

Monoclonal Antibody Treatment Provider Enrollment, Reporting, and Ordering Instructions

Updated: June 1, 2022

The Rhode Island Department of Health (RIDOH) is pleased you are interested in becoming a monoclonal antibody treatment provider. Monoclonal antibody treatment is a doctor-recommended treatment for COVID-19 that is fast, easy, and highly effective. It helps keep people from getting sicker and being hospitalized.

This document provides the following information:

- Section A: How to enroll to become a monoclonal antibody treatment provider
- Section B: How to complete required reporting of monoclonal antibody medication
- Section C: How to place orders to receive monoclonal antibody medication

Section A: How to enroll to become a monoclonal antibody treatment provider

Providers must follow the steps below to be able to receive and administer monoclonal antibodies.

- Step 1: Enroll in the AmerisourceBergen (ASB) program. Healthcare providers and community agencies interested in becoming monoclonal antibody treatment providers must establish a business account with AmerisourceBergen (ASB). If you're not currently enrolled in the ASB program, contact Dawn Lewis at dawnl@hari.org with the subject line "New MAB Provider Information-ASB Account". Dawn will send you an Excel spreadsheet to complete with details such as your shipping address, pharmacy license number, and primary and secondary points of contact. After you complete and return the form, RIDOH will share this information with ASB.
- Step 2: Complete a Teletracking Account form. The Assistant Secretary for Preparedness and Response (ASPR) within the US Department of Health and Human Services (HHS) requires that all providers that want to administer monoclonal antibodies register for a Teletracking Account. The staff within the RIDOH Hospital and Treatment Team can help you to set up an account. Details needed to establish an account include name of company, shipping address, ASB account number, and the name, email, and phone number for a point of contact. Email this information with the Subject line "New MAB Provider Information-Teletracking" to Dawn Lewis at dawnl@hari.org. RIDOH will share this information with Teletracking. For account follow-up, contact hhs-protect@teletracking.com.
- Step 3: Confirm your ability to report daily vaccination data to federal and state agencies. All monoclonal antibody providers must be able to provide inventory-level data to the Hospital Incident Reporting System (HIRS) weekly and patient-level data to the REDCap system within 24 hours of administration.

Inventory and usage data fields are established by the federal government and can be viewed at www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf.

Your practice or organization must submit the required data in two ways:

- 1. HIRS is a RIDOH-managed software system where monoclonal antibody providers report inventory and usage data. The link to access the system is <u>kidsnet.health.ri.gov/kidsnet-apex-prod-fregs</u>. You must get credentials to access the system. A staff member within the RIDOH Hospital and Treatment Team will provide these credentials. The information needed to get credentials includes the data entry person's name, email, and phone number. Email this information with the Subject line "New MAB Provider Information-HIRS" to Dawn Lewis at <u>dawnl@hari.org</u>.
- 2. REDCap is a secure web application for building and managing online surveys and databases. RIDOH uses this system to collect patient-level data for people who have gotten monoclonal antibodies. Access the system at surveys.health.ri.gov/redcap/surveys/?s=NAYWAKFPWF. This system does not require credentials, but your organization must be added to the system for you to enter data. The information provided in **Step 1** of these instructions will be used to add the organization to the REDCap dropdown list selection for agencies.

See **Section B** for instructions on reporting.

- Step 4: Complete training. Once enrolled as a monoclonal antibody provider, a staff member of the RIDOH Hospital and Treatment Team can provide training to walk you through entering data into both HIRS and REDCap. Email a request for training with the Subject line "New MAB Provider Information-Training" to Dawn Lewis dawnl@hari.org.
- Step 5: Confirm federal reporting: Once Step 4 is complete, staff within RIDOH's Hospital and Treatment Team will run a beta test of submitting the HIRS inventory and usage data into the Teletracking reporting system. Once this connection is established, you can begin providing monoclonal antibodies to patients in Rhode Island.
- Step 6: RIDOH website posting: To post your services on the RIDOH website, send an email to
 Dawn Lewis at dawnl@hari.org. Include your company or clinic name, address, days and hours of
 service, contact information, referral form, and whether an appointment is required.

Once you've completed this enrollment process, you can order monoclonal antibody medication. Enrolled monoclonal antibody treatment providers can request medication once a week through HIRS at kidsnet.health.ri.gov/kidsnet-apex-prod-fregs. See **Section C** for instructions on ordering monoclonal antibody medication.

Section B: How to complete required reporting of monoclonal antibody medication

- Step 1: Reporting inventory and usage in HIRS
 - 1. Each Wednesday, no later than 10:30 a.m., log onto HIRS at <u>kidsnet.health.ri.gov/kidsnet-apex-prod-fregs</u> to access the **Low Volume Data Entry Form**
 - 2. Select Add New Record
 - 3. Scroll to Therapeutics Section
 - 4. Enter weekly inventory and usage data for each monoclonal antibody type (do not leave any blanks—enter zero if no medication used)
 - 5. Scroll to top of form and click Save Record

• Step 2: Reporting patient-level data in REDCap

- 1. Each day, log onto REDCap at surveys.health.ri.gov/redcapurveys/?s=NAYWAKFPWF
- 2. Complete the question survey (one survey per patient)
 - a. Facility type
 - b. Patient information
 - c. Treatment Information
- 3. Click Submit

Section C: How to place orders to receive monoclonal antibody medication

- Step 1: Place order in HIRS
 - 1. Each Monday, no later than 10:30 a.m., log onto HIRS at <u>kidsnet.health.ri.gov/kidsnet-apex-prod-fregs</u> to access the **Low Volume Data Entry Form**
 - 2. Select Add New Record
 - 3. Scroll to Therapeutics Section
 - 4. After entering weekly required inventory and usage data, answer the Yes/No question, "Do you need to order Monoclonal Antibody Medication?" If you answer Yes, enter the quantity of courses desired for following week for each monoclonal antibody type.
 - 5. Scroll to top of form and click Save Record
- Step 2: Stand by for RIDOH confirmation that order was placed with ASB

RIDOH will have already received the state allocation of monoclonal antibody information from the federal government, typically received late Mondays. On Tuesday, a staff member within the RIDOH Hospital and Treatment Team will work with the allocation and orders to optimize order fulfillment. If requests exceed supply, RIDOH may contact you to further discuss needs or to request redistribution of unobligated inventory. Note that the prior week's statewide monoclonal antibody administration with a target of 70% inventory usage is a federal metric taken into consideration when authorizing orders.

RIDOH will attempt to fulfill all order requests, but it's possible that, even with negotiations and redistribution, you may only receive authorization for partial fulfillment of your requested order. RIDOH will email your authorized quantity.

Resources

- COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit
- Guidance for Returning Product
 - For bamlanivimab and for bamlanivimab and etesevimab administered together, see The Lilly Return Goods Procedure. Find detailed guidance at www.lillytrade.com.
 - For REGEN-COV, call 844-734-6643
- HHS Protect Therapeutics Dashboard
- Monoclonal Antibody Insurance Website
- Monoclonal Antibody Therapeutics Homepage