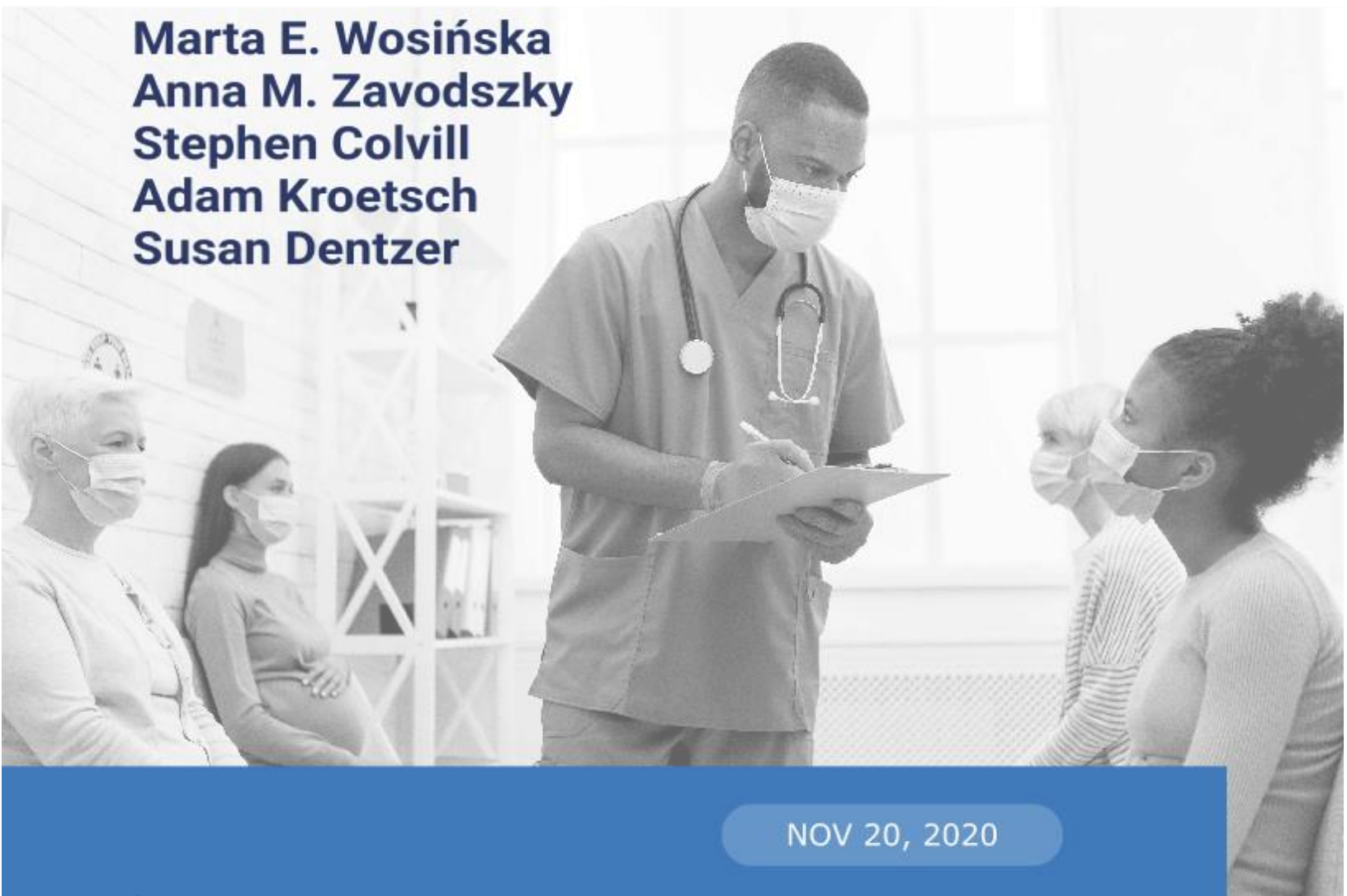


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**Right Patient, Right Time,
Right Place:
A Critical Challenge of
COVID-19 Monoclonal
Antibodies**

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Disclosures

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Right Patient, Right Time, Right Place: A Critical Challenge of COVID-19 Monoclonal Antibodies

November 20, 2020

COVID-19 monoclonal antibodies are new treatments for mild to moderate disease in high-risk patients age 12 and over, with the potential to lower risk of hospitalization and emergency department visits, thereby relieving burden on hospitals and otherwise mitigating the effects of the pandemic. But using them effectively presents challenges we have [described](#) elsewhere, including that the drugs are most effective if given early in the course of disease. For this reason, it is important to identify COVID-19 patients at the highest risk of hospitalization and death, and to administer the drugs as soon as possible. Yet it will not be possible to provide them to all patients who could potentially benefit because the drugs will be in short supply, at least initially, and because administering them to patients via infusion is complex.

This paper outlines these and other key challenges in the use of COVID-19 antibody treatments and proposes a strategy and framework for maximizing the public health benefits of the drugs in the short-term. While the drugs are in short supply, it will be essential to focus on delivering them to the highest-risk patients early in their disease progression and to prioritize the sites of care that are at the most advanced stage of readiness to handle the task. The framework proposed crosses four domains: (1) determining who are the “right” patients, particularly in the context of the limited evidence available to date regarding which high-risk patients are most urgently in need of the therapy; (2) administering the drugs at the “right” time, namely early in the course of disease; (3) determining which sites are most ready to organize and carry out administration of the drugs; and (4) determining how best to deliver the treatment — either by bringing infusion to the patients, such as in long-term care facilities, or by taking patients to standard infusion sites in hospitals or to other locations. It will be important for state allocation boards, health systems, and other stakeholders to think across all four of these domains to develop the most effective local and regional plans for administering antibody treatments in the short-term.

The paper concludes with a set of recommendations to the federal government and those tasked with allocating the drugs within states to ensure equitable distribution and administration. It also highlights the need for generating additional evidence regarding which patients should be considered at highest risk, when the drug should be used, and in what setting. As this evidence accumulates, the recommendations in this paper may need to be adjusted accordingly. Although the paper does not address payment for diagnosis and administration of these drugs, inadequate payment will result in losses for providers and discourage provision of care. Appropriate payment must thus support timely development of robust and safe mechanisms for delivering antibody treatments to COVID-19 patients.

Introduction

With effective vaccines on the horizon, we are entering the largest but hopefully last major wave of COVID-19. New therapeutics have the potential to ease the rising strain on the healthcare system: monoclonal antibodies, which are lab-created proteins that fight the virus by mimicking aspects of the human immune system, are one such therapeutic. In early November 2020, the Food and Drug Administration (FDA) [granted](#) the first [emergency use authorization](#) (EUA) for a monoclonal antibody (mAb) drug directed at SARS-CoV-2. Developed by Eli Lilly and called bamlanivimab, the drug is authorized for treatment of recently diagnosed, mild to moderate disease in high-risk patients. Another combination of monoclonal antibodies, developed by the pharmaceutical company [Regeneron](#), is also under review by the FDA and could be granted an EUA soon.

These therapies could be an important tool in the war on COVID-19, not only until vaccines are widely available but also beyond that point. Even once vaccines are approved for distribution, it may be months before they are broadly available and have immunized much of the population. Many patients may not be able or willing to vaccinate. Vaccines may also be less effective for those with weaker immune systems, including those who are older or have underlying health conditions.

All these factors mean that there may be considerable demand for antibody treatments. However, meeting that demand will not be easy, especially in the short run. The first COVID-19 antibody on the market, [bamlanivimab](#), is given to COVID-19 patients through an intravenous infusion that takes about one hour, followed by at least another hour of monitoring. Using the drug will require skilled staff to administer, monitor, and potentially intervene in rare cases of infusion-related reactions. Moreover, for the drug to work best, it must be administered when patients have mild or moderate COVID-19 within ten days of symptom onset, not when they are already hospitalized. While easier to administer options are in development, including subcutaneous injection, for now providers must contend with this more complex administration protocol.

In addition to challenges with administering the drug, there is likely to be a substantial gap between the supply of these drugs and the demand for them. With the number of new U.S. COVID-19 cases [now exceeding one million per week](#) (as of the publication date of this paper), perhaps as many as half may meet eligibility criteria for age ([16.5% of population](#)), obesity ([40%](#)), and underlying medical conditions that the FDA cited in its authorization of bamlanivimab. The U.S. government has agreed to purchase some supply of bamlanivimab from Lilly, but the [agreement](#) will initially only cover a small proportion of potentially eligible patients: [100,000 doses at the outset](#), with another 200,000 doses to be delivered by January 2021. The U.S. government also has the option to purchase an additional 650,000 doses of bamlanivimab by the end of June 2021. [Regeneron's product](#), if authorized to enter the market, would boost the nation's COVID-19 antibody supply by 50,000 doses immediately and 300,000 doses within the next few months.

This paper outlines key challenges in the use of COVID-19 antibodies and proposes a strategy and framework for maximizing the public health benefits of these drugs in the short-term. The framework builds on and advances [guidance](#) recently issued by Operation Warp Speed, the federal effort to accelerate development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Our framework crosses four domains: (1) determining who are the “right” patients; (2) administering the drugs at the “right” time, namely early in the course of disease; (3) determining which sites are most ready to organize and carry out administration of the drugs; and (4) determining how best to deliver the treatment – either by bringing infusion to patients, such as in long-term care (LTC) facilities, or by taking patients to standard infusion sites in hospitals or to other locations. It will be important for state allocation boards, health systems, and other stakeholders to think across all four of these domains to develop the most effective local and regional plans for administering the drugs in the short-term.

The paper concludes with a set of recommendations for the federal government and those tasked with allocating the drugs within states to ensure equitable distribution and administration.

Determining the “Right” Patient

With a drug in short supply and a non-trivial cost to administer it, the drug must be targeted at those who are most likely to benefit. A bamlanivimab trial analysis highlights the importance of targeting: a [post-hoc analysis](#) of high-risk patients finds that the number needed to treat (NNT) to prevent an ER visit or hospitalization was about 10 patients for the high-risk group (65 and up or BMI of 35 or more) versus about 21 patients in the full study cohort that also included patients at lower risk. In this study, the differential appears related to baseline risk rather than differential efficacy of the drug because the high-risk group had a similar percentage decrease in hospitalizations (71%) relative to the overall group (75%).

Professional societies have indicated that they will analyze existing clinical trial data to provide guidance. The Infectious Diseases Society of America (IDSA) released [guidance](#) on November 18, making a conditional recommendation “against the routine use of bamlanivimab” for outpatients due to low certainty of evidence. IDSA remarked, however, that for high-risk patients, “bamlanivimab is a reasonable treatment option if, after informed decision-making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events.”

Although critically important, it appears that clinical analyses alone will likely provide limited direction for identifying patients at *highest* risk of hospitalization because the [sub-analysis](#) referenced above was for patients aged 65 and older or with a BMI of at least 35, criteria that describe nearly half of U.S. population. Obtaining additional data from clinical trials and other sources of evidence is thus a high priority to determine which patients will benefit the most. In the meantime, decisions regarding which patients to prioritize can be informed by large-scale analysis of baseline risk for hospitalization and death among COVID-19 patients with risk factors listed in the bamlanivimab EUA.

Considerable data on risk factors for COVID-19 related hospitalization and death exist but are not well systematized. Among COVID-19 risk factors, age predominates: the U.S. Centers for Disease Control and Prevention (CDC) [estimates](#) that compared to 18-29 year olds, those aged 65-74 have a 5 times higher hospitalization rate and a 90 times higher death rate from COVID-19, while those 85 and older have rates 13 times higher for hospitalization and 630 times higher for death. According to the CDC, certain [medical conditions](#), such as obesity and diabetes, also increase likelihood of adverse outcomes. It is the existing baseline risk among COVID-19 patients, not antibody clinical trials, that appears to be the foundation for the scope of [EUA's high-risk groups](#).

To support provider decisions for equitably allocating antibodies, more data will be needed on what combinations of risk factors increase the likelihood of adverse outcomes. For example, is a 40 year old obese, diabetic patient at higher risk of hospitalization than a 55 year old with hypertension? The CDC is [already attempting](#) to compile more evidence that can help answer such questions and shed light on disease progression among subgroups of high-risk individuals. This paper recommends below that these efforts be scaled up even further to support decision-making about the use of antibody treatments in addition to considerations, including ethical considerations, that go beyond hospitalization risk.

Determining the “Right” Time

A critical factor in the use of COVID-19 antibodies is getting them to patients at the “right” time: early in the course of disease and before patients need acute care. This issue creates further complexity for state allocation boards, health systems, and others seeking to prioritize use of antibodies, since people in the early course of COVID-19 may be pre-symptomatic or only mildly symptomatic; may be unaware that they have the disease; and thus, may not be actively engaged with the healthcare system at this point in their illness. Below, we discuss relevant considerations and provide recommendations for how patients who can benefit from antibody treatment can be identified as soon as possible.

Existing guidance for use of antibodies suggests that they should be used on patients who test positive for COVID-19 and who are experiencing symptoms of the disease. For example, the [bamlanivimab EUA fact sheet for providers](#) calls for administering the drug as soon as possible after positive test results for SARS-CoV2 are received and within ten days of symptom onset; it also excludes use in patients who are hospitalized or require oxygen therapy. (Lilly [suspended](#) the arm of their trial focused on hospitalized patients for lack of efficacy.) [Regeneron's drug](#), still under review, had an even earlier administration cutoff in an earlier trial report: outpatient participants were randomized within one week of symptom onset and three days of confirmed positive SARS-CoV2 test results.

A public health quandary is that many patients who have tested positive for COVID-19 and who have mild symptoms may not be actively engaged with the healthcare system at this point in their illness precisely when they are most likely to benefit from antibody treatment. This gap

may be even stronger amongst racial and ethnic minority populations in the U.S. who have lower trust of the medical and research communities due to historical clinical abuses. With a COVID-19 antibody on the market, there will be a treatment option for early disease, but it comes at a time when healthcare system capacity is becoming severely strained with an increasing number of hospitalizations.

Amid this quandary, providers must think through how they will address this timing issue, particularly in tandem with the patient-risk considerations outlined above, and the fact that restricting timing from ten days post-symptom-onset to a shorter window may be another way to address shortages. In turn, state allocation boards for COVID-19 antibodies will need to consider provider readiness to administer the drug while it is still effective.

There are additional steps that should be taken by various actors — including health plans and entities running COVID-19 testing sites — to identify appropriate patients. State public health departments, health systems, and others will want to engage with health plans and testing entities to plan for and execute these procedures, as follows:

- **Proactively identifying high-risk individuals.** In some cases, high-risk individuals may be in readily identifiable settings, such as long-term care facilities, while others will be in the community. Health plans are well positioned to identify select high-risk members even before they seek testing about steps to be taken should they begin experiencing COVID-19 symptoms. For example, that process could include directing patients to a dedicated testing site or a request to contact specific healthcare providers should the patient test positive outside of the plan's testing purview. For clinically underserved communities and uninsured individuals, states or community organizations may want to develop tailored public health messaging around antibody treatment eligibility and accessing care.
- **Leveraging testing sites for identification of high-risk patients.** If high-risk patients are not identified before they are tested, opportunity still remains to screen for high-risk criteria at testing sites or concurrently with return of positive results, notifying patients that they may qualify for antibody treatment and that they should take specific steps to obtain care. Such communication could either be payer-specific or collate information across many different payers, including treatment options, if any, for those without insurance.
- **Ensuring prompt COVID-19 test turnaround for high-risk patients.** Assessing patients' risk level before testing, directing them to designated testing sites, and prioritizing the tests of those individuals could be an effective way of identifying patients early in their course of disease, although that may be challenging when balancing other priority groups such as healthcare and essential workers. If identification of high-risk patients only occurs at time of testing (as opposed to before), it may not be possible to expedite these individuals' test results as general testing sites may not have the ability to catalogue such information. If PCR testing capacity is limited, health systems may consider referring

patients to treatment based on point-of-care or rapid testing results alone, a [recommendation](#) also made by Operation Warp Speed.

- **Referring high-risk patients to treatment as soon as they test positive.** Expediting the test-to-treatment timeline may benefit from a direct referral to an infusion site, in addition to notification of the patient’s physician. Referring patients from testing to a smaller cadre of prescribers at referral infusion sites also has the advantage of lowering variation in how shortage protocols are applied.

Determining the “Right” Place

In addition to identifying the appropriate patients at the right time for receipt of COVID-19 antibody treatment, health systems, state allocation boards, and others must consider the “right place” for administering the therapy. There are, in fact, multiple dimensions to this question. One is the state of readiness of a care site to organize, stage, and deliver care. The other is how to deliver care from an operational and spatial perspective.

The state of readiness of a given health system or other care site to organize, stage, and deliver antibody treatment is, itself, a complex question in the time of COVID-19. Hospitals and emergency departments, usually well positioned to administer infusions and engage if reactions occur, may now be so overwhelmed with treating hospitalized COVID-19 patients that they may see themselves as stretched too thin to take on the additional responsibility of treating ambulatory COVID-19 patients with antibodies. Similarly, long-term care facilities may be very ready to help identify the appropriate patients among their residents, but some may be reluctant to bring outside providers onsite to conduct infusions due to infection risk.

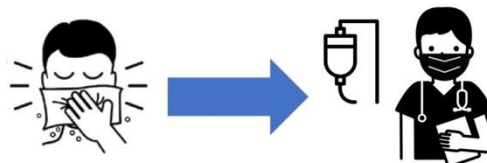
Staffing considerations will also loom large for infusion sites and providers. With the surge of COVID-19 throughout the country, acute care facilities are increasingly experiencing staffing shortages. Infusions need to be administered by nurses with appropriate training, and, in some instances, there may need to be physician involvement and oversight as well. Regulations and medical guidance over appropriate staff-to-patient ratios will apply. In all of these scenarios, inadequate payment would limit availability of staff to administer the antibody treatment.

There are also important considerations regarding the readiness of health systems or others to undertake the multiple steps necessary to ensure timely and safe delivery of care. Infusion sites must schedule treatment so that referred patients obtain antibodies when they need them, and they must ensure that the drugs are available when patients arrive for infusions. However, the timing and exact quantities of antibody shipments from distributors such as AmerisourceBergen, as directed by states, will be uncertain. As long as the supply of drugs remains limited through normal commercial channels, providers may need to assign specific doses to specific patients at the time an infusion is scheduled and avoid overscheduling by bringing in only the numbers of patients they know can be treated based on the number of doses on-hand.

Below, we discuss some of these considerations as well as the broad implications of the two alternative pathways for delivering the drugs to patients.

Bring the patient to the infusion site

Directing patients go to infusion sites for care is the usual option for non-COVID-19 infusion treatment. However, traditional channels of delivering infusions —

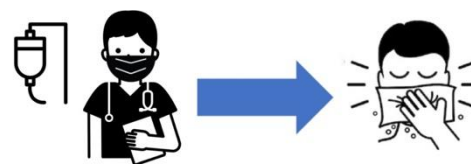


emergency rooms and infusion centers — may not be well suited for delivery of COVID-19 antibodies. Emergency departments are already overwhelmed and are often not well set up for constructing a separate area for patients with COVID-19. Although there is an existing infusion center infrastructure across the country, the main users are immunocompromised patients. Dedicating entire existing infusion centers to COVID-19 patients may only be feasible in dense urban areas with a large infusion center footprint.

Fortunately, the infusion of COVID-19 antibodies does not require much specialized equipment: a refrigerator, IV bag stands, IV tubing with filter, vital sign monitoring equipment, emergency medications, and comfortable chairs. In effect, infusion sites may be no more complicated to set up than pop-up facilities often created to conduct blood drives. As a result, to better target high-risk populations in the community, temporary infusion sites could be set up in convenient, trusted locations such as community centers, school gymnasiums, faith-based establishments, or any large rooms with sufficient air circulation and ability to accommodate patients not only receiving infusions but also those in post-infusion observation. Such a strategy would constitute, in effect, a halfway measure — bringing infusion sites closer to patients in their communities, even if they would still need to travel to those sites from their homes or other locations.

Bring the infusion site to the patient

An alternative, complementary model is the home-infusion model, which brings infusion directly to patients in their residence, be it their homes or LTC



facilities. Although not without its own challenges, this model does have a number of advantages and could be an important supplement to the more traditional infusion site model. Most importantly, the model enables targeting of high-risk patients who otherwise might have limited access to infusion sites. Otherwise, LTC residents, for example, with mild or moderate COVID-19 will very likely miss out on antibody treatments, as there are simply not enough staff and resources to take mildly sick residents to appointments that require at least three-hour round trips and pose infection risk to staff.

Just as with the infusion site model, a bring-to-patient model must address the need to identify the “right” patient and also assure that the process of testing, prescribing, and scheduling will

allow antibody treatment administration to take place early in the disease progression. An existing home-infusion model is well set up to coordinate such care: under this model, a home-infusion company obtains orders from the physician; acquires, prepares, and delivers the drug to the home; and arranges skilled staff to administer the drug and monitor for adverse events. Primarily used by commercial and Medicare Advantage insurance plans because of greater payment flexibility compared to traditional Medicare, home-infusion agencies provide care for select patients with ongoing administration of specialty drugs, including monoclonal antibodies. Adopting this model to COVID-19 antibodies could help alleviate many of the issues that would otherwise arise in coordinating care.

Although scalability of the bring-infusion-to-patients model is unclear, it should be explored for COVID-19 antibodies, in large part because it holds particular advantages for getting the drugs to high-risk patients early. Many LTC facilities already do antigen screening tests to identify potential outbreaks, which would give them a head start on identifying appropriate patients quickly. If home-infusion agencies or companies were notified immediately upon detection of an outbreak, they could help coordinate delivery of drugs and supplies and perform on-site administration.

States and other stakeholders should take steps to test the bring-infusion-to-patients model and its scalability. To assess readiness of the LTC community, state health departments should consider surveying these facilities in their state to determine their willingness and ability to administer antibody treatment directly or through home-infusion providers. The survey accompanying CDC's [Pharmacy Partnership for Long-term Care \(LTC\) Program](#) created for vaccine distribution can serve as a good model for gaining such insights. States should also encourage pilots of partnerships between LTC facilities and home-infusion companies.

Allocating Drug Supplies Equitably

A key issue facing states is how best to allocate supplies of COVID-19 antibodies within their boundaries. At present, to distribute the supply of bamlanivimab it purchased from Eli Lilly, the federal government is using a [model](#) similar to the one it has used in distributing the antiviral drug remdesivir for treatment of COVID-19 patients, as described below. It is unknown at this time whether the federal approach may change in January under the administration of President-elect Joe Biden. For now, state public health departments and state allocation boards will need to establish intrastate allocation protocols and identify other ways to support providers in administering these drugs to the right patients, at the right time and in the right place.

Under the approach used in remdesivir distribution, the federal government allocated specific supplies to states, with states then making further allocation and distribution decisions themselves. Some states appear to have delegated these decisions to their state health departments or public health agencies, while others designated state-appointed boards that include representatives from health systems and hospitals to make these decisions. In the case of COVID-19 antibodies, the federal government will [notify](#) states weekly about their new

allocations of available antibody supply, which will be based on reported data from each state on 7-day new hospitalizations (a lagging indicator, but related to health system stress) and confirmed cases.

On November 10, U.S. Department of Health & Human Services (HHS) [announced](#) an initial [allocation](#) of about 79,000 doses of bamlanivimab. For this first distribution, HHS has asked states to [limit](#) the allocation to hospital systems and hospital-affiliated locations. However, HHS has also announced that following this initial phase, allocation to states will shift towards a model in which states can direct the federal distributor to deliver the drug to other outpatient locations as well.

This second phase will be critical in maximizing the benefit of bamlanivimab in preventing hospitalizations, while preventing the overburdening of already overcrowded emergency departments and hospital settings. Many states already appear to have resurrected their remdesivir allocation boards and tasked them with allocating bamlanivimab. To achieve equitable intrastate antibody distribution, however, states should reassess whether the remdesivir allocation model, which supported a hospitalized patient population, is applicable to COVID-19 monoclonal antibodies.

As discussed above, many of the high-risk populations who are likely to benefit from COVID-19 antibody treatment are in the community or LTC facilities, and thus not within hospital systems' immediate sphere of influence. They also include racial and ethnic minority populations with higher rates of underlying medical conditions but who may be less likely to engage frequently with the healthcare system due to limitations on their finances, time, and transportation options, or due to a general distrust of the medical community. Still another group of potentially high-risk patients may be those with underlying medical conditions who are uninsured or have high deductible health plans that impose further financial burdens on them when accessing healthcare.

To maximize the public health benefit of COVID-19 antibodies will require several modifications of the existing remdesivir-based distribution and allocation system at both the federal and state levels. At the federal level, for example, the government should reinforce states' and their providers' ability to plan by creating some level of predictability over future supply, either by establishing a baseline amount they can expect each week or by making public the amount of product to be shipped and the allocation mechanism across states. These regular updates to states would give them greater ability to plan and allocate supplies to areas and patients of greatest need.

At the state level, concerted efforts should be organized among hospital systems, health plans, public health officials, and the LTC community to consider modifications of the remdesivir-based distribution protocols in the allocation of antibodies. The "repurposed" remdesivir allocation boards within the states should develop a common set of criteria that providers should use, focus allocation on providers that identify readiness, support development of evidence, leverage intrastate data to make the intrastate allocation more responsive to local conditions, clarify

cross-jurisdictional movement of drugs, and evolve the allocation mechanism as more information becomes available. For more detail, please see the Recommendations section.

Recommendations

This section lays out recommendations for the federal government and state allocation boards. Some recommendations will also apply to other stakeholders such as hospitals, health systems, LTC facilities, COVID-19 testing entities, and others, as outlined below.

Recommendations for federal action

To support the states' efforts for equitable distribution of COVID-19 monoclonal antibodies, the federal government should undertake the following measures, many of which are informed by experience with remdesivir and with the more traditional shortages of non-COVID-19 drugs:

- **Collate existing evidence on baseline risk factors** for hospitalizations and emergency room visits, expanding the existing [rate ratios by age](#) to obesity and comorbidities (including multiple comorbidities).
- **Refine clinical guidelines for treatment** with COVID-19 antibodies in light of shortages, using [CDC H1N1 vaccine guidelines](#) as an example.
- **Support development of evidence** around effectiveness of the drugs in specific patient populations and new outreach models, for example in LTC settings or neighborhoods with disproportionate share of high-risk patients.
- **Reinforce states' ability to plan** by informing states of upcoming distribution totals and the allocation mechanism for distribution across states. Greater predictability over future supplies will allow states and providers within that state to adjust their shortage protocols and allocation plans.
- **Allow states to forego a share of their allocation while holding some** with AmerisourceBergen until there is greater readiness among providers. Reallocation of product among providers is challenging, so allocating a product to not-ready providers will result in product not being used in the "right" patients at the "right" time. Holding some product may encourage states to forego some product that could be used more effectively elsewhere.
- **Balance hospitalizations with risk-adjusted cases** when allocating the drugs to states, not only because hospitalizations are a lagging measure but also to avoid capping allocation in states where hospitals are at peak capacity and therefore turning away some patients.

- **Adapt the allocation mechanism** as more and better data becomes available. The data may include newly standardized data, better evidence clinical evidence that would allow for refinement of allocation measures, or improved information about state readiness for using the drugs effectively.

Recommendations for states (state allocation boards and state public health departments)

To maximize the public health impact of COVID-19 monoclonal antibodies, state allocation boards should undertake the following measures:

- **Develop a common set of criteria that providers should use** to allocate the drug to their patients. This effort could be undertaken by relevant stakeholders, such as the state’s allocation board, or especially in smaller states could be delegated to others, such as a large hospital or health system. For example, by delegating remdesivir allocation to one large hospital, one state ended up with a common set of inclusion and exclusion criteria for patients who would be deemed eligible for receipt of remdesivir.
- **Expand the possible set of providers beyond what was used with remdesivir.** Effective models may include stand-up infusion sites, home-infusion companies pairing up with LTC facilities, or administration by internal staff at SNFs.
- **Focus allocation on providers that demonstrate readiness** for identifying high-risk patients early in disease progression. Allocating to providers not ready for the “right patient, right time” will result in a waste of a scarce resource. While reviewing plans for action may not be workable, allocation boards could develop checklists, such as that provided by Operation Warp Speed (OWS) in its [“OWS Therapeutics: Monoclonal Antibody Playbook,”](#) to identify elements that providers need to consider before requesting supply of the drug.
- **Support development of evidence** around effectiveness of the drugs in specific patient populations and new outreach models, for example in LTC settings or low-income neighborhoods. Providers are expressing reluctance over undertaking significant process and staffing commitments for a drug with limited clinical evidence. Concentrating the drug with ready and willing providers, coupled with data collection on outcomes and logistical lessons learned, will enable evidence development needed to instill provider confidence.
- **Allocate product to able providers based on risk-adjusted cases,** leveraging intrastate data on cases across age groups, measures such as the [CDC Social Vulnerability Index, Mapping Medicare Disparities,](#) and other intrastate data that might provide insight on rate and extent of relevant underlying health conditions. Using state data on risk-adjusted cases will not only be timelier than the lagging hospitalizations, but will avoid

capping allocation in areas where hospitals are at peak capacity and therefore turning away some patients. Paradoxically, an allocation model based on hospitalizations could actually penalize particularly successful efforts that are preventing hospitalizations by targeting high-risk patients early. Perversely, allocating fewer doses to these regions could increase hospitalizations.

- **Clarify cross-jurisdictional movement of drugs.** With remdesivir, county-level allocation in one state led to conflicts as to whether patients residing in one location would be eligible for remdesivir if they were hospitalized in a different county. Policies should be clarified as to whether patients should be eligible for antibody treatment based on their residency, health plan membership, infusion site, or other criteria.
- **Evolve the allocation mechanism** by incorporating new evidence from clinical trials and pilots, which stratify high-risk patients, and other efforts that identify best practices for expedient delivery of the drugs to high-risk patients.
- **Ensure that a listing of participating outpatient sites, along with allocation quantities, are communicated to AmerisourceBergen** to leverage the capabilities of the federally-contracted distributor. Operation Warp Speed provides guidance, including weekly stakeholder calls, on communication between states and AmerisourceBergen. Sharing of allocation best practices across states will also be critical.

To identify high-risk patients early in the course of disease, state public health departments should work with health systems, other providers, health plans, entities operating testing programs, and others to undertake the following measures:

- **Launch pilot programs** that can assess feasibility and effectiveness of new outreach models, for example in LTC settings or communities with disproportionate shares of high-risk individuals. For clinically underserved communities and uninsured individuals, states may want to develop tailored public health messaging around antibody treatment eligibility and accessing care.
- **Request that health plans** identify select high-risk members even before they seek testing about steps to be taken should they begin experiencing COVID-19 symptoms. For example, that process could include directing patients to a dedicated testing site or a request to contact specific healthcare providers should the patient test positive outside of the plan's testing purview.
- **Ask testing sites to screen patients for high-risk criteria**, and to encourage them to collaborate with plans and other relevant stakeholders on notifying high-risk patients about treatment options if they already have, or begin experiencing, COVID-19 symptoms. Information about when patients began experiencing symptoms could also be recorded at that time, since under the FDA's current EUA protocol, bamlanivimab must be administered within ten days of symptom onset.

- **Assess readiness of LTC providers** by surveying facilities in their state about their willingness and ability to administer antibody treatments directly or through home-infusion providers. The CDC's [Pharmacy Partnership for Long-term Care \(LTC\) Program](#), created for vaccine distribution, can serve as a good model for gaining such insights.