HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement for Healthcare Systems Providing On-site Services in Ambulatory Settings, Including In-Home, and/or in Long-Term Care Facilities

Please complete Sections A and B of this form as follows:

The Department of Health and Human Services (HHS) greatly appreciates the participation of The Nebraska Medical Center (Organization) in the COVID-19 response effort. Organization's participation is a vital service that will assist individuals who have tested positive for SARS-CoV-2 virus. The United States government has acquired the COVID-19 monoclonal antibody bamlanivimab (bamlanivimab) and is making this publicly funded monoclonal antibody available to certain providers to provide onsite bamlanivimab infusion services to outpatients, including in-home, and/or to residents/staff of long-term care facilities (including skilled nursing facilities, assisted living facilities, independent living facilities, and any combination of the three) (LTCFs).[1]

This HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement for Healthcare Systems Providing Onsite Services in Ambulatory Settings, Including In-Home, and/or in Long-Term Care Facilities (Agreement) specifies the conditions for receiving bamlanivimab at no cost from the United States government.

Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *HHS COVID-19 Monoclonal Antibody Infusion Program Provider Requirements and Legal Agreement* (Section A). An *HHS COVID-19 Monoclonal Antibody Infusion Program Provider Location Profile Information* form (Section B) must be completed for each Organization location that will serve outpatients and/or long-term care facilities.

Section A. HHS COVID-19 Monoclonal Antibody Infusion Program Provider Requirements and Legal Agreement

ORGANIZATION IDENTIFICATION
Organization's legal name: The Nebraska Medical Center
Number of affiliated Organization locations covered by this agreement:

[1] "Healthcare system" means one of three types of arrangements between two or more health care provider organizations: (1) organizations with common ownership, (2) contractually integrated organizations (e.g., accountable care organizations), and (3) informal care systems, such as common referral arrangements. Systems include organizations combined horizontally (e.g., a hospital system) or vertically (e.g., a multihospital system also owning physician practices and post-acute care facilities). This definition is based on the National Bureau of Economic Research (NBER) Center of Excellence definition of health system. https://www.ahrq.gov/chsp/chsp-reports/resources-for-understanding-health-systems/defining-health-systems.html

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

Organization telephone number: 402-552-2000	Email *(must be a monitored email and serve as dedicated contact for the HHS COVID-19 Monoclonal Antibody Infusion program)*: anwatkins@nebraskamed.com
Organization address: 987400 Nebraska Medical Center, Omaha, NE 68198-7400	

RESPONSIBLE OFFICERS

For the purposes of Agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in Agreement. The Responsible Officers listed below must provide their signatures after reviewing Agreement requirements.

Chief Medical Officer (or Equivalent)

Last name Frankel	First name Harris	Middle initial A
Title Chief Medical Officer	Licensure (State and Number) NE 18137	
Telephone number: 402-552-2290	Email: harris.frankel@unmc.edu	
Address: 987400 Nebraska Medical Center, Omaha, NE 68198-7400		

Chief Executive Officer (or Chief Fiduciary)

Last name Linder	First name James	Middle initial R
Title Chief Executive Officer		
Telephone number: 402-552-6192	Email: jlinder@nebraskamed.com	
Address: 987400 Nebraska Medical Center, Omaha, NE 68198-7400		

Primary Organization Contact for HHS COVID-19 Monoclonal Antibody Infusion Program

Last name Watkins	First name Andrew	Middle initial B
Title Pharmacist – Focused Population		
Telephone number: 662-820-1509	Email: anwatkins@nebraskamed.com	
Address: 981090 Nebraska Medical Center, Omaha, NE 68198-1090		

AGREEMENT REQUIREMENTS

I understand this is an agreement between Organization and HHS. To receive bamlanivimab (or any other COVID-19 monoclonal antibody purchased by HHS) at no cost, Organization agrees that it will adhere to the following requirements**:**

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

1.	Organization must use bamlanivimab in conformance with the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) issued on November 10, 2020 for bamlanivimab,[2] the EUA Fact Sheet for Health Care Providers,[3] and all other FDA authorized accompanying materials (and as the FDA may revise the bamlanivimab EUA and accompanying materials), and consistent with all requirements, recommendations, and other guidance of HHS. Organization must provide all necessary ancillary supplies, including saline and gravity delivery sets. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, appropriate crash kits, and the ability to immediately activate the emergency medical system (EMS), as necessary.
2.	Organization must contemporaneously record in the receiving patient's Organization medical record (and, as applicable, provide within 72 hours of infusion to the primary health care provider designated by the patient and, as applicable, to the LTCF for recording in the provider's/facility's patient medical record(s)), at a minimum, the following: a) Patient name b) Age, sex c) Date(s) of positive COVID-19 test results d) Date of symptom onset and disease manifestation e) Lot number of bamlanivimab dose administered, date of administration f) Other drugs administered g) Post-infusion follow-up reports received, including reports of adverse events, hospitalization and mortality (to be timely recorded in the patient's Organization medical record and transmitted to the designated primary health care provider and LTCF, as applicable); and document in the patient's Organization medical record the following: h) Patient (caregiver, as applicable) was given the EUA "Fact Sheet for Patients, Parents and Caregivers"[4] i) Patient (caregiver, as applicable) was informed of alternatives to receiving authorized bamlanivimab (see the EUA Fact Sheet for Health Care Providers) j) Patient (caregiver, as applicable) was informed that bamlanivimab is an unapproved drug that is authorized for use under an FDA Emergency Use Authorization In addition to maintaining the patient information listed above, Organization must also maintain records regarding the dispensed authorized bamlanivimab, including lot numbers, quantity, receiving site(s), receipt date(s), and product storage.

[2] https://www.fda.gov/media/143602/download Agreement expressly incorporates all requirements, recommendations and other guidance that Agreement specifically identifies, including any later issued revisions. Organization must monitor such identified guidance for updates and comply with such updates. Organization shall provide HHS with a point-of-contact email address for update notifications. HHS will use reasonable efforts to provide timely notifications. HHS's failure to do so does not excuse Organization's obligation to monitor and comply with such updates.

[3] https://www.fda.gov/media/143603/download

[4] https://www.fda.gov/media/143604/download (English); https://www.fda.gov/media/143645/download (Spanish)

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

	Organization must preserve the recipient's bamlanivimab medical record, and Organization dispensed authorized bamlanivimab records, for at least 3 years following infusion, or longer if required by FDA or state, local, or territorial law, and make such records available as required by the EUA or otherwise as required by federal, state, local or territorial law.
3.	Organization must not sell or seek reimbursement for bamlanivimab, or any related materials, that the federal government provides at no cost to Organization.
4.	Organization must administer bamlanivimab regardless of the recipient's ability to pay administration or related fees or coverage status. Organization may seek appropriate reimbursement from a program or plan that covers bamlanivimab administration or related fees for the bamlanivimab recipient. Organization may not seek any reimbursement, including through balance billing, from the bamlanivimab recipient.
5.	Before administering bamlanivimab, Organization must provide the approved EUA Fact Sheet for Patients, Parents and Caregivers to each bamlanivimab recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). If the EUA fact sheet is available electronically, Organization may provide it electronically if recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable) agrees to accept it electronically in the file format offered by Organization.
6.	In conducting bamlanivimab infusion services in any location, Organization must take steps to minimize the potential for transmission of SARS-CoV-2 from bamlanivimab patients to staff and others, including through mask-wearing, disinfection of high touch surfaces, frequent handwashing and social distancing, and isolation/quarantine of COVID-19 positive patients.
7.	Organization must comply with FDA EUA requirements for bamlanivimab management, including ensuring that appropriate storage and cold chain is maintained until the product is administered. Organization must preserve all records related to bamlanivimab management for a minimum of 3 years, or longer if required by FDA or state, local, or territorial law.
8.	Organization must report the number of doses of bamlanivimab that were unused, spoiled, expired, or wasted. HHS will provide further instruction on how to report.
9.	Organization must track bamlanivimab medication errors and adverse events that are considered to be potentially attributable to bamlanivimab use and must report these to FDA in accordance with the bamlanivimab EUA Fact Sheet for Health Care Providers.[5] Organization must for a minimum of 28 days post-infusion follow the health status of the patient, including gathering reports of adverse events potentially attributable to bamlanivimab use, hospitalization, and mortality. The post-infusion patient follow-up must be conducted through a method approved by HHS. Records of such follow-up must be made available as required by the EUA or otherwise as required by federal, state, local or territorial law.
10.	Organization must comply with all applicable federal, state, local or territorial laws. Organization must comply with applicable patient assent or consent laws for administration of bamlanivimab.

[5] https://www.fda.gov/media/143603/download

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

11.	Organization must submit to HHS, on a daily basis through designated methods, the number of doses of bamlanivimab that Organization: a) has ordered on hand at each location for administration in each state, locality, and territory; b) has distributed to each Organization location for use in each state, locality, and territory; and c) has administered to individuals in each location served. Organization must submit the information in Paragraph 11. a - c to state, local, and territorial public health authorities insofar as the information relates to bamlanivimab distribution and administration in the respective state, locality, or territory, and such reporting is required by the state, local or territorial jurisdiction. Organization must use reasonable efforts to report such information as soon as practicable and in compliance with any state, local, and territorial reporting requirements.
12.	Organization must order bamlanivimab through HHS-designated systems.
13.	To facilitate planning, Organization must propose, in writing by the date provided by HHS, its minimum capacity for bamlanivimab administration, including: a) the number of Organization facilities that will administer bamlanivimab; b) the location of each of those facilities, and enrollment verification in the Medicare or Medicaid programs; c) the number of bamlanivimab doses that each facility will be able to administer, within defined periods; and d) as applicable, the name, address, location, facility type (outpatient, skilled nursing facility, assisted living facility, independent living facility, or a combination of any of the three), number of residents, and number of staff at each facility for which Organization intends to provide onsite bamlanivimab administration services, as needed; e) as applicable, the estimated number of in-home infusions Organization will be able to provide, within defined periods, by each geographic area Organization intends to serve, and a description of the mechanisms by which Organization will enroll in-home patients for the infusion services; and f) as applicable, the locations of any other non-Organization outpatient locations that Organization locations will serve. Organization will not receive bamlanivimab unless HHS accepts the proposal. Once accepted, Organization must notify HHS within 24 hours, in writing, of any proposed changes. If any of those changes are unacceptable to HHS, HHS may decline to provide further bamlanivimab. Organization must include the information provided under Paragraph 14. b-f in Section B for each location upon HHS approval of Organization's bamlanivimab administration program proposal, and, as applicable, Organization must update Section B with any changes to the list of LTCFs and geographic areas served for in-home infusion for which the Organization will provide bamlanivimab infusion services. As applicable, HHS reserves the right to share the list of geographic areas served for in-home infusion and LTCFs to which the Organization plans to provide requested bamlanivimab infusion services with

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

	jurisdictions and partners, including other healthcare system participants in the HHS COVID-19 monoclonal antibody infusion program providing onsite services in-home, and/or to residents/staff of LTCFs.
14.	Any Organization location receiving bamlanivimab must report supply levels at least daily using the online web platform designated by HHS.
15.	Organization must have processes to ensure timely and proper acceptance of bamlanivimab. Those processes must include, but are not limited to, procedures for accepting bamlanivimab delivery-through-delivery services designated by HHS. HHS will notify Organization of a designated delivery service or services no later than two weeks before delivery commences or no later than two weeks before a delivery service or services change. To facilitate planning, Organization must propose, in writing by the date provided by HHS, its hours for accepting bamlanivimab deliveries at each receiving Organization location. If Organization's current wholesale supplier for such receiving location is servicing that receiving location using the same delivery process that that wholesale distributor uses to deliver other pharmaceutical products to that location, Organization need not propose that receiving location's hours for accepting bamlanivimab deliveries. Organization will not receive bamlanivimab unless HHS accepts the proposal. Once accepted, Organization must notify HHS within 24 hours, in writing, of any proposed changes. If any of those changes are unacceptable to HHS, HHS may decline to provide further bamlanivimab. Organization must report any bamlanivimab that is damaged upon delivery pursuant to the process provided by the delivery service and to HHS within 24 hours. HHS will provide procedures for reporting.
16.	If serving LTCFs, Organization must comply with all applicable COVID-19 testing requirements as set forth in the Centers for Medicare & Medicaid Services (CMS) Interim Final Rule CMS-3401-IFC,[6] "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," related to Requirements for Long-Term Care (LTC) Facilities to Test Facility Residents and Staff for COVID-19. Under Agreement, Organization must ensure that any Organization personnel entering an LTCF to organize, assist, or provide onsite bamlanivimab infusion services are tested pursuant to the requirements for "staff" or "facility staff."[7] Organization shall bear the cost of such COVID-19 testing.
17.	Organization must maintain records for all bamlanivimab ordering and administering providers, including title and license number of each provider for each site listed in Section B.
18.	Organization may use contractors to perform some or all of Organization's duties under Agreement. Organization must ensure that any contractor performs its duties in full compliance with Agreement and Organization is responsible under Agreement for any non-compliance with Agreement by any of its contractors. Furthermore, any knowledge concerning or resulting from performance of Agreement by any of Organization's contractors is imputed to Organization.

[6] 85 Fed. Reg. 54,820 (Sept. 2, 2020), and as may be amended.

[7] *See*, *e.g.*, 42 CFR. § 483.80(h) ("The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19."); 42 CFR § 483.80(h)(5)("Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.").

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling bamlanivimab understand and will comply with Agreement requirements listed above and that the information provided in sections A and B is true.

Paragraphs 1-18 of Agreement set forth material conditions of payment for bamlanivimab administration claims submitted by Organization to any federal healthcare program, including but not limited to Medicare and Medicaid, or any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Paragraphs 1-18 do not, however, list all material conditions of payment for these programs. Organization must review the applicable statutes and regulations governing each federal healthcare program and any HHS-sponsored COVID-19 relief program for program-specific conditions. Reimbursement for administering bamlanivimab is not available under any federal healthcare program or any HHS-sponsored COVID-19 relief program if Organization fails to comply with Paragraphs 1-18 or any other material condition of payment with respect to the administered bamlanivimab dose. Each time Organization submits a reimbursement claim for bamlanivimab administration to any federal healthcare program or any HHS-sponsored COVID-19 relief program, Organization expressly certifies that it has complied with all conditions of payment, including but not limited to Paragraphs 1-18, with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the HHS COVID-19 Monoclonal Antibody Infusion Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq*., and other related federal laws, including but not limited to 18 U.S.C. §§ 1001, 1035, 1347, 1349.

HHS may also terminate this Agreement with two weeks written notice.

Organization may cease its participation in the HHS COVID-19 Monoclonal Antibody Infusion Program. To do so, Organization must provide written notice to HHS no later than two weeks before Organization wishes to end its participation. During that period of at least two weeks, Organization must comply with Agreement and Organization will not receive any further deliveries of bamlanivimab.

Should HHS desire to modify the terms of this Agreement, HHS will provide Organization with at least two weeks' written notice of the modified terms. If Organization does not agree with the changes, Organization may withdraw from the agreement with two weeks' written notice.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.[8]

[8] *See* Pub. L. No. 109-148, Public Health Service Act § 319F-3 and § 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020), and as amended.

HHS COVID-19 Monoclonal Antibody Infusion Program Provider Agreement

Chief Medical Officer (or Equivalent)		
Last name Frankel	First name Harris	Middle initial A
Signature: Harris Frankel		Date: 11/20/2020
Chief Executive Officer (or Chief Fiduciary)		
Last name Linder	First name James	Middle initial R
Signature: James Linder MD		Date: 11/20/2020

For official use only:

Unique Organization ID*:_____

**HHS will issue unique identifiers for the Organization and locations covered under this Agreement. This ID is needed for HHS to delineate Organizations (Section A) and to match them with one or more Locations (Section B).*

Section B. HHS COVID-19 Monoclonal Antibody Infusion Program Provider Location Profile Information

PLEASE PROVIDE A LINE LIST OF ALL ORGANIZATION LOCATIONS THAT WILL RECEIVE BAMLANIVIMAB SHIPMENTS, INCLUDING THE FOLLOWING INFORMATION FOR EACH:

- Store's Organization-assigned ID number
- Store's HHS bamlanivimab ordering ID
- Location address, telephone, and fax number
- Contact information for location's bamlanivimab coordinator (name, telephone, email)
- Contact information for location's backup bamlanivimab coordinator (name, telephone, email)
- Days and Times coordinators are available for receipt of bamlanivimab shipments
- Ability to make appointment for bamlanivimab infusion services (yes/no)
- Does store accept
    - Medicaid? (Y/N) If yes, list Medicaid ID: _____
    - Medicare? (Y/N) If yes, list Medicare ID: _____
    - Other insurance? (please list or note none)
- Storage capacity
- Estimated daily number of bamlanivimab doses that location will be able to administer _____
- As applicable, geographic area(s) to be served for in-home bamlanivimab infusions
- As applicable, LTCFs intends to serve, including details required under paragraph 13.d).
- As applicable, other non-Organization outpatient locations where Organization location intends to provide bamlanivimab infusion services

Healthcare systems should be prepared to use a portion or all components of the system – this will vary based on amount of supply, demand, and populations prioritized to receive bamlanivimab.