

INTRODUCTION

Individuals residing in long-term care settings represent a disproportionate number of death due to COVID-19.¹ When administered within 10 days of symptom onset, bamlanivimab represented an important intervention, capable of reducing the burden on hospital systems and healthcare workers. Home infusion clinicians have expertise with the coordination and administration of monoclonal antibodies in the home setting, and several providers expressed a willingness to assist in the pandemic to the National Home Infusion Association (NHIA). Despite interest, there were barriers to accessing bamlanivimab through state networks and the payment for services was based on facility-based settings versus alternate sites of care. The program launched on December 14, 2020 and NHIA's role was to conduct outreach to the home infusion provider community about the program, verify applicant credentials, coordinate the allocation process with ASPR, and collect outcome data.

PURPOSE

The purpose of the NHIA Bamlanivimab SPEED pilot was to provide COVID-19 monoclonal antibody therapy to eligible patients in high-risk settings defined as skilled nursing facilities, assisted living facilities, correctional facilities, federally qualified health care centers, and dialysis centers.

METHODS

This observational study to describe the high-risk patients receiving bamlanivimab and the associated clinical outcomes of the treatment.

RESULTS

Thirty-six provider organizations enrolled in the program representing 172 locations and 46 states. Over a 10-week period, NHIA allocated 3,429 patient courses of bamlanivimab. A total of 29 enrolled providers infused 426 patients with bamlanivimab in 88 unique facilities predominantly in skilled nursing facilities and assisted living communities (see Exhibit 1). Of the administered Bamlanivimab, 45.76% took place in a community with a population of less than 25,000 (see Exhibit 2). 28 of the 36 enrolled providers administered at least one dose of bamlanivimab to a qualified patient. The average number of doses administered was 17.75 with a median of 13, a mean of 10.21, and a standard deviation of 15.14 (see Table 1).

Exhibit 1 Location of Bamlanivimab Administration

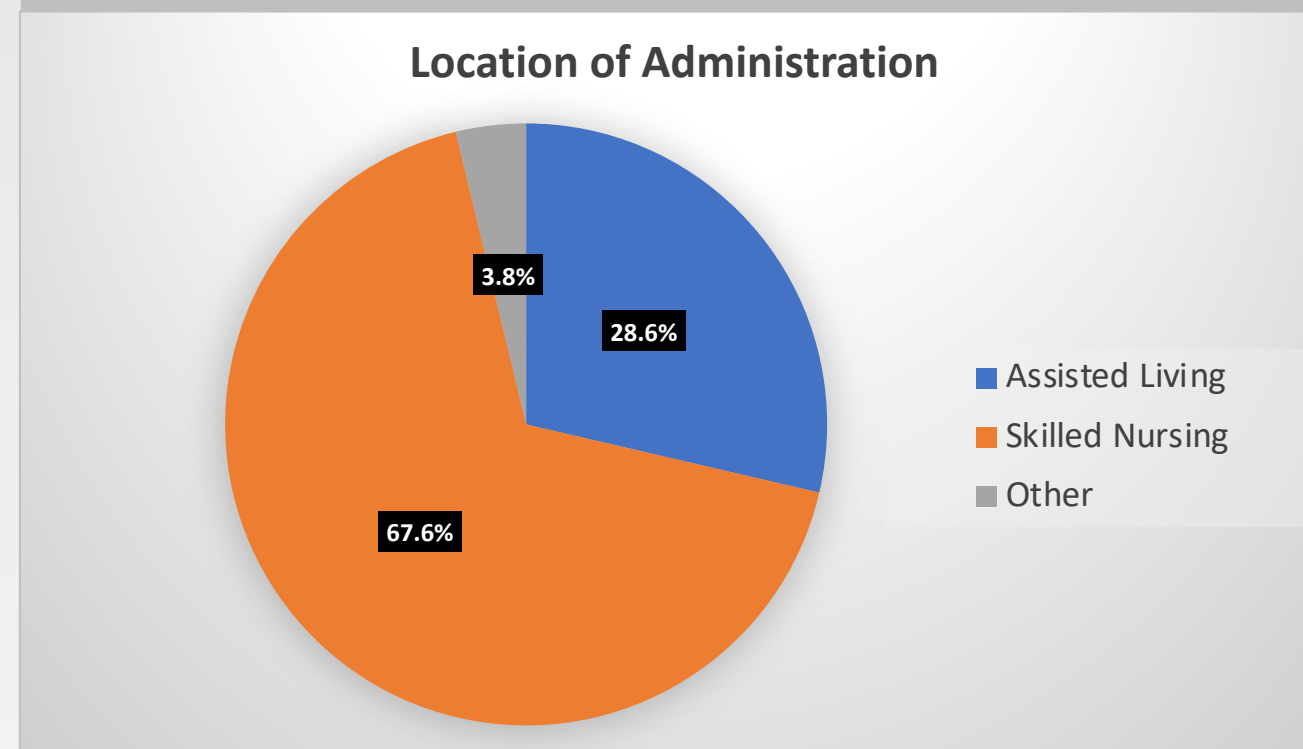


Table 1 Providers Characteristics

Providers Characteristics	
Providers who Administered	28
Total Doses	426
Average/Provider	15.21
Median	13
Mean/Std Deviation	15.21/15.14

Participating locations were asked to voluntarily report clinical outcomes data and demographic information including patient age, gender, ethnicity, race, height, weight, date of symptom onset, date of positive test, date of infusion, rate of infusion, qualifying high-risk criteria, and 7-day follow up outcomes. Data was not collected on all 426 patients, but each variable had ranges from 58 to 224 depending on which variable was analyzed. 68.2% of patients were female, while 31.8% were male (n = 223). The mean age was 81.95 with a minimum of 45 and a maximum of 101 (n = 224). One variable assessed was the time from symptom onset to time of administration of bamlanivimab. According to data on 114 patients, the time from symptom onset to time of administration of bamlanivimab was 4.04 days (SD = 2.42). This is indicative of a very streamlined process from time the patient first had COVID-19 symptoms. Adverse drug event data was reported for 224 of the infused patients. Table 2 shows the event and the frequency of occurrence. 92.83% of patients reported no adverse event. Table 3 shows post infusion 7-day clinical outcomes showed 2 patients who expired and 1 patient who required hospitalization.

Table 2 Adverse Drug Events

Adverse Drug Events	n = 224 (%)	Totals
None	92.41%	207
CV-Hypotension	1.79%	4
Fever	1.34%	3
Other-Not Reported	0.89%	2
Chills	0.45%	1
GI-N/V/Diarrhea	0.45%	1
Neuro-Headache	0.45%	1
Derm-Pruritis/Urticaria/Flushing/Angioedema	0.45%	1

*Patients may have experienced more than 1 adverse event

Exhibit 2 Population Distribution of Bamlanivimab Administration

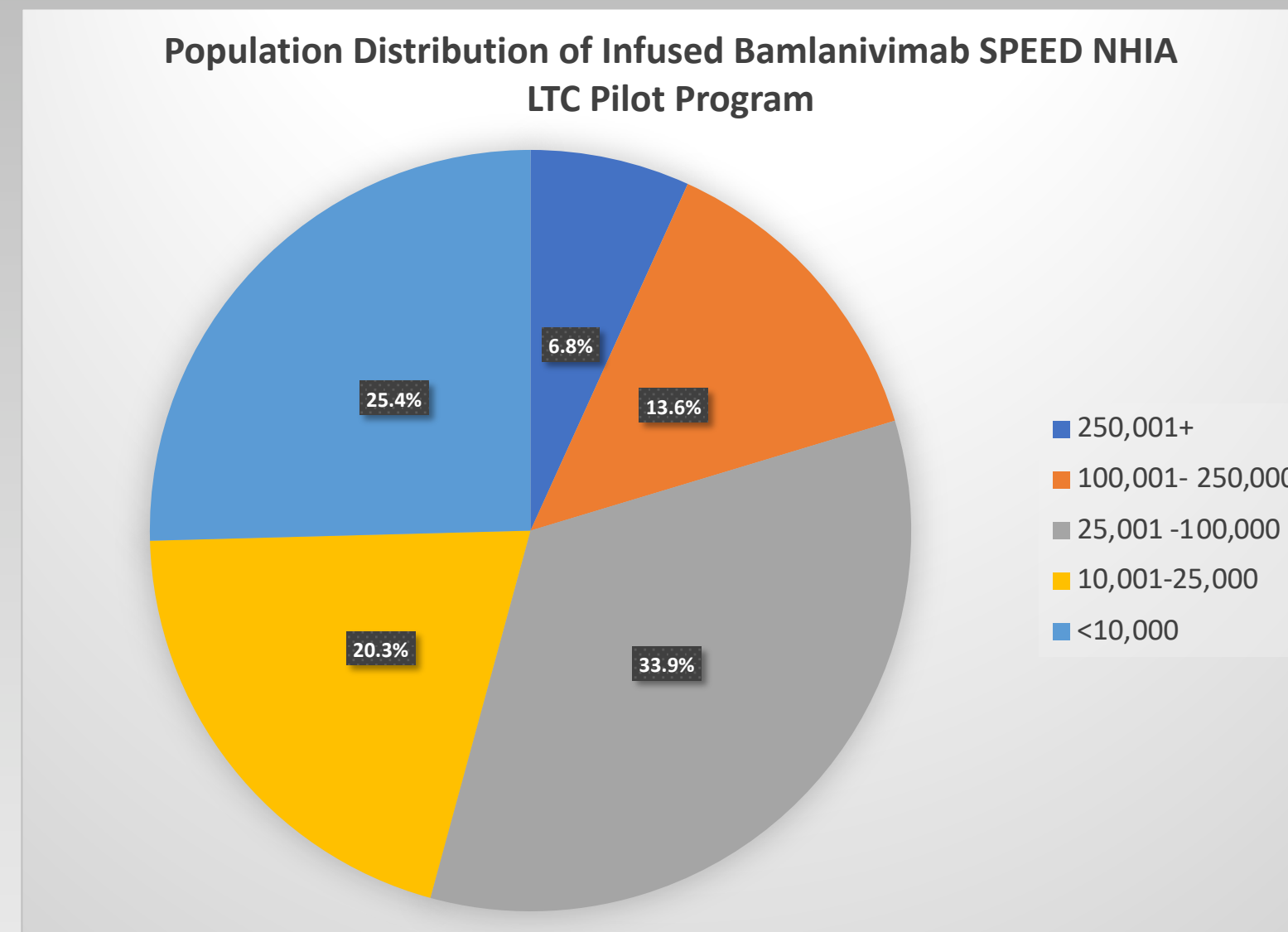


Table 3 Clinical Outcomes

Outcomes (n=426)	Incident	%
Death within 7 days	2	0.47%
Hospitalization	1	0.23%
ER Visits	0	0.00%

DISCUSSION

This program program succeeded in engaging home infusion providers willing to provide bamlanivimab in high-risk settings and established an efficient system for allocating product. This experience with bamlanivimab indicates the therapy has a favorable adverse event profile and improves clinical outcomes in high-risk patients. The time from symptom onset to infusion is indicative of a very streamlined process. This program also served as an opportunity for home infusion clinicians to gain experience with the product, increasing confidence in the safety of bamlanivimab and other monoclonal antibodies for home administration.

CONCLUSIONS

The home infusion industry displayed its strength and empathy by the willingness of providers from across the country to want to participate in the pandemic efforts. While providers were working to ensure patients and staff were protected from this virus, they continued to help in the battle against COVID-19. As the need for treatment becomes less urgent in long-term care settings, this program's success shows home infusion providers could expand home-based access to monoclonal antibodies. The only challenge to this today is the payment rate for home administration and the ability to cover the higher costs associated with this service in the home setting.

DISCLOSURES

NHIA has no disclosures or conflicts of interest to report and was not compensated for this project.

ACKNOWLEDGEMENTS

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REFERENCES

1. Department of Health and Human Services (HHS). Long-Term Care and the Impact of COVID-19: A First Look at Comparative Cross National Statistics. ASPE Research Brief. December 2020. Available at: <https://aspe.hhs.gov/basic-report/long-term-care-and-impactcovid-19-first-look-comparative-cross-national-statistics>