



Participation Agreement

Re: National Home Infusion Association and the Department of Health and Human Services
Bamlanivimab-LTC Pilot Program

This agreement is between _____ (“_____”), (“Participant”), with a principal place of business of _____, and the National Home Infusion Association (“NHIA”), having a principal place of business at 1600 Duke St., Suite 410, Alexandria, VA 22314. This agreement is effective as of executed date below.

WHEREAS, The Department of Health and Human Services (HHS) and the National Home Infusion Association (NHIA) wish to increase access to bamlanivimab for treatment of COVID-19 in eligible, high-risk individuals residing or working in long-term care facilities, including assisted living facilities; and

WHEREAS, NHIA has the capacity to identify and qualify home infusion providers capable of providing bamlanivimab in accordance with established industry standards for quality and safety; and

WHEREAS, home infusion providers have an interest in assisting with providing bamlanivimab in accordance with the Emergency Use Authorization (EUA) approved by the Food and Drug Administration to eligible and consenting individuals residing or working in long-term care, skilled, and assisted living facilities; and

WHEREAS, the Participant desires to provide bamlanivimab (“the product”) for the purposes described below.

NOW, THEREFORE, the parties agree as follows:

1. SERVICES & RESPONSIBILITIES

PARTICIPANT agrees to:

- Conduct outreach to skilled facilities and assisted living facilities within their home infusion service area to promote utilization of bamlanivimab for qualified patients who consent to treatment;
- Assist with patient assessments for eligibility per the EUA, obtain physician orders, coordinate nursing services, dispense, deliver, and administer the product;
- To make every effort to perform infusions within 24 hours of receiving a qualified referral;
- Provide NHIA with a list of long-term care (LTC) facilities, skilled nursing facilities (SNFs) and assisted living facilities (ALFs) in their service area;
- Participate in pilot program status update calls as determined by NHIA and/or HHS;
- Provide NHIA with information to satisfy criteria of eligibility in the program for each

participating location, including:

- Evidence of a valid pharmacy license in good standing.
- Evidence of a valid home health or nursing license, if applicable.
- Evidence of accreditation for home infusion (according to commercial payer standards) from one of the following organizations:
 - Accreditation Commission for Health Care (ACHC)
 - The Joint Commission (TJC)
 - Utilization Review Accreditation Commission (URAC)
 - The Compliance Team (TCT)
 - Community Health Accreditation Program (CHAP)
 - National Association of Boards of Pharmacy (NABP)
 - Center for Pharmacy Accreditation (CPPA)
- PTAN confirming enrollment with the Centers for Medicare & Medicaid Services (CMS) as a pharmacy or vaccine/immunization provider
- Provide NHIA with a single point of contact for communications and collection of required data;
- Grant NHIA permission to include PARTICIPANT company name, location, and contact information on the NHIA website as an eligible provider of bamlanivimab;
- Report all Serious Adverse Drug Events as outlined in the Food and Drug Administration Emergency Use Authorizations for monoclonal antibody products.
- Make every effort to collect and submit outcome data to the National Home Infusion Foundation according to established deadlines, including, but not limited to the following:
 - The name and address of each facility where patients received infusions
 - The age, gender, and ethnicity of each patient treated with the product
 - Patient outcomes, including whether the patient experienced adverse events, hospitalizations, emergency department visits, or death as of day 7 post treatment

NHIA Agrees To:

- Inform and educate PARTICIPANT about how to provide bamlanivimab and related services according to the program criteria;
- Create resources for skilled and assisted living facilities interested in taking advantage of the program and facilitate finding a home infusion provider in their service area;
- Create a publicly accessible database of approved, qualified home infusion providers (as defined above) to assist State Health Departments, hospitals, and other entities in allocating monoclonal antibody products for patients in long-term facilities and other settings;
- Provide HHS with PARTICIPANT information according to the predetermined schedule for purposes of facilitating allocations bamlanivimab;
- Make every effort to ensure equitable distribution of product across all HHS jurisdictions and to prioritize access for rural and underserved populations.
- To communicate with HHS regarding the status of the program and provide data required.

2. TERM & TERMINATION

- a. Term. This Agreement will begin on the Effective Date and will end on June 1, 2021 unless terminated sooner.
- b. Termination. Either party may terminate this Agreement upon ten (10) days written notice delivered to the other party.

3. BILLING

- a. PARTICIPANT will bill the payer source directly for all services and supplies provided in accordance with the program criteria;

b. NHIA is not responsible for unpaid claims associated with services provided by PARTICIPANT.

4. PROTECTION OF HEALTH INFORMATION

PARTICIPANT represents and warrants that it will comply with all federal, state and local laws, regulations, ordinances and guidance pertaining to confidentiality, use and disclosure of patient health information with regard to all information and records obtained, reviewed and/or generated in the course of providing services hereunder and shall permit access to such information and records only as authorized by law. Without in any way limiting the foregoing, this obligation includes all requirements set forth in the Health Insurance Portability and Accountability Act (HIPAA), as amended, and regulations and guidance issued pursuant thereto.

5. INDEMNIFICATION AND LIMITATION OF LIABILITY

PARTICIPANT will indemnify, defend and hold harmless NHIA, its affiliates and their respective officers, directors and employees from and against all claims, damages, losses, liabilities and expenses, including court costs and reasonable attorney fees, which arise from or are related to PARTICIPANT'S: (a) negligent acts or omissions or willful misconduct in performance of the services; (b) breach of this agreement; or (c) failure to comply with any applicable laws, rules, statutes, ordinances, or regulations in performance of the services. NHIA will provide Participant with prompt notice of any such claim and will reasonably cooperate with Participant and its legal representatives in the investigation of any matter regarding the subject of the indemnification, at Participant's expense. Participant shall not enter into any non-monetary settlement or admit fault or liability on NHIA's behalf without NHIA's prior written consent.

6. FORCE MAJEURE

Neither party will be liable to the other for any delay in, nor failure of performance of their respective obligations under this Agreement caused by occurrences beyond the control of the party (as the case may be).

IN WITNESS WHEREOF this Agreement has been executed by the parties hereto:

National Home Infusion Association

Signature

Signature

Print Name/Title

Print Name/Title

Date

Date

Appendix A

Participating Locations for: _____

(Company name)

*Company may provide the location list using the format below or by attaching a separate document.

Street Address	City/State/Zip	Phone	State Pharmacy License #	Nursing License #
1. _____	_____	_____	_____	_____
2. _____	_____	_____	_____	_____
3. _____	_____	_____	_____	_____
4. _____	_____	_____	_____	_____
5. _____	_____	_____	_____	_____
6. _____	_____	_____	_____	_____
7. _____	_____	_____	_____	_____
8. _____	_____	_____	_____	_____
9. _____	_____	_____	_____	_____
10. _____	_____	_____	_____	_____