



DATE: November 5, 2021
TO: Health Care Providers and Health Care Facilities
FROM: New York State Department of Health

Guidance on How to Request a Supply of COVID-19 Monoclonal Antibody (mAb) Therapeutics

Summary:

- This document supersedes the September 18, 2021 and September 23, 2021 “Guidance on How to Request a Supply of COVID-19 Monoclonal Antibody (mAb) Therapeutics.”
- Requests to the NYS Department of Health for a supply of monoclonal antibody (mAb) therapeutics for COVID-19 will need to be submitted through the Health Commerce System.
- The Department has implemented a process to enroll additional qualified providers – see section “New Provider Enrollment Process.”

This announcement provides updated details on how New York State (NYS) providers can submit requests for a supply of monoclonal antibody (mAb) therapeutics.

On Monday, September 13, 2021, the U.S. Department of Health & Human Services (HHS) changed the distribution system for mAb therapeutics. HHS transitioned from a direct requesting process whereby providers requested directly from the distributor, AmerisourceBergen, to a state/territory-coordinated distribution system. Each state/territorial Health Department will now determine where mAb product goes within their jurisdiction. The states and territories will be assigned a weekly allotment of mAb product by HHS. The amount will be based on COVID-19 case burden and mAb therapeutic utilization. The mAbs therapeutics affected are:

1. Bamlanivimab/etesevimab (Lilly)
2. Etesevimab (Lilly – to pair with bamlanivimab already on hand)
3. Casirivimab/imdevimab, i.e., REGEN-COV (Regeneron)
4. Sotrovimab

The NYS Department of Health (Department) is now intaking requests for mAb therapeutics from NYS providers. The distribution of these therapeutics will remain with AmerisourceBergen. The Department will inform AmerisourceBergen of each provider’s request and how much of the request should be filled. As the State will be allotted a finite amount of mAb product each week, providers may not receive the total amount of product they requested. The Department will determine how much product each provider receives based on the supply allotted to the State from HHS.

New Provider Enrollment Process

Follow the steps below to register to begin requesting mAb therapeutics.

Step One – Complete the COVID-19 Therapeutics Provider Enrollment Form

Complete the form located within the Health Commerce System (HCS) here: <https://mabrequest.health.ny.gov/nysmab/newprovider>. Fill out all applicable fields and upload a copy of (1) your valid NYS license and (2) an AmerisourceBergen Letter of Affiliation (LOA) if you are a physician and the address on your physician's license does not match the shipping address provided on the enrollment form. A link to the LOA can be found in the enrollment form.

- If you do not have a HCS account, please visit the [Health Commerce System](#) website, and click on “Don't have an Account? Sign Up Here” to register for an account.

Step Two – NYS Review

The mAb therapeutics team at the Department will review your enrollment form to make sure the necessary documentation has been submitted and that you are licensed and in current good standing in NYS. If your submission is rejected, you will receive an email from the Department via COVID19therapeutics@health.ny.gov with an explanation and any next steps (if needed). If your submission is accepted, the Department will move to Step Three.

Step Three – Department Sends Information to AmerisourceBergen

In order to receive mAb product from AmerisourceBergen, your site must be included in their system. You will also need an AmerisourceBergen account.

- If you already have an AmerisourceBergen account, your site information, along with the copy of your license and completed LOA (if applicable), will be sent to AmerisourceBergen. They require this information to be able to send you mAb product.
- If you do not have an AmerisourceBergen account, the Department will submit your site location information, copy of your license, and completed LOA (if applicable) to AmerisourceBergen, and they will create an account for you.

Step Four- Site Locations and HHS TeleTracking Account

Once your AmerisourceBergen account has been set up:

- The Department will email you a link to an additional form to complete, which asks you to identify all site locations mAb product will be dispensed or administered. This information will be used by the Department to understand the number and location of the sites you are sending mAb product to.
- You will need to sign up for a HHS Protect, TeleTracking or NHSN account by following the directions here: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx>. For more information on Federal reporting requirements, please see the next section, “Provider Requirements.”

Step Five – Request Therapeutics

Once you have submitted a complete list of all your site(s), the Department will notify you via email that you can request mAb product for your site. Follow the process outlined below to submit requests to receive mAb product.

Provider Requirements:

In an effort to ensure ongoing equitable distribution of mAb therapeutics, the Department will require providers to identify all sites associated with their organization. The Department will email all enrolled providers a form to complete, which asks the primary shipping site to identify all site locations mAb product will be dispensed or administered.

In order to receive mAb product, providers **must** also continue to report their weekly utilization data to the Federal government through the appropriate system of HHS Protect, TeleTracking or NHSN, depending on facility type. These reports continue to be due every Wednesday. For more information on the federal reporting requirement, including account information, please visit: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx>.

How to Request COVID-19 mAb Therapeutics:

Requests for mAb product will no longer be submitted using the spreadsheet as outlined in the September 18th guidance. Requests should be submitted online as per the following directions:

1. Go to the following link: <https://mabrequest.health.ny.gov/nysmab/>. You'll need a HCS account to access the form.
 - a. If you do not have a HCS account, please visit <https://commerce.health.state.ny.us>, and click on "Don't have an Account? Sign Up Here" to register for an account.
2. Complete all fields of the online form. When you have completed all fields, click the "submit" button. You will receive an email notification confirming your submission.

As a reminder, the amount a provider requests may not be the amount the provider receives. The amount received will be based on the supply allotted to the State from HHS.

Deadlines:

All requests must be submitted using the online HCS form every week by Monday, 5:00PM. These requests will be reviewed that same week and entered in the AmerisourceBergen portal by the Friday deadline for each weekly cycle. Sites will receive an email from AmerisourceBergen letting them know the amount of mAb product that has shipped so they can prepare for delivery. The online HCS form will be open for entry every week from Thursday at 8AM through the due time of Monday by 5PM.

Please visit the Department's *Monoclonal Antibody (mAb) Therapeutics: Information for Providers* website for further information: <https://coronavirus.health.ny.gov/monoclonal-antibody-therapeutics>. For questions, please send an email to COVID19therapeutics@health.ny.gov.