, and again, reinforcing a lot that Dr. Eisnor just mentioned, including consumer knowledge of test to treat guidance. So those key points around testing with symptom onset and not knowing who is at high risk and would benefit from treatment, understanding that treatments may be available and to contact a medical professional or their doctor within a few days, again, given that short timeframe for treatment effectiveness, and so really trying to focus on enhancing that awareness. The second is ensuring that there is access to tests upon symptom onset. Third is access to a healthcare provider or a treatment site for monoclonal antibodies, again, within that time frame for treatment effectiveness. Fourth is around provider knowledge and comfort level with prescribing therapeutics, ensuring an equitable distribution of therapeutics especially in the

setting of a limited supply and as we know that supply is growing and then once the patient or the provider gets to the point of actually writing a prescription for oral antiviral, for example, locating the site with a medication in-stock. Recognize these are not all of the challenges, but these are just some of the challenges that we keep in the back of our mind as we have worked on our test to treat efforts.

Next slide. So with that in mind, again, as we think about our overall goals, the first is really is to increase COVID-19 test and treat health literacy. So awareness by both the patient as well as the provider around available treatments, the current guidelines, how and when to access; that was our key goals that we're trying to accomplish here. Second is to ensure access to test for early, early diagnosis with a specific focus on high-risk individuals. We'll talk about that specifically today, but I will say that considerable effort has been put in to ensure that there now is widespread access to test, but again still need to focus on ensuring individuals know how to access tests, when to access tests, and most importantly to test early on symptom onset. The third is to facilitate rapid linkage to care after positive result, again, with a specific focus on high-risk individuals and again, I'll talk a little bit about those efforts and then finally, to ensure access to therapeutics with a focus on equitable distribution. We know significant work is being done in that area and needs to continue.

Next slide. So, just to highlight a few of the efforts that we have done in as part of our strategy to increase COVID-19 test to treat health literacy, we are trying to make sure that this test to treat messages are widespread among testing websites and this slide is just two snippets, one from the CDC, self-testing webpage. The other is from covidtests.gov, which is the website that individuals have been going to, to order their four free tests that can be delivered to each household. You can see the message, the test and treat messages where if you test positive and are at high risk due to a medical condition or due to age, treatment may be available, to contact a health care professional and do so right away because treatment needs to be started within a few days to be effective, again, working to get these messages widespread and available to really increase patient awareness of these effective treatments.

Next slide and this slide shows a graphic, an infographic that is also available on the CDC website and we're encouraging providers and health department organizations and others to use this widely, again, to convey these, these test and treat messages. They are also being used in social media campaigns and other places to really get that message across that don't delay, test soon, treatment may be available if you're high risk and, and treat early again for the treatment to be effective. Next slide. We also recognize that as people are testing in different settings, including increased use of at-home testing to really find innovative ways to get these test and treat messages in locations where people are using tests. Those of you that didn't see, there was a recent article published in JAMA that looked more at individual's adherence to isolation and quarantine guidance after taking a test. What they found was when there was, when included an easy-to-use, kind of patient-friendly guidance around what those isolation quarantine messages were, people were much more likely to follow them, especially with a negative test. So again, extrapolating to our test and treat efforts to make sure that there are widespread, widespread patient friendly messages available, especially where people are taking tests and we continue to explore different ways to do that.

Next slide. In addition to patient or consumer awareness of our test and treat messages, we're also doing considerable work to increase provider awareness, especially as the changing guidelines and medications and treatments that are currently available, as well as how to access those. ASPR and others are engaged in significant stakeholder engagement, including weekly roundtables that are accessible to many different providers, health care organizations, and state and territory and health departments and we'll see a slide at the end that just highlights a few of these. I really want to encourage individuals to join these or providers to join these really get the most up-to-date information about prescribing therapeutics and how to locate them. In addition, what you can see on this slide is a COVID-19 therapeutics locator, where we're really trying to make transparent the information about where supply has been allocated and where it is currently available, again, for providers who have a patient that is eligible and when they're writing them a prescription, they can use this website as a way to identify places where they could potentially send that prescription for individuals to get out.

Next slide. So this is the slide that shows the weekly stakeholder engagements. Again, this is just a snapshot of many of the engagements that ASPR is holding, as well as many other agencies within HHS to promote test and treat health literacy, both for consumers as well as for providers. Next slide. We also have been working very closely with different organizations, including with HRSA. We know right now as we allocate our therapeutics a specific percentage of the therapeutics are allocated directly to HRSA-funded health centers. Again, equity has been a core focus of all of the efforts around test and treat many other aspects of COVID response. We've been working directly with HRSA to increase utilization of the therapeutics to ensure that the public is aware of these centers, as well as to ensure that providers at these centers have the tools that they need to prescribe these therapeutics and this will continue to be a central effort of our test and treat initiative.

Next slide. As we think about that third goal of facilitating linkage to care, you know what, as we think that specifically on this slide, thinking about oral antivirals, and the requirements for that successful test to treat model. So getting an individual to test early, they test positive, getting it linked into a healthcare provider for, in a timely manner for access to evaluation and prescription, and then timely access to medication all within a few days after symptom onset. We continue to explore different locations where this model is either already in effect or could potentially be in effect, and are working to consider opening up new channels or new initiatives to really promote this test to treat model and, and increasing access to therapeutics among, among patients and expect to have more information coming out in the next few days about this.

Next slide. Finally, I'll just end by saying as we think about test to treat, it is not just a one simple strategy. It is multiple different efforts that I talk through that includes public education campaigns to, to enhance patient or consumer education and messaging, provider outreach to increase knowledge of and comfort level with prescribing therapeutics, again, ensuring access to tests and prepositioning them in high priority settings, also ensuring access to and prepositioning therapeutics in high priority settings, whether it's through our HRSA-funded health centers, whether it's the incredible work of our states and territories to distribute to high priority locations, and continue to work to prioritize other settings which support that end-to-end test to treat model, as well as we continue to have ongoing efforts to increase the supply of therapeutics and are exploring further opportunities for telehealth and other options for linkage to care and

treatment. I'm now going to turn it back over to Dr. Eisnor to just talk about one other specific initiative that we are working on.

Dr. Eisnor: Thank you, Meg, appreciate that very thorough review of test to treat. So, along the same lines in terms of, you know, our ultimate goal is to secure timely access to our therapeutics and focusing specifically on the oral antivirals. The RAPID program or Reliable Acquisition of Pharmaceuticals for Immediate Distribution focuses on the particularly the vulnerable populations that reside in long-term care facilities to really make sure that they have ready access to oral antivirals, understanding not only their vulnerability, but the speed in which infection can spread amongst those in a congregate care setting. You know, as we continue to work with our jurisdictional and territorial partners along these lines, but you know, we hear your concerns and have tried to structure the program to facilitate without creating a heavy administrative burden, nor biting into your current allocation.

So, our program as it stands would involve a separate federal cash and again, in no way shape or form would this impact current partner's allocations, we see that we know that there's products still on the shelf and, and unfortunately, our most recent utilization data shows roughly a little over 62% against ordering for Paxlovid and again, only 14% with molnupiravir. This initially due to the fact that molnupiravir is at least currently our only therapeutic that is not supply constrained, we would start with molnupiravir and then again, looking to add Paxlovid in the coming 6 to 8 weeks when prior to that, but again, looking forward one, two months down the road, when as I've mentioned in our stakeholder calls, our supplies of Paxlovid should go up significantly. We're working with all partners to identify the long-term care supporting pharmacies, understanding that the support network and how these pharmacies function with long-term care facilities and skilled nursing facilities is somewhat different than, than some of how we individuals outside of these facilities would access pharmaceuticals through retail pharmacies and also being able to leverage those existing supporting networks in their current efficiencies.

As always, we want to ensure maximum visibility with our partners and this is predicated on good communication and ongoing work between all parties, including sites. As always, key to and paramount to our planning is equitable distribution of therapeutics and we will be watching utilization data and continually getting feedback from all parties involved on these projects as they move forward and again, our ultimate goal is to really help enhance access and provide an efficient and flexible distribution structure to meet any of the current or future demands for therapeutics, again, in these various specific, vulnerable populations, where timely access to our therapeutics is essential. Next slide, please. So, it looks like at this point, we will turn to our Q&A and roundtable discussion and I'll turn it back to, Cicely.

Cicely: Thank you very much, Dr. Eisnor and thank you Dr. Sullivan for those updates. We will now turn to the question and answer portion of our call and I do invite Dr. Michael Anderson to also join our panelists for this portion of today's webinar and as a reminder for our participants, if you do have questions, you can please input those into the questions portal of the GoToWebinar panel and your questions will be received by our team there. Turning to our first set of questions and Dr. Sullivan, I'll turn to you first please for this question. We know that many American homes are now receiving at-home test kits either ordered through covidtests.gov or they may

even be purchasing themselves as we know that a lot of private insurance companies are now reimbursing for the purchase of at-home tests. So if I am a provider and I have a patient who comes in with a positive notation from an at-home test, do I need to retest that patient to confirm that they are COVID-19 positive or can I take that result and begin prescribing treatment immediately, especially given what we know to be that short opportunity for treatment?

Dr. Sullivan: Yeah, so I think what, how I would answer that question is to say, there's no specific guidance on this question, meaning that it's really up to the provider to use their clinical judgment based on what the patient is reporting, what their symptoms is, what they think their risk factors are, and their history of, of their reporting that that positive test to make that decision. So, there's nothing that says you have to have – the provider themselves have to perform that test and it's really up to the provider.

Cicely: Thank you very much for that and Dr. Eisnor, I'll turn to you for our next question. We know that you work intimately with the allocation, the distribution and the administration of COVID-19 therapeutics and from the initial clinical trial results, there appear to be a difference in the clinical efficacy between the oral antivirals and with molnupiravir appearing to be the less effective therapeutic, maybe causing some patients or providers to express some hesitation for the use of molnupiravir or to have a preference for Paxlovid. Under what circumstances would molnupiravir be preferred?

Dr. Eisnor: Thank you, Cicely and that's a great question. Certainly, the clinical efficacy demonstrated in the various trials with different products, there is some variation and unfortunately, molnupiravir with its 30% reduction in hospitalization in many ways does not measure up to some of our other products, but I will say that drug-drug interactions with Paxlovid is, you know, probably one of my chief concerns in terms of making sure that providers not only have nowhere to go and have access to some of the resources. Liverpool has a very specific COVID-19 drug checker that I find extremely useful. There's some very good guidance that's put out by both NIH guidelines panel and IDSA along these same lines. And so understanding that currently again, there may be situations where Paxlovid is not available, hopefully, based on our utilization data and as we look to the future, this will not be a concern, but again, there are going to be situations where some of these products, specifically Paxlovid may not be clinically indicated due to major concerning drug-drug interactions where the individual's concurrent medications, you know, a perfect example would be something like amiodarone would not allow for, potentially for that medication to be stopped and, and what my concern is specific to molnupiravir is, is and again, we know as we get into the higher risk groups that we're trying to identify, we're trying to avoid hospitalization, many more comorbidities, older individuals, they're on a lot more medications. And so my concern is that I want to do what we can, we all want to do what we can to make sure that providers that are in front of patients and are faced with this decision where Paxlovid is not clinically indicated to what I've discussed, that they have another option in that molnupiravir is available and, and again, these products need to be readily available given the very, very narrow five-day prescribing timeline that is again outlined in their EUAs. Thanks.

Cicely: Thank you for those thoughts, Dr. Eisnor. Dr. Anderson, you're a pediatrician, so I'll turn to you for this next question. What therapeutics are available to some of our youngest Americans?

Dr. Anderson: Thank you, Cicely. Both Dr. Sullivan and I are pediatricians. So, we outnumber my dear friend Derek by two to one. As Derek pointed out in his wonderful summary, we've got a bit of an issue with kids under 12. Everything with the exception, as I understand the Merck product are approved for kids 12 and older, up until Omicron, the BAM-ETE combination from Lilly was EUA approved for kids down to 3.5 kilos. When Omicron reared its ugly head, we unfortunately lost that tool in our pediatric tool belt. So for high-risk kids under 12, currently, we have EUA approval for remdesivir as an outpatient as Derek showed and that's third category of patients. That's good that at least is one tool for high-risk kids and think about the high-risk criteria, kids with oncologic disorders, sickle cell anemia, congenital heart disease, that's good.

The problem is the operational issues behind it same as adults is kind of, kind of big but you have to have an intravenous infusion once a day for 3 days, the dose on day one is higher than days two and three. So, we're working as hard as we can, both with the manufacturer as well as leading pediatric societies to, to get word out. It's one tool in the tool belt, but hopefully, it's another way for us to make sure kids don't progress and get sicker with COVID. Dr. Eisnor, can I ask you a question just to keep the conversation going?

Dr. Eisnor: Certainly, certainly.

Dr. Anderson: There's more press out there about VA2 and what, if anything, it's going to mean in the coming weeks. Could you just sort of review for the audience how FDA works with CDC, works with HHS to, to, to figure out the, the sensitivities of a new variant to the therapies over?

Dr. Eisnor: Sure, happy to. So, you know, a lot of this is predicated on a good partnership and communication with a number of both public and private labs, including working closely with our sponsor manufacturers, pharmaceutical companies and their considerable assets to really look forward, rapidly identify any sub-variants or variants of concern and test them again, beginning with in vitro studies against the prospective products, but also, you know, we're also working with other partners to try to gather as quickly as possible real-world evidence. VA2 is high on our radar. You know, currently it is a very small portion as Meg outlined in the Nowcast data, 3.8% in terms of prevalence, the point estimate for VA2.

But again, just forward looking and planning and how we would pivot in terms of some of our mAbs we've seen in the recent past, you know, two out of our three of our legacy mAbs, speaking specifically to BAM-ETE and REGEN-COV and how quickly they were rendered inefficacious in the setting of significant search and thankfully, our numbers are coming down, but this is something that is inherent to the MABs and this, I take this opportunity to highlight the strengths of our, our antivirals because of their different mechanisms of action versus the mAbs, in some ways they are, they have less of an Achilles heel in this regard and so I think in the future, where we may be handicapped with some of our mAbs becoming inefficacious and again being on pause or having to be limited in their use. This is where our oral antivirals can really shine and hopefully that helps a little bit.

Cicely: Thank you, Dr. Eisnor, and apologies for those technical difficulties. Our next question, Dr. Eisnor, I'll turn back to you for this one, as well as Dr. Sullivan and Dr. Anderson, if there's any feedback that you may have, and this is regarding patients and their concern with any cost sharing or cost bearing that may come along with receiving treatments. Could you talk a little bit about as a patient, I go in to receive COVID-19 therapeutics treatment, am I going to see a cost, or does that depend on the type of insurance I may have? And I'll turn to you first, Dr. Eisnor, for any feedback there.

Dr. Eisnor: Yes, thank you, Cicely and great question. So, it certainly does depend on where you may reside in terms of specific insurance, CMS, Medicaid, and they have published – so, essentially, let me back up a step. So, the US government is purchasing and providing these therapeutics to states and jurisdictions at no cost. The delivery of these products is somewhat different and so specific to products that require an infusion, some of our monoclonal products, the, the reimbursement for that can vary greatly and so the CMS and Medicaid, Medicare, they have published reimbursement schedules for this and for those individuals that have those questions can contact their regional max on that regard. Private insurers, there is, you know, we hope particularly in the setting of the public health emergency that we find ourselves in that they would follow the lead of our USG guidance in terms of the rates, but understanding that CMS cannot influence or require a specific rate. So there may be variances there, there may be copays involved. Above all, what I think should be key in terms of our messaging is that, that there are not system financial barriers that are put in place that would prevent patients to be able to access these therapeutics. I'll turn it over to Meg and Mike to add to that if they would like.

Cicely: Thank you very much, Dr. Eisnor. Dr. Sullivan, I'll turn to you please for this next question and it's about again, that focus on helping to decrease the amount of time between testing and treatment. The question asks has HHS reached out to retail pharmacies to partner with this initiative?

Dr. Sullivan: Yeah, I think first of all, I think that's a wonderful question and I think, as I tried to talk about and Dr. Eisnor did too, the test to treat initiative or the work that we're doing encompasses several different assets and several different strategies and one of them is engaging with many different stakeholders that includes pharmacies, that includes health departments, that includes other locations that are prescribing these medications, and really trying to address any challenges or reduce any barriers to making sure they are eligible. Just like with vaccines, just like with masks, we are working incredibly closely with pharmacies on this initiative and will continue to do so going forward.

Cicely: Thank you very much. This next question I'll offer to the three of you please and it notes, you know, many of the COVID-19 patients that providers are most concerned about are often the ones who are on several different medications, they may be immunosuppressed and, and or may generally have a complex medical history. The monoclonal antibodies seemed like the safest option with these patients, but what can you tell us about the safety profile of the oral antivirals? Can they be used in complex patients who take several other medications? And Dr. Eisnor, I'll turn to you first please.

Dr. Eisnor: Yeah, great question, Tiffany – Cicely, sorry. Tiffany is my deputy and I was catching up on email's apology. So, this is a great question. Obviously, this is also an area where the two oral antivirals molnupiravir and Paxlovid are very different. So, again, Paxlovid, obviously superior in efficacy, but considerable effort is required to sort out these potentially dangerous drug-drug interactions. And so the good thing is, is that there are a number of excellent resources out there for frontline providers who have probably like myself, I've never written a prescription for a product containing ritonavir in it. And so understanding that, you know, your patients, actually, you can almost pre-identify some of those individuals where you would have a sense whether Paxlovid would be useful for them or not. I think in the individual, in the individual provider setting, comfort level is another key consideration and I think that, that, again, in that regard, where you have an individual where there are one or more significant drug-drug interactions, and you are not comfortable making an adjustment or holding the medication, or it's just, it's just contraindicated, then in that setting, certainly this is where MABs would have an excellent place for those high-risk individuals. Thanks.

Cicely: Thank you. Any additional thoughts there, Dr. Sullivan or Dr. Anderson?

Dr. Sullivan: I think the only other thing that I will add is I think Dr. Eisnor did a wonderful job of answering that question, but we also recognize that there is a lot of information in the public setting right now about monoclonal antibodies, about oral antivirals and patients may come in with a lot of questions or concerns and they may be at high risk, they may have tested positive, they may be a great candidate or maybe concerned because it's something they've read and I think this is an opportunity for provider education when they're taking the time to spend with a patient to educate them that yes, these meds, these medications are safe and they're effective, and obviously to evaluate the personal risk profile and drug-drug interactions for that patient, but in many instances, they can be used and reassurance for the patient will be really effective in increasing uptake.

Dr. Anderson: I would also just make a quick plug for a couple of tools that Dr. Eisnor's team has helped develop a side-by-side comparison of all these therapies, mechanism, indications, contraindications, as well as I call it a flowchart. It's really, there are so many different choices, I think, which is a good thing for the individual patient in front of you, but just helping the clinician who's very busy and taking care of both COVID and non-COVID patients, how do you think about these therapies for the individual patient in front of you? So I think we can provide a link to those two and there's multiple tools as well.

Cicely: Absolutely, thank you very much for flagging those, Dr. Anderson and I would like to draw everyone's attention to the website and the email address that's currently on the screen. Those resources that Dr. Anderson highlighted can be found at the ASPR.HHS.gov website and following this webinar, if you do have additional questions, you can always reach out to the HHS federal team at COVID-19Therapeutics@HHS.gov. And Dr. Sullivan, I'll turn to you next. We talk about working to close that time between testing and treatment, but do we have any idea right now what that average time is?

Dr. Sullivan: I don't know if we have specific data. I know that that is one thing that we have been working really hard to do is not only to get utilization data, but also some of the clinical

data in terms of how and where these medications are being used. I do think though, I think more than anything, one of the big take-homes from today's webinar is how important it is that timely access to test, to test results, access to a provider and getting that prescription or referral for a monoclonal started within that timeframe. I think as from an ASPR and HHS perspective, we'll continue to try and gather that data to see what that average time is, but again, just emphasizing putting those strategies in place to make that time as short as possible.

Cicely: Thank you and I know that each of you often engage with national organizations and foundations and various stakeholder groups and so I'd like to ask what are you hearing through these conversations as the biggest barriers or challenges in access to therapeutics? And Dr. Anderson, I'll turn to you first, please, for your thoughts on what you're hearing in terms of what those major obstacles are or what the largest barriers are to accessing therapeutics.

Dr. Anderson: Thanks, Cicely and as – and Derek, and Derek and Meg's slide points out, all the engagements we have, like we are trying to actively reach out, although people have COVID fatigue and I know, you know, both clinicians and Americans are tired, we are trying to get as many engagements on the books as possible because every patient deserves access to these therapies. I think one of the things we're not hearing as much as we used to, and Derek pointed this out, is access to drug that, that we have been in an access constraint or a supply constrained environment for a while and to the credit of NIH and other organizations, we've come up with triage criteria and how to think about constrained resources. We are not hearing that as much as we used to, I think, and part of Dr. Sullivan's wonderful work here is getting word out that we've got to do a better job of saying, you've turned positive, I'm very sorry about that. We'll talk about vaccine another time, but there are therapies available. So I think we're hearing from clinicians, people know about vaccine, you know, vaccine has been around a while, but continuing to get word out to both clinicians as well as patients, there are therapies, but the turnaround time for us to get this therapy for you is really tight.

Cicely: Thank you and Dr. Eisnor, please, same question to you. Throughout your engagements in outreach, what are some of the things that you're hearing that are serving as barriers or obstacles to access for therapeutics?

Dr. Eisnor: Thank you, Cicely and again, to echo also Meg's response, you know, so we've been messaging, utilizing prioritization and tiering of risk groups based on scarcity of product and, you know, I think that that can create a scenario where providers are facing ongoing frustration and trying to locate product, trying to make sure that they're secured product and again, doing that all in an extremely tight and narrow window, understanding that most patients are going to present maybe a couple of days into their symptom onset. And so I think these are considerable ongoing hurdles with providers. You know, we also in our, in our, in our non-pandemic system, in many ways, you know, direct advertising to patients and consumers is very robust, you know, anyone who sits down in front of the television in terms of pharmaceutical commercials.

And so, you know, this is a bit of a paradigm change from when I first went to medical school and so, I think in that regard, it, it, it potentially looking at our utilization data, it really highlights that putting information in the hands of patients and consumers and empowering them is really essential. And so, you know, I know that we are striving in this regard, but we need to continue

to do a better job and not only the federal government, but really with all of our partners in this, in this aspect. And so I think when we could do that, that will really help us kind of shave down any of these, you know, many and potential points along the pathway for delays in care and accessing that care.

Cicely: Thank you, and Dr. Sullivan, any thoughts as well in terms of what you're hearing throughout your conversations in outreach as to what some of the barriers and obstacles may be for both providers and potential patients?

Dr. Sullivan: Yeah, I think I'll just echo Dr. Anderson and Dr. Eisnor's comments and a lot of the work that we've been doing to really enhance awareness and comfort level from both the patient and provider side and then really reducing those barriers. We know that linkage to care, for example, is a big barrier, not just for COVID, but in general for many individuals. So again, exploring models that reduce those barriers, working with, with entities that we know are already doing amazing work there is, is some of the, some of the ways we're trying to address that, but I think all of these challenges are all, they all contribute to this, but I think also there's just an incredible amount of work being done. You know, some of the work we talked about, you know, at the state and local level to address some of these barriers and competency going forward, especially supply increases, we can increase that awareness and comfort level, we will really see that decrease in people getting sick and dying because of these effective treatments.

Cicely: Thank you very much and Dr. Eisnor, I'll turn back to you for this. So we know that the federal government is overseeing the allocation and distribution of COVID-19 therapeutics to help ensure a fair and equitable distribution of these products and to help ensure that these products remain available for patients who need them across the country. Can you talk a little bit to the distribution amounts and whether or not we'll begin to see an increased availability of these therapeutics moving forward?

Dr. Eisnor: Yeah, happy to, Cicely, so and good question. And so as I've alluded to, I mean, I can't get into specific numbers beyond what has been shared on our stakeholder slides through mid March, but again, in the coming months, we know that or we expect that our Paxlovid supplies will increase considerably. I think it's key also for those that may not be already joining me on those regular weekly meetings that understand that we are pushing out our therapeutics as quickly as possible, understanding that our planners, you know, we want to maintain temporal equity and our planners also need some level of even keel in terms of their regular planning operations, but you know, making sure that product is available and then again, also making sure that our providers have the tools that they need, you know, as a toxicologist in an emergency physician, but understanding that, you know, a bad complication with a drug-drug interaction could certainly make a provider really gun shy in terms of writing another prescription for Paxlovid in the future. So really making sure that our providers feel that they are well prepared, that they're armed with not only the right resources and tools, but they have the information to be able to have the appropriate conversations with their patients in regards not only to that agent, but all of our therapeutics, so that really we do not have products sitting on the shelf while we have patients in the hospital over.

Cicely: Thank you very much, Dr. Eisnor. Dr. Sullivan, when we think about at-home care and at-home treatment, is this a part of considerations when we think about test to treat and how to close that test to treatment gap, and where does that fall in terms of the federal government's thought process in including that in the new initiative?

Dr. Sullivan: Yeah, I think that's such a great question and, you know, I think a couple of things that we've already talked about. The first is the importance of testing and testing early on symptom onset and we have seen during COVID and especially over the last few months, the growing, growing, growing utilization of at-home tests, which is something that we haven't seen previously, and I think has to be a consideration here. We've also seen during COVID, an increased utilization in role of telehealth and the impact that it can have, as well as home delivery of medications. So I think those models – the test to treat models that really are end to end, so provide access to the test, the test result with linkage to a provider and rapid access to medication. There's many different models of those but, but a telehealth or one that can take place in the home is absolutely one of them and it is absolutely one of the priorities of the work that we are doing and we hope to continue to expand that access.

Cicely: Thank you very much and we are approaching time for this webinar, but I want to offer each of our panelists just an opportunity to leave some closing remarks for the participants. If there's just one thing that you want them to walk away from this webinar with, Dr. Anderson, from your perspective, what would that be for the group?

Dr. Anderson: I think that this test to treat, the focus is so very, very important because there are still thousands of patients every day that can benefit from this and I think we partner with the right organization, the testing companies, the pharmacies and our efforts, but you know, having 500 plus people on this call sort of causes me to say and if you think of anything else we can do to decrease that timeline and to get more therapies onto patients, please let us know because we, we are always open to innovative ideas and projects and just an honor to join you. Thank you.

Cicely: Thank you and Dr. Eisnor, parting remarks for the group?

Dr. Eisnor: Appreciate that, Cicely. So, you know, I think, you know, awareness, access, assessment and treatment, and really shining a spotlight on the logistics that are involved in a variety of different settings and really studying where we can optimize any and all of the steps along that pathway and also looking forward to we understand that eventually we will be switching back to a commercial type market, making sure that there are not patients and vulnerable populations that are left, left behind in terms of ensuring that that we've looked at these systems, we have made the changes to really maximize access for all of these individuals and that we continue to do that as, as we, as we shift to a non-pandemic type world.

Cicely: Thank you very much and Dr. Sullivan?

Dr. Sullivan: Yeah, I think first, I would just echo both of those amazing statements and say, you know, I think we, unfortunately COVID is still with us and will be with us for a while, but we know that we now have incredibly incredible tools to prevent people from getting sick, coming to the hospital or dying. You know, first and foremost vaccines, vaccination is the most

effective way and we need to continue to encourage it and to make sure that it is widely available. We also now have widespread access to test and we have effective treatments. So the work that this, we are doing and invite others to share ideas, to participate, that feedback is so important, but to recognize that we provide everyone with access to these tools, again, COVID may still be with us, but we will see much less morbidity and mortality and, and I think that that's just incredible estimates of these tools that we have.

Cicely: And once again, thank you to our amazing panelists for joining in today's discussion and for your participation in today's webinar, but most importantly, thank you for the work you have done and the work you continue to do throughout this pandemic response. I'll now turn it over to Audrey to close out today's webinar.

Audrey Mazurek: Thank you very much. Thank you, Ms. Waters, for moderating and to all of our presenters for this informative webinar. That is all the time we have today. Again, this webinar will be archived and posted on ASPR TRACIE's website at asprtracie.hhs.gov. Thank you and have a wonderful rest of your day.

[Audio Ends] [00:59:20]