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# PROMISING PRACTICES FOR PROMOTING UTILIZATION OF COVID-19 MONOCLONAL ANTIBODY TREATMENTS

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Dr. McClellan, who directs the Duke-Margolis Center for Health Policy, was Commissioner of the Food and Drug Administration from 2002-04 and Administrator of the Centers for Medicare and Medicaid Services from 2004-06. He is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomiQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

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## Promising Practices for Promoting Utilization of COVID-19 Monoclonal Antibody Treatments

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This Duke-Margolis resource on COVID-19 response policies is intended to inform and help guide policy makers addressing the evolving COVID-19 pandemic in the United States and around the globe, and will be updated as the pandemic and response capabilities change over time.

It contains recommendations for a U.S. Federal response as well as steps and resources for stakeholders across the health care ecosystem. We will add further resources to address a range of related, critical policy challenges.

We thank our many collaborators, co-authors, and reviewers who have contributed significant expertise and guidance on these rapidly evolving issues. Please reach out to us with additional suggestions for resources and effective policies at [dukemargolis@duke.edu](mailto:dukemargolis@duke.edu) - we welcome your input.

Health care providers are increasingly using [monoclonal antibody treatment for COVID-19](#) with intent of avoiding downstream hospitalizations or serious complications for newly infected, high-risk COVID-19 patients. While the initial COVID-19 antibody treatments were authorized for emergency use based on limited clinical trial evidence, recently reported [results](#) from larger clinical trials have confirmed substantial benefits with little evidence of safety problems for patients who have not progressed to more severe symptoms. These studies show similar efficacy across available treatments, benefits with [shorter infusion times](#), and benefits as potential prophylaxis in [households](#) and [nursing homes](#); further studies are nearing completion and more products in development. A range of innovative infusion practices across a number of different care settings are contributing to increased access and use. And supplies are growing for the approved treatments—Eli Lilly’s bamlanivimab and bamlanivimab/etesevimab combination and Regeneron’s casarivimab/imdevimab combination—as well as other COVID-19 antibody treatments that could soon file for emergency use authorization.

However, a number of [obstacles](#) to routine use still remain. Setting up infusion sites requires a redesign of usual COVID-19 care, and many providers do not have systems in place to refer patients to nearby COVID-19 antibody treatment in a timely manner. Some providers are still not aware of how to access COVID-19 antibody treatment. Many patients and providers may not have adequate information or referral materials that can enable informed decisions to be made and access to treatments in a timely manner. Furthermore, in some care settings like in-home infusion for patients who cannot easily reach an infusion center, payment challenges are

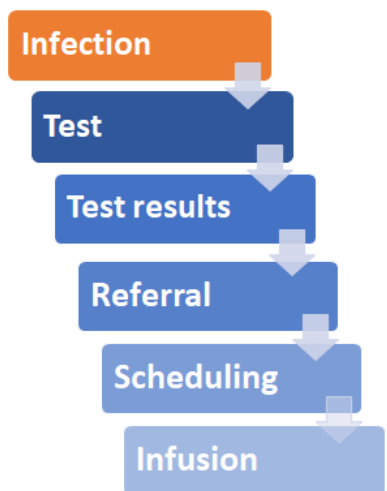
impeding access to these treatments at scale. An additional obstacle to more widespread use is the limited but improving evidence on COVID-19 antibody treatments; evidence issues and how to address them are the subject of a recent Duke-Margolis [issue brief](#).

**In this report, we highlight a range of promising practices and approaches to overcoming access and administration obstacles and summarize steps that a variety of actors within the patient care process can take to further improve use of COVID-19 monoclonal antibodies.** These practices have been distilled from ongoing contributions from a multi-stakeholder working group, individual stakeholder interviews, and publicly available materials. They include a number of practical approaches that health systems, community providers, long-term care (LTC) facilities, testing sites, in-home infusion practices, payers, and others can take together to realize the potential of these treatments and significantly reduce serious complications for early-stage, high-risk COVID-19 patients.

### *The Care Pathway for COVID-19 Antibody Use*

Figure 1 illustrates the key steps in the care pathway for COVID-19 antibody use. These steps must be completed in a timely manner because emergency authorization by the U.S. Food and Drug Administration (FDA) stipulates use within no more than 10 days of symptom onset, with evidence suggesting that earlier use may be more beneficial.

**Figure 1: Care pathway for COVID-19 antibody treatment**



The care pathway for COVID-19 antibody treatment includes multiple steps, with potential failures at each: a patient must obtain a COVID-19 diagnosis backed by a positive test, obtain a prescription for an infusion, and then identify a site for infusion either on their own or in collaboration with their prescriber, schedule the infusion, and have the treatment administered.

Unless the patient is in an integrated system, each one of these steps may involve a different organization: the patient’s primary clinician may be in a community practice; the COVID-19 test may occur at a pharmacy or other standalone testing site; and the infusion site may be affiliated with a hospital or infusion clinic.

Especially if patients and clinicians do not have up-to-date information related to COVID-19 antibody treatment, patients may not advance through all of these steps. Individuals at high risk of adverse outcomes from COVID-19 may not be aware that a treatment is available and thus may not start on the care pathway (beginning with testing or health care provider visit) until their condition becomes severe. Patients who receive a COVID-19 test without consulting their usual

health care provider may not receive clinical guidance in a timely manner. Prescribers may also be reluctant to prescribe or not know where to refer their patients for treatment. And some patients drop off between scheduling and infusion—either because they are feeling better, have trouble finding transportation to the infusion site, or have other reservations about treatment.

Despite these challenges, antibody use is rising due to the emergence of successful approaches to implementing effective care pathways across a range of settings. Here, we have compiled examples of promising practices in four major areas that increase the likelihood that a patient can successfully access an infusion:

- Steps that health care providers can take to streamline the **care process**;
- **Education** of patients, prescribers, and infusion providers on opportunities to improve access and make decisions about effective use;
- **Footprint** expansion to improve equitable access for patients; and
- Adequate **payment** for infusion, particularly for patients who cannot easily reach an antibody infusion center.

These four areas are described in greater detail below, with examples of how providers, payers, and state and local leaders are expanding access to COVID-19 antibody treatment and assuring that patients receive timely information on treatment.

### *Care Process*

Many **integrated health plans** have implemented reforms to advance patients through the entire care pathway in a timely manner, because the care pathway either does or can fall entirely within their control—testing, results reporting, referral, and infusion may either occur with the entire process supported by an integrated electronic health record (EHR) system or with EHR supports for the entire process. A positive test result can be automatically matched to a patient’s risk profile and the patient referred to a clinician or care manager to assess their eligibility for infusion, to obtain treatment permissions, and to schedule the patient for infusion. Some systems noted in stakeholder interviews that they are utilizing rapid tests and standing prescription orders as part of this expedited pathway.

UnitedHealth Group (UHG), in a real-world [study](#) setting supported by Eli Lilly, has taken further steps to streamline the care pathway. UHG provides members with at-home tests to use in case of a possible exposure or unexpected appearance of symptoms, with rapid telehealth consultation enabling assessment and referral for COVID-19 antibody treatment, utilizing both in-home testing and in-home infusion as appropriate.

But for many COVID-19 patients, the path to COVID-19 antibody treatment is through independent health care providers not affiliated with a health system or infusion site. These

health care providers can take steps to streamline parts of the COVID-19 antibody treatment pathway. **Clinicians in stand-alone practices** or other **non-integrated systems** can use their EHR systems to proactively identify and alert their high-risk patients. These providers can then support patients in gaining access to timely testing when they have symptoms and quickly refer them for testing if results are positive using established relationships with testing centers.

**Stand-alone testing sites** can also help connect appropriate patients to testing. For example, LabCorp and Quest have electronic notification systems about positive results for most referring health care providers. In general, test centers can inform patients who may be eligible about the availability of COVID-19 antibody treatment and how to get an infusion in the area (some refer patients directly to clinicians at nearby infusion centers), bridging testing to care by educating patients about next steps. Coram, the home infusion arm of CVS, worked with Mass General Brigham to develop educational leaflets to be distributed at Mass General Brigham testing centers, informing COVID-19 positive patients about antibody infusion. However, the practice of testing sites providing such information does not currently appear to be widespread—a missed opportunity.

Bridging between testing and infusion may be possible not only in integrated health systems, but in all settings that can administer tests and infusions, such as **Federally Qualified Health Centers** (FQHCs) and urgent care clinics. St. John's Well Child and Family Center, an FQHC in Los Angeles, California, was already running testing sites for their community before becoming the [first community health center](#) in the U.S. to set up a COVID-19 antibody infusion program. Urgent care clinics and emergency rooms are also well suited for bridging testing and infusion. Cigna is [using](#) its network of urgent care centers to offer treatment for qualified high-risk patients that test positive.

To bridge testing, referral and infusion, some primary care groups have partnered with independent infusion companies. For example, one primary care group in the Northeast entered into an arrangement with [OI Infusion Services](#) to provide bamlanivimab infusions to COVID-19 positive patients 18 years or older within 10 days of mild to moderate symptom onset. As part of the arrangement, the primary care group is the provider, responsible for billing and collecting of the services, and providing suitable space for the infusion center and physician oversight. The infusion provider is responsible for clinical nurse staffing and equipment and supplies procurement.

To help **independent health care providers** make timely referrals to unaffiliated infusion sites, the National Infusion Center Association (NICA) has expanded their preexisting [infusion center locator](#) to include specific information about COVID-19 antibody treatment locations. Mass General Brigham also created a portal for prescribers outside its system to make it easier for them to refer patients to Mass General's infusion sites.



**Skilled nursing facilities** (SNFs) and assisted living facilities with patients at relatively high risk for COVID-19 infection and complications can also take steps to streamline the antibody care pathway. The Centers for Medicare & Medicaid Services (CMS) requires SNFs to provide regular screening testing and timely symptomatic testing for residents and staff. Other elderly congregate living facilities have also taken steps to provide timely testing for those with COVID-19 symptoms or exposure. However, SNF residents with early COVID-19 will likely miss out on antibody treatment if they must be transported with staff support to an infusion center, something that is challenging for both the infected patient and the staff.

The antibody care pathway for patients in such settings depends on whether the facilities can administer infusions. SNFs capable of administering infusions can obtain access to COVID-19 antibody treatments through LTC pharmacies, which can obtain COVID-19 antibody treatment doses directly from the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response's [Special Projects for Equitable and Efficient Distribution \(SPEED\) program](#). Other facilities may have existing relationships with health systems that can provide in-facility infusion. For example, SSM Health developed referral protocols for their affiliated nursing homes to provide COVID-19 antibody treatment through the system's infusion program.

**SNFs and other LTC facilities without staff to administer infusions** likely need to arrange antibody administration through home infusion providers. This is another area where the [SPEED program](#) can help create a more direct pathway for LTC facilities, FQHCs, dialysis centers, and correctional facilities to improve access to antibodies. Such programs may need additional funding or higher reimbursement rates to scale, as we describe in more detail below.

### *Education*

With emerging evidence, continually updated recommendations and practices, and evolving access to infusion sites, many health care providers may not be familiar with the best options for antibody use for their patients. A growing array of resources are available to address these information gaps.

#### *Informing prescribers*

Many organizations that have implemented programs to support timely antibody access have shared their experiences to increase familiarity with their use. Mayo Clinic, for example, has disseminated [patient](#) and [health care provider](#) experiences via various modes of communication. Other health systems are also taking steps to educate their clinicians about referral processes. Northwell Health, a New York **health system**, [has sent a number of informational resources](#) about COVID-19 antibody treatments and referral processes to in-system and affiliated health care providers to promote awareness.



Some state and local health authorities have created [resources](#) to inform prescribers about how to refer patients to regional infusion sites. [Los Angeles County](#), for example, provides clear steps online for SNFs to request antibody treatment.

#### *Supporting potential infusion providers*

COVID-19 antibody infusion requires an infusion capacity with appropriate infection precautions separate from infusion centers serving non-infected patients. There are multiple resources to help potential providers of these antibody infusions set up the capacity to do so. ASPR's website includes a descriptive [example](#) of a 15-chair antibody infusion center, describing important factors including staffing needs, facility layout, criteria and protocols, additional resources, and payment considerations.

Project ECHO (Extension for Community Healthcare Outcomes), with support from ASPR, has been hosting a weekly [Outpatient Therapeutics Mini-Series](#) webinar educating clinicians about various aspects of COVID-19 antibody treatment from managing infusion reactions to implementing infusion programs in diverse settings like FQHCs and LTC facilities. Project ECHO also has an extensive list of resources on their website regarding COVID-19 antibody treatment for a wide range of providers.

Professional societies and trade organizations have also developed resource libraries. NICA has extensive sets of resources on their website to support COVID-19 infusion [providers](#). The American Society of Consultant Pharmacists (ASCP) and the Society for Post-Acute and Long Term Care Medicine (AMDA) jointly developed a [readiness document](#) to assist **LTC pharmacies and facilities** in obtaining COVID-19 antibody treatment doses through the [SPEED program](#) and effectively implementing treatment programs.

#### *Informing patients*

A range of promising practices and resources have been developed to help clinicians, health systems, insurance plans, public health officials, and state leaders provide timely information to patients about antibody use. ASPR has released a [Monoclonal Antibody Therapeutics Digital Toolkit](#) with educational material about treatment options tailored for various social media platforms and a variety of patient demographics to increase patient awareness of treatment availability and eligibility criteria. Additional materials from HHS can be found [here](#).

State leaders can play an important role in communicating about the availability of COVID-19 antibody treatment. The governor of Texas, for example, has made [favorable statements](#) to raise awareness of COVID-19 antibody treatment, and the infusion centers the state has helped open received significant [media coverage](#) that can play a part in expanding patient awareness of COVID-19 antibody treatment.

Many health care organizations that proactively identify high-risk patients with confirmed COVID-19 test results have developed educational materials to help patients make timely, informed decisions about antibody use. For example, Mayo Clinic has developed a [video](#) to educate patients identified for treatment. In addition to direct outreach by their health care team, [Houston Methodist](#) has created culturally appropriate materials to facilitate education and engaged in community outreach both in English in Spanish. For patients affiliated with independent health care providers, NICA developed a COVID-19 antibody treatment [patient portal](#) and an [infusion center locator](#).

Some health care providers are implementing partnerships to inform high-risk patients about availability of COVID-19 antibody treatments and the need to get tested and engage with a clinician soon after symptoms appear. With support from the [COVID Plasma Initiative](#), Mount Sinai Health System has [developed](#) patient resources and organized patient-focused webinars featuring Mount Sinai clinicians. Initially launched in the Orthodox Jewish community in New York City, the program is now expanding not only to Latino communities in New York City but also other areas of the country. Their innovative approaches include awareness campaigns through synagogues, churches, and social media; a dedicated 24/7 call center; liaising with hospitals and other infusion sites; an infusion site [locator](#) in the communities they serve; and engaging, pro bono, a marketing [firm](#) to help develop and deploy [TV news stories](#) in Spanish.

### *Expanding Footprint to Reach Underserved Populations*

Many of the high-risk populations who are likely to benefit from COVID-19 antibody treatment may not be in organized systems of care. Racial and ethnic minority populations have higher rates of underlying medical conditions but are less likely to have a consistent and reliable source of care and assistance with care coordination due to limitations on their finances, time, and transportation options or 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. Such patients may not be aware that COVID-19 testing and treatment are available without [charge](#). Residents of LTC facilities may also face barriers to accessing COVID-19 antibody treatment unless the infusion is brought to their facility.

To ensure equitable access to COVID-19 antibody treatments, it is critical for providers and states to consider innovative partnerships and outreach plans to expand their footprint to include such patient populations. In the absence of these steps, it is likely that disparities will continue to emerge in antibody use just as in other aspects of COVID-19 care where substantial disparities in outcomes have been stark.

Some **health systems**, such as [St. Peter's Health Partners](#), are using their urgent care clinics and emergency departments to reach patients who are unable to readily access care elsewhere. [Mount Sinai](#), meanwhile, is partnering with urgent care centers, FQHCs, and grassroots

community organizations to expand the range of patients who can access treatment. They have helped develop educational resources for both patients and clinicians and provided technical expertise to new infusion sites outside their system, including at RefuahHealth and Ezra Medical Center. They have also created an [app](#) that partners can use to refer patients to Mount Sinai for infusion. In addition, [Nebraska Medicine](#) has partnered with a local FQHC to implement a COVID-19 antibody infusion program. In this partnership, the FQHC completes the testing and consent process and the patient can then be infused at Nebraska Medicine, an academic medical center.

Infusion-ready **FQHCs** can request product directly through the ASPR [SPEED program](#) or request it directly through ASPR. The SPEED program was utilized by the previously mentioned St. John's Well Child and Family Center in their efforts to set up a COVID-19 antibody infusion program. To help other FQHCs stand up infusion capability, St. John's put together a [white paper](#) on operationalizing antibody infusion in FQHCs. RefuahHealth, a New York FQHC, has also created a set of [best practices](#) for other FQHCs to follow, taking advantage of rapid COVID-19 testing to speed up the testing to infusion process.

In recognition that many patients especially in urban areas rely on public transportation and may not be able to access same-day infusions, [Mass General Brigham](#) established transportation arrangements with ambulance companies to improve access to treatment. Similarly, the major Maryland regional infusion site at the [Baltimore Convention Center](#) also offers patients free transportation to and from their infusion appointment.

**Home infusion providers** can also help fill barriers in access to treatment in infusion centers. For assisted living facilities or SNFs without adequate staff to administer infusions, participating home infusion providers in the SPEED program [effort](#) in collaboration with the National Home Infusion Association (NHIA) can provide infusions in LTC settings (home infusions are not part of the pilot). The [CVS Coram infusion pilot](#) is currently providing access to COVID-19 antibody treatments in seven metro areas around the country; this pilot could potentially be scaled. Below, we describe issues related to the adequacy of payment in home infusion settings.

In some cases the antibody treatment **manufacturers** themselves are helping to increase access footprints by partnering with regional providers to establish sites that these providers and their patients can then access. Eli Lilly, for example, has set up [infusion centers in Indiana](#) that can also provide access in outbreaks for patients in areas without convenient access to infusion.

**States** can also take steps to promote equitable access to COVID-19 antibody treatment. For example, [Maryland](#) collaborated with health providers and local public health authorities to help stand up regional antibody infusion centers in all regions of the state. Texas also set up various [regional infusion sites](#) through collaborations between the Texas Division of Emergency Management (TDEM), local providers, and county/city governments.

In addition, select states have established strike teams that can be deployed to administer COVID-19 antibody treatments. For example, the Utah Department of Health partnered with the Utah National Guard to establish an [antibody treatment strike team](#) targeting LTC facilities with outbreaks. Similarly, Austin Public Health and the TDEM has set up [strike teams](#) in partnership with [Austin-Travis County EMS](#) and local hospitals to provide mobile units that can travel to nursing homes and provide antibody treatment to those in need.

Finally, states have attempted to encourage uptake by facilitating access to antibody treatments for providers that demonstrate readiness. Massachusetts, for example, has developed criteria for [hospitals](#) and [LTC facilities](#) to receive antibody treatment allocation. The settings must “confirm their capabilities and capacity to safely perform infusions and agree to equitably deliver [COVID-19 monoclonal antibodies] to residents authorized under EUA and consistently with this guidance.” Texas developed an online survey which allows locations to [request](#) antibody allocation from the state and is promoting usage in a variety of settings from acute care hospitals to [nursing homes](#).

### *Infusion Cost and Payment*

Payment adequacy is a key factor in supporting timely, straightforward, and equitable patient access to COVID-19 antibody treatment. If payment is inadequate, providers have an economic disincentive to participate and that may adversely impact patient access to treatment, particularly for lower-income patients in areas with more limited access to care. Currently, antibody supplies are purchased by the Federal government and distributed at no cost to infusion providers. COVID-19 antibody administration is reimbursed by Medicare at \$309 per infused patient, with no patient copays and delivered in any setting—a rate followed by Medicare Advantage plans and most commercial payers.

COVID-19 antibody infusion centers can achieve economies of scale by administering multiple infusions or managing multiple patients simultaneously. The centers can lower upfront costs by leveraging data systems to qualify and schedule a patient. Infusion centers in integrated health systems that rely on person-level payments rather than fee-for-service also benefit from cost savings that infusions might generate downstream by preventing hospitalizations. But independent infusion centers without the benefit of downstream savings may be reluctant or unable to make capital investments to adapt their facilities to safely serving COVID-19 patients while protecting the vulnerable immunocompromised patients typically served by such centers. Infusion centers may also find it challenging to dedicate adequate nursing resources when diverting them towards a lower margin service with uncertain demand.

Larger payment adequacy concerns remain for home infusion providers, which are particularly important for supporting LTC facilities and home-bound patients. These providers have a high marginal (per-patient) cost if they are only infusing one to two patients per individual visit rather

than the more substantial throughput in an infusion center. Table 1 outlines the estimated cost ranges as compiled by NHIA, the home infusion industry association, for the contributing factors to high marginal costs for home infusion. These include the time associated with travel, labor needs associated with sending nursing staff out to individual sites, courier delivery of the COVID-19 antibody treatment itself, and supportive medications that must be ordered by the referring provider and present in case of an adverse event during or after infusion.

Home infusion efforts like the Coram pilot are currently able to manage these costs due to the nature of pilot contract developed with HHS. In the majority of cases, Coram is reimbursed by the infused patient’s primary insurance plan (usually Medicare) at the CMS-set \$309 rate, with HHS paying the balance of a negotiated rate that enables Coram to operationalize the home infusion across the 7 metro areas in the pilot. The impact of tighter reimbursement for other home infusion providers may be contributing to limited and uneven participation in COVID-19 antibody infusion: there [are](#) close to a thousand home infusion providers in the U.S., but only about 5% of them have infused limited quantities of COVID-19 antibody treatment through the SPEED program.

**Table 1: NHIA Home Infusion Cost Survey**

<b>Service or Product Description</b>	<b>Cost (Range)</b>
Onboarding	\$108 - \$420
Other Pharmacy Services (i.e., dispensing, billing)	\$75 - \$300
Direct Costs (i.e., administration supplies, PPE, anaphylaxis kits, delivery)	\$70 - \$313
Nursing	\$180 - \$560
General Administration (35%)	\$151
<b>Total</b>	<b>\$584 - \$1,746</b>

\*Amount paid by Medicare: \$309

Source: [NHIA-SPEED-SUMMARY\\_FINAL\\_020921.pdf](#)

The [newly authorized](#) reduction in infusion time for one of the COVID-19 antibody treatments (bamlanivimab) from 1 hour to 16 minutes has a modest impact on these home infusion costs. With nursing time representing around 1/3 of the infusion cost and lasting around 4 hours, savings of 45 minutes would be expected to lower the home infusion cost by around 5%.

A higher reimbursement rate for home infusion for patients who cannot easily travel to receive services would enhance the availability of needed home antibody infusion services. Options for increasing the payment rate for home infusion and temporary infusion sites include:

- A higher CMS payment rate and private insurer payment rates for home infusion for appropriate patients;
- An add-on payment for home infusion-related services to supplement the base payment rate;

- Combining the enhanced payment rate (aiming to be above marginal cost) with advance purchase contracts involving ASPR (e.g., pilot expansion), states (as described above), or private insurance plans with a home infusion provider to reduce uncertainty about investing in adequate infusion capacity.

### *Conclusion and Next Steps*

States, providers, and payers must take active steps to enhance the impact of COVID-19 monoclonal antibody treatments to prevent hospitalizations and do so equitably. This includes actions that health systems, community providers, LTC facilities, testing sites, and in-home infusion practices can take to improve and streamline the process for access and administration; partner on patient and provider education; and reinforce existing networks to broaden their access footprint. It also includes several potential payment adjustments that could be made for certain settings like in-home infusion to make all potential avenues of access viable at scale. As has been noted here and [elsewhere](#), it also must include continued linkage to evidence development efforts and advanced planning not just for the impact of variant COVID-19 strains but also for access adjustments that may come with potential subcutaneous administration of these therapies.

COVID-19 antibody treatments have already shown considerable potential for reducing hospitalizations and serious health consequences during the short time that they have been available to patients, and the promising practices described here can significantly enhance their impact. Future COVID-19 antibody treatments may be easier to administer, for example in subcutaneous form, so that treatment pathways may become easier and less costly over time. In any case, COVID-19 antibody treatments are likely to continue to provide important benefits as part of a comprehensive short- and long-term response to the pandemic, particularly for patients who are unable or unwilling to be vaccinated or who do not mount an adequate immune response. COVID-19 antibody treatments can also be adapted to neutralize genetic variants of the virus that may reduce vaccine effectiveness to help contain their spread. The sooner effective mechanisms for timely and routine access to COVID-19 antibody treatments can be implemented, alongside progress on vaccination and other therapies, the sooner such a comprehensive approach to moving beyond the pandemic will succeed.