



DATE: September 23, 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 “Guidance to Providers on How to Request 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.
- Providers who have an active account from AmerisourceBergen can submit a request.
- The Department is working to put in place a process to enroll additional qualified providers. More information will be forthcoming in a separate announcement.

This announcement provides updated details on how New York State (NYS) providers can submit requests for a supply of monoclonal antibody (mAb) therapeutics. **At this time, only providers who have an active account from AmerisourceBergen can submit a request.**

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)

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.

Provider Requirements:

Only providers who have an active account from AmerisourceBergen can submit a request for product at this time. We are working to put in place a process to enroll additional qualified providers. More information will be forthcoming in a separate announcement.

In order to receive mAb product, providers must 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 now be submitted online as per the following directions:

1. Go to the following link: <https://mabrequest.health.ny.gov/nysmab/>. You'll need a Health Commerce System (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.

For questions, please send an email to COVID19therapeutics@health.ny.gov.