

A Home Infusion Program for Administration of Bamlanivimab in High-Risk Settings

Authors: Connie Sullivan, BSPHarm, Ryan Garst, PharmD, Jennifer Charron, RN, MSN, MBA, VA-BC, Danell J. Haines, PhD

Introduction

Individuals residing in long-term care settings represent a disproportionate number of the deaths due to COVID-19.¹ On November 9, 2020, Eli Lilly and Company received an emergency use authorization (EUA) for bamlanivimab, which has been shown to reduce hospitalizations in patients with mild to moderate COVID-19.² When administered within 10 days of symptom onset, bamlanivimab represents an important intervention, capable of reducing the burden on hospital systems and health care workers that have been pushed to capacity by the pandemic.

Home infusion clinicians have expertise with the coordination and administration of monoclonal antibodies in the home setting, thus several home infusion providers expressed a willingness to the National Home Infusion Association (NHIA) about providing bamlanivimab to eligible patients. Despite this interest, barriers to carrying out infusions in the home setting quickly emerged. First, home infusion pharmacies had difficulty accessing bamlanivimab through state networks, as distribution was primarily limited to hospital settings. Second, the payment for administering bamlanivimab was based on facility-based settings that offer economies of scale and does not cover the additional costs associated with the individualized home infusion delivery model.

NHIA responded to these difficulties by engaging with the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS) about the challenges home infusion providers were facing related to access and reimbursement. Over the course of several discussions with ASPR it was determined that home infusion providers could immediately support the pandemic response by improving access to bamlanivimab in certain high-risk settings. With ASPR's support to provide direct allocations of bamlanivimab to home infusion pharmacies, NHIA agreed to facilitate a program to accomplish this goal. The program is now part of HHS's Special Projects for Equitable and Efficient Distribution (SPEED).³ Allocations to home infusion pharmacies through the SPEED program were limited for use in high-risk settings, such as long-term care (LTC) facilities. Allocations of bamlanivimab for home infusion were not included in the program due to the rate of payment being below the costs to provide the service.

Program Summary

NHIA launched the program on December 14, 2020. 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. Enrolled locations were responsible for promotion of the

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-impact-covid-19-first-look-comparative-cross-national-statistics>

² Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Bamlanivimab. Eli Lilly, Indianapolis, IN. 2020. Available at: <https://www.fda.gov/media/143603/download>

³ Special Projects for Equitable Distribution (SPEED) of COVID-19 Outpatient Therapeutics. <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx>

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program to facilities in their service areas, assessment of patient eligibility per the EUA, provision of drug and supplies for administration, coordination of nursing, and billing Medicare or commercial payers for administrations. For patients with Medicare or Medicare Advantage as a primary payer, the home infusion provider was paid \$309 per infusion. For patients with commercial insurance, the home infusion provider was required to negotiate a payment rate directly with the payer source.

The process was initiated by inviting interested home infusion companies to complete a short online survey. Upon verification of licensure and accreditation status, initial allocations were made based on the number of LTC facilities within the pharmacy catchment area. As of February 5, 172 individual pharmacy locations representing 36 organizations were enrolled in the program, and at least one provider was identified in all but 4 states (AK, ND, SD, WY). The first infusion took place 9 days after launch on December 23, 2020. Over a 7-week period, 3,384 doses of bamlanivimab were allocated, and 309 administered.

Patient and Location Demographics

NHIA requested locations submit data about the geographic location, the type of facility, patient demographics, and clinical outcomes for bamlanivimab infusions. Age and gender information was collected for 223 patients. The mean age of patients receiving bamlanivimab from NHIA SPEED locations was 81.95 (SD=11.96), ranging from 45 to 101 years. Females outnumbered males 152 (68.2%) to 71 (31.8%). Ethnicity was reported for 116 patients revealing most were non-Hispanic, white (95.69%) while 4 (3.45%) were African American/black.

Residents of skilled nursing facilities received 197 (63.8%) doses, while residents of assisted living facilities received 99 (32%). In late January, the program was expanded to include other settings such as correctional facilities, dialysis centers, and federally qualified health care centers. To date, 13 (4.2%) doses have been provided in these settings. NHIA analyzed the population size of the cities where bamlanivimab doses were provided. Of the 48 cities where doses were administered, 23 (47.9%) had a population of less than 25,000.

Table. 1 Population size of cities where bamlanivimab was administered.

Population Size	Count	Percent
250,001+	4	8.33%
100,001- 250,000	6	12.50%
25,001 -100,000	15	31.25%
10,001-25,000	12	25.00%
<10,000	11	22.92%
Total Cities	48	100.00%

*Source for census information: <https://www.census.gov/en.html>

Clinical Outcomes

Home infusion providers are accustomed to responding quickly to new referrals. In most cases, a home infusion provider can initiate care within 48 hours of being notified of a patient need for service. Since efficacy of bamlanivimab improves with early administration, the response time for bamlanivimab was measured in terms of the number of days between onset of initial symptoms and the day of infusion, rather than from the time of referral to infusion. Data was received for 114 patients revealing a mean of 4.04 days (SD=2.42) between first symptoms and infusion.

Outcome data from the NHIA SPEED program is consistent with other reports in that bamlanivimab is seemingly well tolerated. All bamlanivimab doses provided during this 7-week period were administered over 1 hour. For the 223 bamlanivimab infusions for which adverse event data was submitted, no side

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effects were reported for 207 (92.83%). One patient experienced severe hypotension and discontinued treatment before the infusion was completed. A fluid bolus was subsequently administered, and the patient fully recovered. A total of 16 (7.17%) patients reported at least 1 adverse event, all of them mild with the exception of the previously mentioned case. Locations were asked to follow up with the facility 7 days after the infusion to determine the outcome of treatment. Of the 75 patients for which 7-day follow up data was submitted; 2 hospitalizations and 2 deaths were reported. Both deceased patients were 86 years of age and had multiple co-morbidities.

Table 2. Reported Adverse Events

Event Description	Frequency	Percent
None	207	92.83
Hypotension	4	1.79
Fever	3	1.35
Other	2	.90
Chills	1	.45
Diarrhea	1	.45
Fever	1	.45
Flushing	1	.45
Headache	1	.45
Headache, Nausea, Fatigue	1	.45
Pruritis	1	.45
Total	223	100.0

**This was a free response question.*

Cost of Home Infusion

The NHIA SPEED program succeeded in helping home infusion providers obtain supply of bamlanivimab. However, the issue of insufficient reimbursement for home infusion of monoclonal antibodies has not been resolved. By focusing on high-risk settings, home infusion providers were able to contribute to an important need while maximizing nursing resources. Efficiency is an important consideration when establishing models for delivering COVID-19 monoclonal antibodies, however the need to ensure equitable access for individuals without transportation, who are non-ambulatory, and/or living in under-served areas must also be addressed. Therefore, NHIA has interest in expanding the program to include home infusion.

To assess the level of reimbursement needed to facilitate home-based administration, NHIA collected data about the various costs of home infusion. Costs to provide bamlanivimab at home fall into 3 main categories: pharmacy professional services, direct expenses for supplies and delivery, and nursing. A flat 35% was added to the low range of the estimates to account for administrative overhead.

Table 3 Summary of costs for providing bamlanivimab at home

Service or Product Description	Cost (Range)
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
Total	\$584 - \$1,746

**Amount paid by Medicare - \$309*

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The onboarding process associated with home infusion is extensive. Patients and the orders for therapy are assessed ahead of time to ensure safety for administering the IV medication at home. The onboarding team includes pharmacists, nurses, support staff, and reimbursement specialists. The time frame to complete this process can range from less than an hour to several days depending on the complexity of the case. Upon completing the assessment, the team processes the order, coordinates nursing services and arranges the first delivery of medication and supplies. The costs for this process are associated primarily with staff time and product preparation.⁴ Estimated expenses for onboarding ranged from \$108 to \$420. This up-front investment is typically recovered over the course of treatment, which usually spans several weeks, to years. For bamlanivimab, the onboarding cost must be recovered as part of the one-time payment for administration.

Direct expenses for supplies and delivery ranged from \$70 to \$313. The cost for personal protective equipment (PPE), administration supplies (e.g., tubing, IV insertion kits), anaphylaxis kits, and delivery depend on factors such as availability of certain products (e.g., source of epinephrine, N95 masks, gloves), and lead-time for delivering the product. Most providers reported that PPE expenses have increased by a factor of 3 compared to pre-COVID costs. Delivery is accomplished either by driving product (using delivery staff or contracted couriers), or by commercial overnight shipping services (i.e., FedEx, UPS). Geographic conditions are a factor in estimating delivery costs, with rural areas often requiring pharmacies to drive product to patients living several hours away due to limited overnight delivery options from commercial shipping services.

The geographic region and the home health regulatory environment are the major drivers of nursing expense in home infusion. NHIA estimates each nursing visit to administer bamlanivimab lasts approximately 4 hours, allowing for 30 minutes of drive time each direction; 1 hour for donning PPE and conducting the initial patient assessment, obtaining consent for treatment, and reviewing the care plan; and 2 hours for administration and post-infusion monitoring. The cost for nursing ranged from \$180 to \$560. In some states, home infusion providers may obtain a home health nursing license and hire nurses directly to provide home visits. In other states, a home health nursing license requires a certificate of need, therefore nursing services are subcontracted and pay market rates of \$140 to \$200 for a 2-hour visit during regular business hours. Considering all of these factors, the cost to provide bamlanivimab in the home setting ranged from \$584 to \$1,746, significantly higher than the \$309 being offered by the Medicare program.

Discussion

The NHIA SPEED program succeeded in engaging home infusion providers willing to provide bamlanivimab in high-risk settings and established an efficient system for allocating product. Low utilization of allocated product in some areas was attributed to overlap with vaccine launch in skilled facilities, and the lack of general education about prescribing and using monoclonal antibodies by LTC personnel. Despite these challenges, NHIA was pleased with the level of participation, and specifically with utilization rates in less populated areas.

Finally, this experience with bamlanivimab indicates the therapy has a favorable adverse event profile and improves clinical outcomes in high-risk patients. The program also served as an important opportunity for home infusion clinicians to gain experience with the product, increasing confidence in the safety of bamlanivimab as a candidate for home administration. As the need for bamlanivimab becomes less urgent in long-term care settings, NHIA is confident that home infusion providers could expand home-based access to monoclonal antibodies if the payment rate for home administration were increased to cover the higher costs associated with this service.

⁴ The National Home Infusion Foundation conducted a salary study in 2019 and found that pharmacists in home infusion align with the U.S. median pharmacist pay of \$126,120 annually, according to the U.S. Bureau of Labor Statistics. Home infusion nurses are paid slightly higher than the national average at \$79,881. Mean support staff wage is \$24 per hour. (Infusion Industry Trends 2020)

Acknowledgments

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About NHIA

NHIA represents companies that provide infusion therapy to home-based patients as well as companies that manufacture and supply infusion and specialty pharmacy products. For additional information about this report contact Connie.Sullivan@nhia.org. For more information about NHIA visit www.nhia.org.