



Implementation of an Emergency Department-Embedded Infusion Center for the Administration of Monoclonal Antibody Therapy in Patients With Early COVID-19 Infection

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ABSTRACT

The coronavirus disease 2019 (COVID-19) pandemic has tested nurse staffing and other resources necessary for life-saving treatment. The emergency use authorization in November 2020 of bamlanivimab as monotherapy and casirivimab/imdevimab as combination therapy brought hope to many as an option for outpatients at risk for severe illness. However, logistical concerns were soon revealed, because safe administration requires a location where patients can receive specialized care and monitoring for a period of 2 hours. This type of therapy would normally be offered at an outpatient infusion center. These centers often serve persons who are immunocompromised, and introducing COVID-19–positive individuals could threaten the safety of this population. This article describes the deployment of an emergency department–embedded infusion center set up for the purpose of supporting community members and providers electing for this treatment option.

Key words: bamlanivimab, casirivimab/imdevimab, coronavirus, COVID-19, infusion center, monoclonal antibodies

The coronavirus disease 2019 (COVID-19) pandemic has tested nursing staffing models around the globe.¹ Multiple news agencies have reported that demand for nursing care has been especially challenging in the United States, because it leads the world in number of cases and deaths.² As of September 30, 2021, the United States has reported >43 million cases

and nearly 700 000 deaths.³ Many novel therapies have been researched, including neurohormonal modulating agents and antiviral drugs with equivocal results.^{4,5} Most COVID-19–related deaths are associated with patients hospitalized with respiratory failure, often consistent with acute respiratory distress syndrome, an inflammatory condition of the lungs resulting in decreased lung compliance

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and increased mortality, up to 40% to 50%.^{6,7} Clinicians have become much more adept at managing patients with interventions such as prone positioning and the administration of steroids.⁸ The result is decreased mortality in the critically ill, which had been reported to be as high as 50.0% in winter/spring of 2020⁹ to 22.9% in winter/spring of 2021.^{9,10} Preventing clinical deterioration to respiratory failure is much more effective in preserving life than trying to reverse it.

In November 2020, the US Food and Drug Administration (FDA) approved emergency use authorization (EUA) for the administration of 2 investigational monoclonal antibody therapies (mABs), bamlanivimab as monotherapy and casirivimab/imdevimab as combination therapy.¹¹ Bamlanivimab in combination therapy with another mAB etesevimab had demonstrated effectiveness in preventing deterioration to respiratory failure in at-risk individuals (Table 1).¹² On June 25, 2021, a pause was issued on the use of bamlanivimab/etesevimab because of possible ineffectiveness against emerging variants.¹³ This was ratified by the FDA on September 2, 2021, as variant frequency data from most states supported effectiveness of the therapy.¹³ Administration of mABs for outpatients is usually done in outpatient infusion centers, staffed by infusion nurses with specialized training or certification in infusion nursing.¹⁴ Because infusion centers often care for patient populations who are immunocompromised, this poses a challenge in arranging infusion center appointments for COVID-19–positive patients who could potentially serve as vectors of disease, putting immunocompromised patients at increased risk. Implementation of an emergency department (ED)-embedded infusion center was an innovative approach to overcome barriers to access mAB infusion for COVID-positive ED patients.

BAMLANIVIMAB

Therapeutic mABs are laboratory-synthesized proteins that have been available since the 1980s for the treatment of a variety of conditions, from cancers to autoimmune diseases and multiple sclerosis.¹⁵ Bamlanivimab, an investigational mAB codeveloped by AbCellera Biologics (Vancouver, British Columbia, Canada) and Eli Lilly and Company (Indianapolis, IN) is an immune globulin G1 (IgG1) neutralizing antibody that specifically targets the COVID-19 spike protein, preventing its transport into the cells.¹⁶ Administration of bamlanivimab has been shown to decrease hospitalizations in the 28-day period postadministration for COVID-19–positive patients who are high risk for deterioration.¹⁷ Administration of bamlanivimab to hospitalized patients or patients who are already on oxygen may be associated with poor outcomes.¹¹ Administration of bamlanivimab for COVID-19–related illness is still under investigation. In November 2020, bamlanivimab was approved by the FDA under EUA for patients who meet certain criteria, including COVID-19–positive patients over age 65 years and patients

TABLE 1

Criteria for Monoclonal Antibody Therapy Infusion

Must check ALL of the following:

- Positive COVID-19 rapid antigen test
- Mild-to-moderate COVID-19 symptoms
- Symptom onset within 10 days
- NOT hospitalized due to COVID-19
- NOT receiving oxygen or NO increased oxygen requirement due to COVID-19

AND must check AT LEAST 1 of the following:

- Body mass index ≥ 35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or receiving immunosuppressive treatment
- ≥ 65 years of age
- ≥ 55 years of age AND have cardiovascular disease, OR hypertension, OR chronic obstructive pulmonary disease/other chronic respiratory disease

under age 65 years with certain comorbid conditions (Table 1).^{18,19} Recommended time to administration from symptom onset is <5 days and up to 8 to 10 days.²⁰ The EUA was authorized for those with mild-to-moderate symptoms for ≤ 10 days.¹⁹

INFUSION NURSING

Infusion nursing is a specialty of highly skilled nurses who administer infusion therapy, with best practices guided by the Infusion Nurses Society.²¹ Practices include safety in delivery of infusions and management of adverse reactions. Many infusion nurses are credentialed by the Infusion Nurses Certification Corporation (INCC) as a Certified Registered Nurse Infusion (CRNI®).²¹ Some infusion nurses may also hold an Oncology Nurse Chemotherapy Immunotherapy Certificate from the Oncology Nursing Certification Corporation²² (ONCC) to administer chemotherapy. Infusion nurses may work in outpatient clinics administering a variety of infusion therapies or practice on hospital vascular access teams (VATs).

In order to ensure that the ED-embedded infusion center would be in compliance with best practices in infusion therapy, oversight for the development of the program, including safety (prevention and management of adverse events), didactic education, and competency of the infusion team, was under the supervision of a registered nurse (RN) with a CRNI®. This individual also served as the manager of the VAT and therefore has specialized knowledge of the workflows.

SAFE MONOCLONAL ANTIBODY ADMINISTRATION

Cytotoxic anticancer medications given in an infusion center by infusion nurses are known to be associated with

immunoglobulin E (IgE)-mediated reactions or reactions associated with allergy or anaphylaxis.²³ These reactions include mast cell and basophil activation, which results in histamine and leukotriene release, triggering inflammation and hypotension, requiring certain medications to reverse symptoms. Reactions usually manifest within 3 minutes to 2 hours after initiation of infusion.²⁴ For this reason, empiric monitoring for reaction postinfusion is standard care per the *Infusion Therapy Standards of Practice (the Standards)*.²⁵ A 2020 review of the relationship between infusion rate and infusion reactions reported that, with only 2 exceptions (trastuzumab and cetuximab), reactions associated with the administration of monoclonal antibodies invoke an alternate pathway: cytokine release syndrome (CRS).²⁴ Reactions occurring within 1 minute are more often IgE mediated, suggesting allergy, whereas reactions occurring after 1 hour are more often not IgE mediated, associated with CRS.²⁴ Per FDA guidelines, due to the unavailability of data regarding administration of bamlanivimab, an IgG1, parameters for recognition and treatment of both reaction pathways were recommended and therefore established.¹⁹

CRS is dynamic immune system activation of cytokines that can be secondary to exposure to drugs, toxins, or disease processes.²⁶ Cytokines are peptides released by most cells that have multiple functions serving the immune system. Some examples are interleukins, interferon, and tumor necrosis factor.²⁷ Symptoms of CRS can be very similar to allergic reaction and can range from mild (more common) to severe (less common). Some of these symptoms include rash, itching, asthenia, hypotension, and shock.²⁸ Other symptoms of CRS include fever, fatigue, nausea, chills, headache, and sympathetic activation.²⁷

Some drugs are associated with an increased risk of reaction. Reaction severity in the oncology population has been linked to disease burden on onset of therapy.²⁷ However, prediction of mAB reactions in the context of disease burden cannot be applied to the COVID population, because the therapy has been insufficiently investigated, as it has in the cancer population. For this reason, clinical monitoring for at least 2 hours and readily available empiric pharmacological resources to reverse signs and symptoms of reaction are imperative. Per the *Standards*, any platform administering infusion therapies should be embedded with an event reporting system, and reactions should be reported for the purpose of continuous improvement.²⁵ Although bamlanivimab therapy in patients with COVID-19 is still under investigation, adverse outcomes are rare, and there are no known drug-to-drug interactions.²⁰ There is also no indication for renal-adjusted dosing.¹⁹

Program Development

mAB therapies (bamlanivimab and casirivimab) were made available from the state of California at no cost to patients after the FDA established EUA in November 2020.¹¹ Due to a labeling concern with casirivimab, bamlanivimab was selected as the therapy of choice. At the time of this

writing, the full utility of bamlanivimab for the treatment of COVID-19 remains unknown, including the full scope of risks and benefits; however, variant frequency data support its effectiveness.¹³ Additionally, the infusion center was operational before EUA of bamlanivimab/etesevimab combination therapy. Although the US later offered mAB administration at another site, that site was >20 miles away from the region most heavily burdened by COVID-19.

The location of the hospital described in this article is a 449-bed community hospital in southern California. The 43-bed ED serves approximately 71 100 patients annually. During the height of the COVID-19 pandemic in 2020, acuity of the patient population increased, as demonstrated by a 5.0% increase in admissions, from 18.6% pre-COVID-19 to 23.7% during the COVID-19 pandemic. As the US–Mexico border was overwhelmed with cases of COVID-19,²⁹ proximity of this hospital to the international border (within 5 miles) significantly affected the ED with cases of COVID-19. An executive decision was made that there was a social responsibility to serve the community in need and that patients who elected for the therapy under physician guidance should be able to receive it in a safe environment. Allotment of bamlanivimab to hospitals was determined based on need and provided at no cost. As this location was one of the most significantly impacted by volume of patients with COVID-19 in the county, sufficient amounts of medications were made available from the state to deploy to the infusion center. Supply and demand needs were determined on a week-to-week basis, with oversight from the clinical pharmacy manager for the health care system. The ability to sustain the center was dependent on sufficient supply.

A Plan-Do-Check-Act (PDCA) model of continuous process improvement was chosen to guide deployment of the infusion center.³⁰ This type of model encouraged stakeholders to decide on a readily available strategy, with rapid cycle evaluation and modifications made toward meeting the goal of the program,³⁰ which was to offer a location for safe administration of bamlanivimab outside of the existing parameters of the ED, without compromising ED throughput. Accomplishing this goal required identifying space that could be converted to a patient care area equipped with oxygen and other supplies necessary for life support.³¹ Additionally, new workflows and a staffing model needed to be created. Educational materials and competency validation of staff were required.

Throughout the pandemic many patients have presented to the ED with acute respiratory failure or the need for immediate resuscitation (triage level 1 or 2 on the Emergency Severity Index), with a noted decrease in ED visits for less acute patient complaints (triage level 4 or 5).³² Significant inpatient census increases resulted in extended boarding of critically ill admitted patients in the ED. All of the available ED-zoned beds were needed to accommodate these proportionately higher-acuity patients, leaving no room within the department to accommodate patients

eligible for bamlanivimab infusion who required 2 hours of monitoring for potential adverse effects.²⁵ The determination was made that the ED would expand into neighboring zones within the brick and mortar of the hospital setting to establish a dedicated space for the safe administration of bamlanivimab to eligible patients.

Infrastructure Expansion

In addition to the FDA recommendations, the US Department of Health and Human Services (HHS) provides online resources to guide hospitals in step-by-step measures to take to set up an infusion center.³³ A location on the main floor of the hospital outside of the ED was identified by ED leadership (and approved by the internal space allocation committee) for the setup of the infusion center. Consideration was made for safe transport of highly infectious patients, adequate ventilation, and social distancing. The center was set up to accommodate 6 patients at a time. The area was outfitted with 6 recliners, intravenous (IV) pumps, vital sign monitors, personal protective equipment (PPE) cart (gowns, gloves, hair covers, face shields, and shoe covers), emergency medications, and supplies for general patient comfort. A room divider separated each patient bay. The infusion center was operational during the hours of 16:30 and 00:30, with screenings beginning at 16:00 and the last patients accepted at 22:30. This was to avoid COVID-19 exposure to hospital employees conducting their work duties during regular business hours. The center was staffed with 2 RNs and 1 certified nursing assistant per shift, all of whom received education and competency validation.

Workflow Modifications

Workflow modifications were created prior to education (Figure 1). The initial point of workflow modification occurred as patients presented to the ED with COVID-19–related symptoms, during the specific catchment hours for operation of the infusion center (16:00–22:30). All patients or visitors presenting to the hospital were provided with a surgical mask. Any patients presenting with symptoms outside of these hours would remain in the main ED as part of the normal workflow.

Patients were then screened to meet the eligibility requirements for administration of bamlanivimab (Table 1). Patients meeting criteria had consultation with the physician regarding risks and benefits for the purpose of informed consent. Patients were also provided with the fact sheet from the manufacturer.³⁴ Informed consent was then documented by the physician to meet specific requirements for administration of the therapy under EUA.¹¹ Patients who elected for the therapy received a COVID rapid antigen test. The COVID rapid antigen test was recommended as the best practice over polymerase chain reaction screening for eligibility due to its rapid turnaround time and reduced process steps recommended by the Infectious Disease Society of America (IDSA).³⁵ Patients who tested positive were escorted to the infusion center by way of a dedicated pathway for COVID-positive patients.

Patients remained registered as patients receiving care within the ED. Patients presenting outside of the infusion center hours of operation received the infusion by the infusion-trained ED nurse if they were available. No data were captured regarding patients who did not receive treatment based on the staffing model. Treatment was offered to ED patients only; there was no structure in place to accept outside referrals.

The ED infusion nurse assigned to the patient cared for the patient from infusion to discharge. The nurse documented the patient's arrival to the infusion center, the location of the patient (infusion chair number), and logged the time that the patient was ready for infusion in the electronic health record. The nurse then administered the infusion over 1 hour via an IV pump, followed by a complete flush of the infusion line to ensure delivery of the required dose. Postinfusion, patients were observed for 1 more hour while remaining in their infusion recliner. In case of reaction, treatment guidelines were established based on severity of reactions as outlined by the Oncology Nursing Society 2018 guidelines.³⁶ Reactions were stratified as mild (flushing, localized rash, myalgia, dizziness), moderate (flushing, generalized rash, itching or edema, wheezing, shortness of breath or chest discomfort, nausea, vomiting, abdominal pain), or severe (severe rash, itching or edema, seizures, hypoxia, throat tightness, hypotension).³⁶ Reactions were reported immediately and directly to the ED physician. Anaphylaxis kits were provided in a tackle box (epinephrine, diphenhydramine, famotidine) to be used as necessary under the existing standard procedure for rescue. In the event of emergency or severe transfusion reaction, the existing emergency standing orders and response plans were to be implemented. Any adverse events were to be reported using the hospital's internal electronic reporting structure and reviewed by the patient safety officer and pharmacy leadership. Per hospital policy, any of the following events were to be reported to FDA MedWatch within 7 days¹⁹:

- Death
- Life-threatening event
- In-patient hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Congenital anomaly/birth defect
- Medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

Discharge From Infusion Center

Patients were evaluated for discharge 1 hour postcompletion of the infusion (2 hours after initiation of infusion). Once patients were cleared for discharge, vital signs were obtained, and the ED-infusion nurse provided discharge instructions and follow-up information to the patients. Discharge instructions were specific to the individual presenting complaint and personalized by way of the online

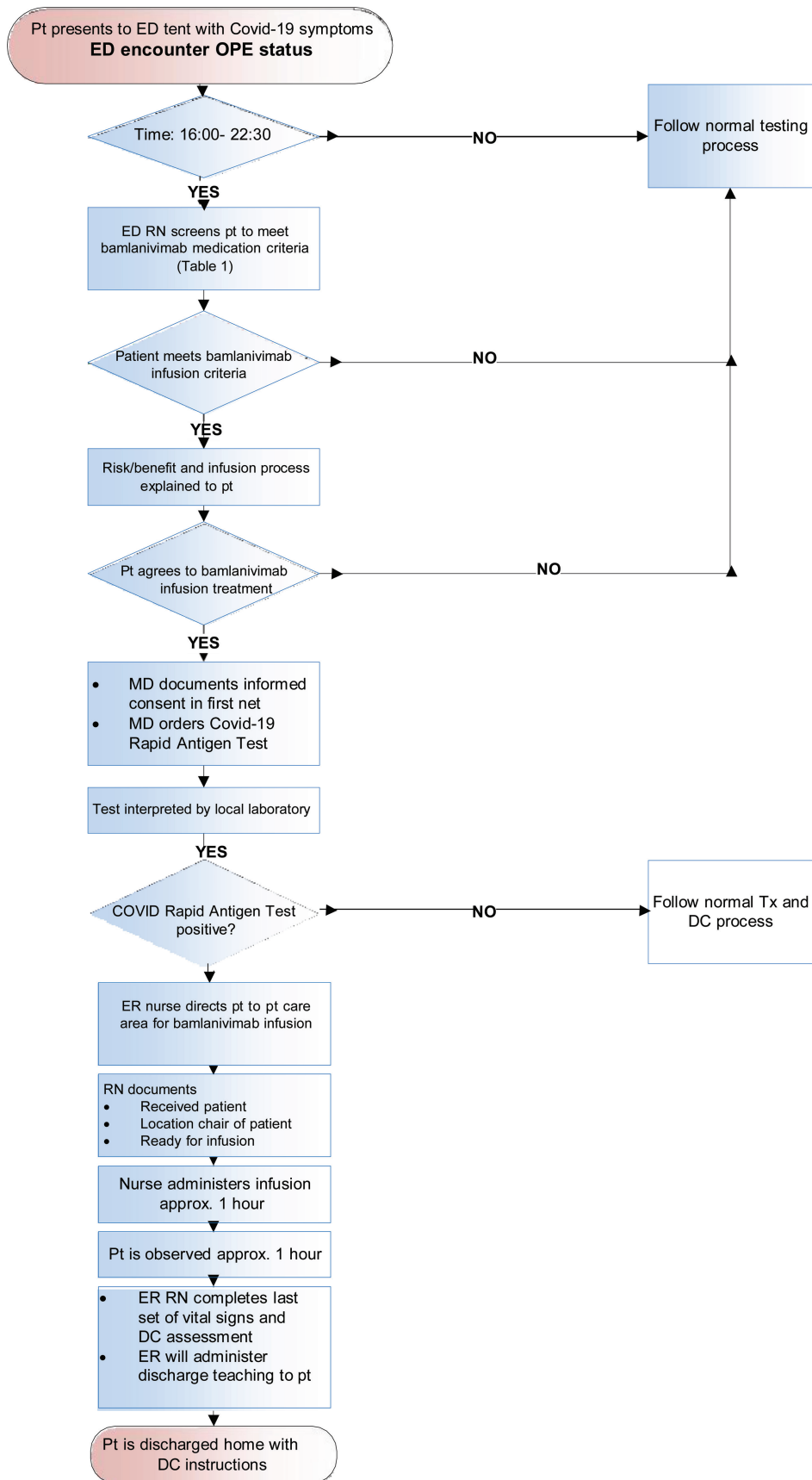


Figure 1 Bamlanivimab infusion: COVID-19 patients in emergency department. *Abbreviations: Approx. approximately; DC, discharge; ED, emergency department; ER, emergency room; MD, medical doctor; OPE, outpatient encounter; Pt, patient; RN, registered nurse; Tx, treatment.*

discharge instructions platform. Patients were instructed to follow up with their primary provider or return to the ED for any new or worsening symptoms. Patients were provided with the fact sheet released by Eli Lilly, which described any reaction that should be immediately addressed by a care provider.³⁴

Education and Competency Validation

Education and competency validation was a collaborative effort between vascular access and ED leadership. The ED clinical nurse specialist oversaw education specific to ED workflows and practice. The nurse manager (CRNI®) of the infusion center provided education on therapy administration and monitoring. Four RNs from the VAT were selected to staff the infusion center to cover 2 RNs on each shift. Preference was given to nurses who had previous ED experience. Three of the 4 RNs selected had ED experience within 2 years. Because the patients remained classified as ED patients, education was provided on safe administration of the therapy ED workflow (including chain of command and escalation of patient safety concerns) and safe patient discharge. Nurses and providers in the ED intake area were educated on identification of eligible patients, criteria for patient selection based on the EUA, the informed consent process, and the FDA bamlanivimab fact sheet. Nurses were then educated to the side effects and potential complications of bamlanivimab, as well as appropriate documentation of therapeutic administration. Monitoring for changes in condition that required physician intervention was reviewed, as well as expectations for reporting concerns directly to the assigned ED physician by direct telephone communication to the provider. Appropriate reversal agents were presented to the nurses for specific adverse outcomes.

Education on the full ED discharge process was provided to the infusion clinic nurses. This helped with throughput and not having to return the patient back to the main ED, unless an emergent situation existed that required a patient to return. Education and competency were delivered over one 8-hour workday.

Competency was evaluated by verbalization of knowledge (safe administration of bamlanivimab, assessment for deteriorating conditions that required emergency intervention, reversal of adverse events as a result of the bamlanivimab infusion, basic ED routines, and discharge process) and demonstration where appropriate (setup of IV infusion set with filter and use of electronic selection of appropriate discharge instructions).

DISCUSSION

Access to novel therapies to treat COVID-19, including infusion therapy, is of concern for patients and providers. Embedding a nurse-run infusion center serves as a viable option to offer patients with milder illness at risk for more

severe illness with COVID-19 a safe and efficient option if they are seeking to receive infusion therapy. Additionally, the ED-embedded infusion center offered providers an option for administration of infusion therapy to outpatients with COVID-19 where one did not exist before.

During the 3-month period when the infusion center was active (December 2020 to February 2021), 150 patients received bamlanivimab infusions. None of these patients required eventual hospitalization for COVID-19. Additionally, no adverse reactions were reported, and no process inconsistencies were reported via the electronic event reporting system, including no inadvertent exposures of staff to COVID-19. A sufficient supply of bamlanivimab was available to support the initiative.

LIMITATIONS

The infusion area had a positive impact on ED throughput by offloading the waiting area and therefore reducing waiting time and avoiding the unnecessary occupation of ED beds. Because this initiative was not conducted as research and the relationship between variables unknown, data on throughput were not collected for analysis. However, staff described improved workflows and satisfaction at their ability to care for the patients who needed them.

Identification of eligible patients did prove to be a more nuanced assessment than the original algorithm offered, and clinical decision-making on the part of the physician was necessary. For example, some patients required hydration, steroids, or a brief trial of oxygen before it was determined that they would meet eligibility for enrollment (not require admission to the hospital or continued supplemental oxygen). In such cases, a modified walk test was performed to rule out the need for ongoing oxygen therapy.³⁷ No issues were identified in terms of supply/demand for PPE or for mAB therapy. The impact to the community was appreciated when several community members showed their gratitude by making financial donations to the hospital to honor the nurses who cared for them in the infusion center.

IMPLICATIONS FOR CLINICAL PRACTICE

Since the infusion center was originally deployed, the manufacturer's recommendation for administration time has decreased from 60 to 16 minutes if administered in a 50-mL solution of normal saline.¹⁷ This recommendation could make it feasible to administer within the original parameters or the ED; however, patients would still require monitoring posttherapy for up to 2 hours. Patients who receive mAB therapy for COVID-19 must abstain from COVID-19 vaccination for 90 days postinfusion, and providers should have discussions on the risks and benefits of this decision as part of the informed consent process.¹¹

At the time of this writing, the National Institutes of Health (NIH) recommends bamlanivimab and etesevimab combination therapy for mild-to-moderate COVID-19.¹³ The EUA for was announced in February 2021, however Eli Lilly distributed a press release in June to notify the public of the FDA's pause on EUA for bamlanivimab and etesevimab due to in vitro evidence that the drugs were ineffective against the emergence of the delta variant of COVID-19. Hospitals were advised to keep their supplies of the drugs awaiting any further notification.¹³ In August 2021, the FDA announced an expansion of the use of casirivimab and imdevimab combination therapy to patients (aged 12 and older, >40 kg) for postexposure prophylaxis of COVID in high-risk individuals.³⁸

CONCLUSION

An ED-embedded infusion center can be successfully deployed to serve as a platform for patients who seek to access mAB therapy and for providers looking for a safe option for administration of this therapy for their patients. This can offer an improved experience for patients and providers and decreased waiting times. Future studies are still needed to offer sufficient evidence (beyond safety) of the clinical utility of bamlanivimab and other mABs for the treatment of COVID-19.

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