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International Journal of Infectious Diseases 118 (2022) 214–219

Contents lists available at ScienceDirect

International Journal of Infectious Diseases

journal homepage: www.elsevier.com/locate/ijid

Implementation of a Collaborated Antimicrobial Stewardship Program and Outpatient Parenteral Antimicrobial Therapy (OPAT) Unit-driven Monoclonal Antibody Therapy Program for COVID-19 at an NYC Hospital

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ARTICLE INFO

Article history:
Received 3 December 2021
Revised 15 February 2022
Accepted 26 February 2022

ABSTRACT

Objectives: This study aimed to assess the processes and clinical outcomes of a joint collaboration between Antimicrobial Stewardship Program (ASP) and the outpatient parenteral antimicrobial therapy (OPAT) unit for delivery of monoclonal antibody therapy for mild-to-moderate COVID-19.
Methods: We carried out a retrospective, interim analysis of our COVID-19 monoclonal antibody therapy program. Outcomes included clinical response, incidence of hospitalization, and adverse events.
Results: A total of 175 patients (casirivimab-imdevimab, n = 130; bamlanivimab, n = 45) were treated between December 2020 and March 1, 2021. The median time from symptom onset was 6 (IQR 4, 8) days at time of treatment. Of 135 patients available for follow-up, 71.9% and 85.9% of patients reported symptom improvement within 3 and 7 days of treatment, respectively. A total of 9 (6.7%) patients required COVID-19–related hospitalization for progression of symptoms, all within 14 days of treatment. A total of 7 (4%) patients experienced an infusion-related reaction.
Conclusions: ASP-OPAT collaboration is a novel approach to implement an efficient and safe monoclonal antibody therapy program for the treatment of mild-to-moderate COVID-19.

Introduction

SARS-CoV-2 has inflicted global devastation, causing nearly 400 million infections and resulting in over 5.7 million deaths (CSSE 2021). The Food and Drug Administration (FDA) approved 4 monoclonal antibody therapies, bamlanivimab and casirivimab-imdevimab (November 2020) followed by bamlanivimab-etesevimab (February 2021) and sotrovimab (May 2021), for emergency use to treat high-risk patients with mild-to-moderate COVID-19 to prevent progression to severe disease and/or hospitalization (NIH 2021). At NewYork-Presbyterian Queens (NYPQ), we began administration of outpatient monoclonal antibodies against SARS-CoV-2 in December 2020, coordinated through our Antimicrobial Stewardship Program (ASP) and administered through our outpatient parenteral antimicrobial therapy (OPAT) unit. We report

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https://doi.org/10.1016/j.ijid.2022.02.056

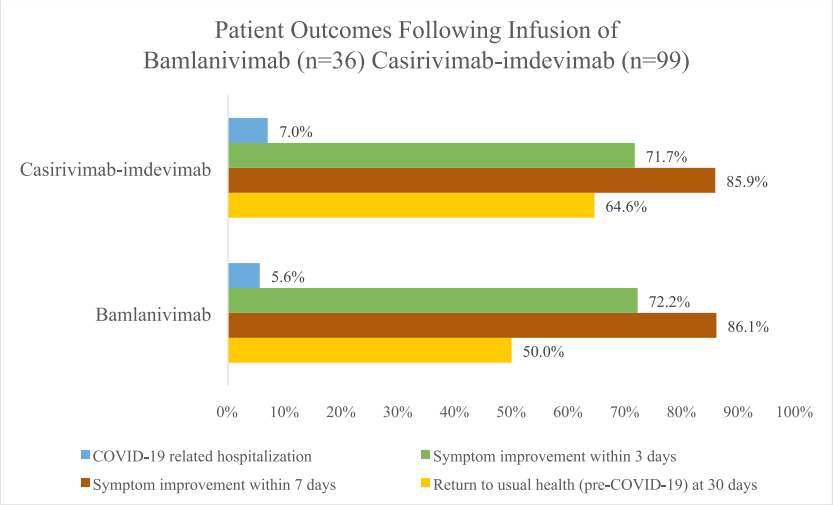

Figure 1. Results
Data in figure includes percent from total number of patients evaluated (Bamlanivimab [n=36] Casirivimab-imdevimab [n=99]).

results of the interim analysis of our quality assurance initiative, highlighting our novel process.

Methods

NYPQ is a 535-bed academic, community-based medical center in Flushing, Queens, New York, and was at the epicenter of the first wave of COVID-19 in the United States. As a result, over 5,000 adult patients were admitted and treated for COVID-19 between March 2020 and April 2021. Criteria for admission and treatment followed the National Institutes of Health COVID-19 treatment guidelines (NIH 2021). As a clinical service, our ASP was responsible for reviewing, implementing, and monitoring COVID-19 treatments to facilitate a safe and standardized approach. Established in 1999, our ASP consists of a multidisciplinary team, including an infectious diseases (ID) attending physician, a managing ID clinical pharmacist, and 3 senior ID-trained physician assistants. In November 2020, ASP took on an additional role to collaborate with the hospital's high-volume OPAT unit to provide outpatient monoclonal antibody (mAb) therapy to identified patients. The OPAT infusion unit is a hospital-based outpatient service operating from 7 am to 4 pm, 365 days a year, for over 10 years, and staffed by a full team of infusion nurses, 2 nurse practitioners, a navigator, a dedicated case manager, and ID residents and attending physician. It was chosen as an appropriate site owing to its stable structure with daily appointments and ability to implement infection control practices (described later).

The management and responsibilities of the ASP/mAb service (in addition to inpatient COVID-19 therapeutic responsibilities) rotated weekly among the clinical pharmacist and physician assistants. During times of extremely high referral volume (i.e., more than 10 patients per day), a second member of ASP was assigned to assist. Institutional review board approval was not obtained because this was a quality assurance and patient safety project.

Figure 1.

Patient Identification/Screening

Adult patients aged ≥18 years old were considered eligible for treatment if they met the high-risk criteria defined in the FDA's Emergency Use Authorization (EAU) (Appendix), which remained constant over the time of this evaluation. Treatment was not provided to patients who had received at least 1 dose of a SARS-CoV-2 vaccine owing to the lack of guidance from FDA. Subsequently, the criteria were updated to reflect updated FDA guidance, which included broader inclusion criteria, decrease in age requirement, monoclonal antibody selection depending on epidemiological influences, and guidance to provide regardless of vaccination status. The clinical data, criteria for use, and referral process were presented to the hospital's medical group outpatient providers and emergency department (ED) leadership via teleconference by ASP. In addition, a 1-page summary of eligibility criteria and referral contact information was shared with providers. Patients were identified in the following ways: by their outpatient provider (i.e., primary care provider or subspecialist provider) following either in-person or remote telehealth visit; by an ED provider if evaluated in our ED; or by a member of ASP upon daily review of all positive SARS-CoV-2 test results obtained either from ED discharged patients or from those having undergone preprocedure testing at affiliated outpatient practices.

Referral Process/Scheduling

The referring outpatient provider was instructed to contact ASP to refer a patient for treatment. This occurred via phone, text, email, or fax, 7 days a week during the hours of 7:30 am–5:00 pm. A member of ASP then contacted the patient via telephone to obtain information regarding underlying comorbidities, current medications, COVID-19 symptoms and duration, and to provide information regarding monoclonal antibody treatment (including the emergency use approval status, mechanism of action, goal of therapy, potential adverse effects, administration process, and logistics). Patients referred by ED providers received the same information either by a member of ASP or by the ED provider before being discharged from the ED or via follow-up phone call by ASP within 24 hours of ED discharge. Administration in the ED was not possible owing to the high volume of patients undergoing evaluation and lack of resources to ensure FDA-required monitoring during and after infusion. In addition, a member of ASP would contact any qualifying patient with a positive SARS-CoV-2 test who was not referred by the ED on behalf of the ED Director. For all other positive SARS-CoV-2 results, ASP would contact the ordering provider and the patient as applicable. Patients were scheduled by ASP for the earliest available appointment time, generally within 24 hours of referral. Interpreter services were used as necessary to communicate with patients. Treatment was provided in OPAT 7 days a week, from 9 am to 4 pm. A daily schedule was

provided to staff screening visitors and patients at hospital entrances, and arrangements were made to escort the patients directly to the location where the infusion was provided. Initially, a single, negative-pressure patient room was designated to accommodate treatment. As the number of referrals increased, treatment was provided in an adjacent, larger, negative-pressure procedure room that was adapted to accommodate 4 patients simultaneously. Care was delivered by a dedicated OPAT unit nurse and provider, limiting potential staff exposure and optimizing infection prevention and control practices. Patients were scheduled in 3 sessions daily of 3 hours each (maximum of 12 patients daily).

Treatment Process

One hour before patients' scheduled arrival, a member of ASP or OPAT ordered the medication to allow time to thaw, prepare, and deliver it on time.

Patients were responsible for their transportation to OPAT (via self, family, friend, or paid car services). In the rare occasion when patients were unable to access transportation, our OPAT case manager explored transportation benefits included with patients' healthcare insurance. Upon arrival to the procedure room for the infusion, an OPAT nurse and provider greeted the patient and performed a formal evaluation. The latter was important as some patients deteriorated between the referral and admission to OPAT, requiring transfer to the ED for necessary acute care. All outstanding questions were answered, as well as completion of a written informed consent. The infusion was administered over 60 minutes and patients were observed for 60 minutes after infusion for signs of delayed hypersensitivity reactions. After infusion and completion of observation period, patients were escorted back to the main hospital entrance and released to return home.

Either bamlanivimab or casirivimab-imdevimab was planned to be used according to supply as both were available and considered therapeutically equivalent at the start of the program; otherwise, patients received specific mAb as requested by the provider. If a request was not made, casirivimab-imdevimab was the default infusion until supply was exhausted. Under EUA and New York State provisions, the medication was provided without cost to the patients. We opted for infusion of only casirivimab-imdevimab upon release of data, suggesting a decreased in vitro susceptibility of bamlanivimab to potential, newly circulating strains (e.g., B.1.1.7, B.1.351, P.1, B.1.427/B. 1.429, B.1.526), and owing to our inability to routinely test for variant type (REGENERON 2021).

Follow-up Process

Feedback from the OPAT team and outpatient providers was provided to ASP both in real-time and during scheduled meetings to enhance the process. A member of ASP was responsible for contacting the patient via telephone after treatment for follow-up. Patients were asked to recall symptom improvement at days 3, 7, and 30; presence of residual symptoms; development of adverse effects; and need for hospitalization within 14 and 28 days.

Results

Between December 2020 and March 1, 2021, we treated 175 patients (casirivimab-imdevimab, n = 130; bamlanivimab, n = 45). Outpatient providers referred 137 patients, and 38 were identified by ASP via ED providers/SARS-CoV-2 positive test screening. An average of 15 to 20 minutes was spent with each patient discussing the medication and coordinating the visit. Median age was 66 (IQR 59, 74) years (54.9% over 65 years old); 51.4% were male, 31.4% had diabetes, and 12.6% had BMI $\geq$ 35 kg/m^2. One-quarter of patients were deemed immunocompromised based on an underlying condition or treatment. Two-thirds of patients were aged $\geq$55 years with a history of cardiovascular disease, hypertension, or pulmonary disease. Differences in race and qualification were observed between patients treated with casirivimab-imdevimab and bamlanivimab. The median time from symptom onset was 6 (IQR 4, 8) days at time of treatment (Table 1). Of the 175 patients, 135 were available for follow-up, 2 did not complete treatment owing to infusion reactions (both with chills, rigors, and hypotension, 1 requiring a dose of epinephrine), and 38 did not respond to follow-up phone calls. Of 135 patients available for follow-up, 71.9% and 85.9% reported symptom improvement within 3 and 7 days of treatment, respectively. Most patients treated (79.6%) reported their overall physical health at 30 days to be "good," "very good," or "excellent," with 60.7% of patients reporting feeling back to their "usual pre-COVID-19 health" at day 30. Nine (6.7%) patients required a COVID-19-related hospitalization for progression of symptoms, all within 14 days of treatment. The median duration of symptom onset at time of treatment for these patients was 7 (IQR 4, 9) days. Seven (4%) patients experienced an infusion-related reaction, including chills (3), fever (1), rigors (2), hypertension (2), and hypotension (2). Twelve (6.9%) patients reported an adverse effect after the infusion. This included diarrhea (4), headache (3), rash (3), fever (2), chills (2), constipation (1), and an oral ulcer (1); all of which resolved within 24–48 hours (Table 2). Formal statistical analysis was not performed as this was a single-arm study.

Discussion

Operationalizing the EUA poses challenges to healthcare systems because it requires considerable outpatient resources to properly identify patients, communicate drug information with providers and patients, and prepare and administer safely. Our results highlight the outcome of a novel collaborative effort between seasoned OPAT and ASP teams to operationalize monoclonal antibody treatment for high-risk patients with COVID-19 during times of high demand and limited resources. In addition, our results support the benefit of monoclonal antibodies for preventing the progression of COVID-19 and/or hospitalization in a high-risk patient population.

The FDA accorded emergency use status on the basis of initial randomized controlled trials, in which both bamlanivimab and casirivimab-imdevimab showed a reduction in COVID-19 hospitalizations compared with placebo, and patients reporting symptom improvement at a median of 2 days (REGENERON 2021, ACTI-3/TICO LY-CoV555 Study Group 2020, Weinreich DM, et al 2021.). Over time, the FDA expanded inclusion criteria (risk factors, age, vaccination status), indications for use (treatment and post-exposure prophylaxis), and selection of monoclonal antibody on the basis of epidemiologic and in vitro data to predominant strains.

The hospital-based OPAT infusion unit model serves as an extension to the acute care setting, providing intravenous therapy without the need for invasive venous catheters and the benefit of skilled healthcare providers to monitor closely for efficacy and safety. Alternative models have expanded to skilled nursing facilities and patient homes, including an emphasis on the use of oral antimicrobials for difficult to treat infections, termed complex outpatient antimicrobial therapy (COpAT) (Mahoney et al., 2021; Norris et al., 2019). The influence of ASP in OPAT can be limited depending on structure and resources. Before the COVID-19 pandemic, ASP and our hospital-based OPAT collaborated frequently on empiric and definitive antimicrobial selection, expertise with pharmacokinetics and/or pharmacodynamics, therapeutic drug monitoring, treatment of complex nontuberculous mycobacterial infections, and monitoring for adverse events. In addition, ASP provided education to OPAT staff and helped our case managers interface

Table 1
Baseline Demographics, Select Underlying Comorbid Conditions, and COVID-19 Symptoms

	All (n = 175)	Casirivimab-imdevimab (n = 130)	Bamlanivimab (n = 45)
Age	66 (59, 74)	66 (58, 75)	64 (60, 71)
Sex, male	90 (51.4)	70 (53.8)	20 (44.4)
Race			
African American	10 (5.7)	7 (5.4)	3 (6.7)
Asian	55 (31.4)	30 (23.1)	25 (55.6)
Hispanic	11 (6.3)	10 (7.7)	1 (2.2)
White	64 (36.6)	52 (40)	12 (26.7)
Unknown	35 (20)	31 (23.8)	4 (8.9)
BMI (kg/m^2)	27.7 (24.6, 32.4)	28.3 (24.6, 33.2)	26.2 (24.7, 30.2)
EUA Qualifier			
BMI ≥ 35 kg/m^2	22 (12.6)	18 (13.8)	4 (8.9)
CKD	9 (5.1)	7 (5.4)	2 (4.4)
DM	55 (31.4)	41 (31.5)	14 (31.1)
Immunosuppressive disease	30 (17.1)	24 (18.5)	6 (13.3)
Immunosuppressive treatment	12 (6.9)	10 (7.7)	2 (4.4)
Age ≥ 65	96 (54.9)	74 (57)	22 (48.9)
Age ≥ 55 AND CV or HTN or Pulm Disease	111 (63.4)	85 (65.4)	26 (57.8)
Symptom duration, days	6 (4, 8)	6 (4, 8)	5 (4, 7)
Symptoms			
Cough	113 (64.6)	83 (63.8)	30 (66.7)
Fever	100 (57.1)	74 (57)	26 (57.8)
Fatigue	51 (29.1)	45 (34.6)	6 (13.3)
Body aches	45 (25.7)	36 (27.7)	9 (20)
Headache	28 (16)	23 (17.7)	5 (11.1)
Sore throat	26 (14.9)	19 (14.6)	7 (15.6)
Diarrhea	23 (13.1)	19 (14.6)	4 (8.9)
Dyspnea	20 (11.4)	16 (12.3)	4 (8.9)
Loss of taste and/or smell	19 (10.9)	13 (10)	6 (13.3)
Loss of appetite	11 (6.3)	8 (6.2)	3 (6.7)
Chest pressure	11 (6.3)	11 (8.5)	0 (0)
Nausea/vomiting	7 (4)	7 (5.4)	0 (0)
Abdominal pain	6 (3.4)	3 (2.3)	3 (6.7)
Night sweats	3 (1.7)	2 (1.5)	1 (2.2)
Insomnia	1 (0.6)	1 (0.8)	0 (0)
Temperature (°C)	36.9 (36.7, 37.3)	36.9 (36.6, 37.3)	37.1 (36.9, 37.4)
Oxygen saturation %	97 (96, 98)	97 (95.5, 97)	97 (96, 98)

Abbreviations: BMI, body mass index; CKD, chronic kidney disease; CV, cardiovascular; DM, diabetes mellitus; EUA, Emergency Use Authorization; HTN, hypertension; Pulm, pulmonary.
All continuous data listed as median (IQR).
All categorical data listed as n (%).

Table 2
Adverse Events Experienced During and After Infusion

	All	Casirivimab-imdevimab	Bamlanivimab
During infusion[a]			
Chills	3 (1.7)	3 (2.3)	0 (0)
Rigors	2 (1.1)	2 (1.5)	0 (0)
Fever	1 (0.6)	0 (0)	1 (2.2)
Hypertension	2 (1.1)	1 (0.8)	1 (2.2)
Hypotension	2 (1.1)	2 (1.5)	0 (0)
After infusion[b]			
Diarrhea	4 (3)	4 (4)	0 (0)
Headache	3 (2.2)	3 (3)	0 (0)
Rash	3 (2.2)	3 (3)	0 (0)
Fever	2 (1.5)	2 (2)	0 (0)
Chills	2 (1.5)	2 (2)	0 (0)
Constipation	1 (0.7)	1 (1)	0 (0)
Oral ulcer	1 (0.7)	1 (1)	0 (0)

All categorical data listed as n (%).
[a] Casirivimab-imdevimab (n = 130), bamlanivimab (n = 45).
[b] Casirivimab-imdevimab (n = 99), bamlanivimab (n = 36).

with pharmaceutical companies to obtain treatment for indigent patients.

The COVID-19 pandemic introduced additional infection control risks for patients in OPAT, capacity challenges within the acute care setting, and ultimately, an opportunity for ASP expansion and collaboration to expand OPAT services to deliver optimal care to the community (Mansour et al., 2020; Rivera et al., 2020). Our unique ASP/OPAT collaborative workflow allowed us to overcome usual challenges of providing monoclonal antibody infusion requiring monitoring to outpatients. Our experienced ASP expanded its responsibilities to outpatient COVID-19 to coordinate logistics and communicate directly with patients and to provide oversight to our OPAT unit. Periodic meetings were essential for feedback to optimize the process. Hospital leadership provided extensive support, including select administration area with negative pressure, dedicated nursing, protective personal equipment, and pharmacy services. Clinical leadership, ASP, and OPAT developed contingency plans for patients either too ill for treatment or experiencing a severe adverse event and streamlined access to onsite ED services.

We observed a higher number of patients requiring COVID-19-related hospitalization than the original trials (6.9% vs ~1–2%) (REGENERON 2021, ACTI-3/TICO LY-CoV555 Study Group, et al. 2020, Weinreich DM, et al. 2021). Patients treated at our facility had a greater underlying risk than those described in the original trials (REGENERON 2021, ACTI-3/TICO LY-CoV555 Study Group, et al. 2020, Weinreich DM, et al. 2021). We observed a higher median age (66 vs 45 years), higher number of patients aged 65 years and older (54.9% vs 10.7%), and longer duration of symptoms (6 vs 4 days) (REGENERON 2021, ACTI-3/TICO LY-CoV555 Study Group, et al. 2020, Weinreich DM, et al. 2021). Of note, patients requiring hospitalization owing to progression of disease had a slightly higher median duration of symptoms of 7 days (IQR 4, 9). Similar findings were reported by Kumar et al. who reported a COVID-19-related hospitalization rate of 7.8 % with the use of bamlanivimab (Kumar RN et al., 2021). In ad-

dition, Verderese et al. treated patients with either bamlanivimab or casirivimab-imdevimab compared with placebo and observed a COVID-19-related hospitalization rate of 5.8% in the treatment arm compared with 11.4% in the placebo arm (Verderese JP, et al. 2021). In both studies, the authors reported a patient population with risk factors more closely aligned to our experience than the original clinical trials.

We observed differences in baseline demographics such as sex, race, and qualifying risk factors between the bamlanivimab and casirivimab-imdevimab groups. We feel that these differences may be due to chance based on our methodology of introducing casirivimab-imdevimab first, followed by bamlanivimab once supply was exhausted. Patient factors did not influence the monoclonal antibody selected by our program. We believe that as awareness of the program increased over time, an increase in referrals from throughout our surrounding region may have affected referrals both in volume and possibly different patient demographics. Of note, patient outcomes, including COVID-19 hospitalization and subjective reporting of symptom resolution, were not influenced by treatment type and were consistent throughout the period of our report.

Our initiative is not without limitations. First, this is a single-arm, nonplacebo-controlled quality assurance initiative. Second, our experience is subject to provider bias, as outpatients were referred to us rather than our program screening all potential patients. Given the novelty of the medication, providers may have lacked awareness of the treatment or hesitated to refer. Referral bias may have influenced our patient demographics as referring providers may have chosen patients who were sicker and/or had comorbid conditions and who they felt would experience greater benefit from receiving the infusions than all patients who simply met criteria. In addition, we did not collect the total number of referrals nor the reasons for ineligibility owing to the high volume of calls and limited staffing (ASP team was continuing all regular inpatient job duties in addition to outpatient COVID-19 program). Third, being at the epicenter of COVID-19 at the time of this study, it is possible that there was a delay in primary care visit availability that may have resulted in our median duration of symptom onset before treatment to be higher than that observed in the original clinical trials (not all patients were able to access or master telehealth successfully). Fourth, we were unable to perform follow-up on 23% of patients, and this may have affected our data analysis and possible difference in hospitalization rate. Potential resolutions to address this loss to follow-up may be contacting the referring provider to obtain follow-up or harnessing additional nonclinical staff for aid in continued attempts at contact. In addition, we did not assess for patient satisfaction during our follow-up. Although we received frequent positive and constructive feedback that influenced our processes, we did not record such data owing to the limited resources mentioned earlier. Finally, follow-up calls for symptom resolution were subject to recall bias, as we did not request daily diaries after treatment.

Since the data presented earlier, our program has cared for an additional 600 patients. Patients received either intravenous casirivimab-imdevimab, bamlanivimab-etesevimab, or more recently, sotrovimab with the emergence of the Omicron variant. We did not note changes in above reported outcomes or those seen in previously published data (Dougan M, et al. 2021). The most common side effects reported by our patients—although infrequent—were chills, several hours after the infusion, occasionally accompanied by headache or gastrointestinal upset; all of which resolved within hours. We had no known COVID-19–related hospitalizations after infusions were completed.

We continued to adjust our practice on the basis of new data and criteria in accordance with changing FDA guidance (i.e., changes in eligibility criteria and decreasing infusion times) (REGENERON 2021, NIH 2021). Although we have not administered any treatment subcutaneously, this alternative route of administration has been discussed as a potential time saving modality if referral volume were to increase substantially (McCreary et al., 2021; O'Brien et al., 2021). More recently, EUA has been accorded to use of these agents for post-exposure prophylaxis (REGENERON 2021, Cohen MS, et al. 2021, O'Brien MP, et al. 2021). For this, we have considered separate treatment locations for patients who were confirmed SARS-CoV-2 positive and those referred for post-exposure prophylaxis to limit potential transmission of COVID-19. More data to support such an approach are needed.

Our data shows the favorable safety profile of monoclonal antibody therapy for COVID-19, supporting administration in nonacute care setting. This would allow wider access to individuals lacking mobility or support structure. Opportunities for the future include implementation of best practices similar to those described in this report of the ASP and OPAT infusion unit collaborations to provide COVID-19 treatment. ASP teams can provide the expertise and education regarding treatments to referring providers, and OPAT units can look into best ways to deliver care. It may be helpful for OPAT infusion units to partner with home-infusion services to coordinate and safely administer future agents. Successfully seeking financial support and/or grants will require incorporation of metrics such as hospital admission avoidance and patient satisfaction scores, as well as decreased burden on acute care facilities.

Conclusion

We found a collaborative approach consisting of ASP, ID, and OPAT teams allowed for a rapid, safe, and effective implementation of the EUA protocol for the administration of COVID-19 monoclonal antibody treatments. The interim analysis of our quality assurance initiative and real-world experience with a diverse patient population supports their use in preventing progression of disease and/or hospitalization in patients who are at a high risk of developing severe disease.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding Source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Monoclonal antibody therapy was provided by the U.S. federal government without cost to the patient.

Acknowledgments

We acknowledge our dedicated outpatient parenteral antimicrobial therapy (OPAT) infusion unit staff, our referring outpatient primary care and emergency department (ED) providers, patient access team, and entire Pharmacy Department.

Ethical Approval Statement

Written informed consent was obtained from each patient before receiving any treatment.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijid.2022.02.056.

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