



Monoclonal Antibodies for COVID-19

Change Package: Last Updated 10.13.21

Objective: In addition to vaccines and antivirals, monoclonal antibodies (MAB) are important treatment options against the virus that causes COVID-19 and are another service that can be offered by community pharmacies. The change packages and Workflow Wednesdays webinar series focus on “how to(s)”, pragmatic marketing, personnel and operational issues.

Additional questions or have a best practice to share?

Email mab@cpesn.com

LEGAL AND POLICY CONSIDERATIONS

Authority to Order and Administer:

“The 9th amendment to the COVID 19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for **pharmacy technicians and pharmacy interns** to administer COVID 19 therapeutics” under certain criteria. Access the 9th Amendment here: [Expanding Access to COVID 19 Therapeutics HHS PREP Act Declaration](#)

Review your Liability Insurance Coverage:

Liability insurance carriers may require pharmacists to oversee or supervise other professionals (nurses, etc) in order to be covered for any liability claims.

Emergency Use Authorizations:

1. [REGEN-COV EUA](#)
2. [Bam with ETA EUA](#)

LOGISTICS

Site preparation

Ordering Product:

On Monday, September 13, HHS transitioned from a direct ordering process to a state/territory-coordinated distribution system. State/Territorial Health Departments will determine where product goes in their jurisdictions. There is likely not going to be a Federal Pharmacy Partner option for ordering or distribution, unlike the COVID-19 vaccination system.

Special Considerations for COVID positive patients:

- Patients have been confirmed positive for COVID19 or post-exposure meeting certain conditions.
- Patients will need to be separated from other pharmacy patrons; either using a separate clinic space, separate entrance, and clear signage on where to go.
- Consider offering home visits.
- Patients must wear masks!

Safety and Cleaning Procedures:

- Cleaning supplies pharmacies are using include:
 - Caviwipes
 - Purple wipes on Amazon
- For infection control, one pharmacy's precautions to filter potentially contaminated air:
 - CIMR that produces peroxide in the air
 - Two separate ventilation systems
 - Everyone wears masks
 - They see post-exposure prophylaxis patients earlier in the day
 - They sanitize everything in between patients

NEW

Decide if offering for prophylactic exposure and/or confirmed COVID-19 infection:

- REGEN-COV is indicated for active infection in high risk individuals with mild to moderate symptoms AND post-exposure prophylaxis in vulnerable persons.
 - Pharmacies in Arkansas are reporting to do both indications. We have not identified anyone restricting to just prophylactic exposure.
- Bamlanivimab and etesevimab is only authorized for confirmed COVID-19 infection

Develop a referral process:

Advertise on social media, the pharmacy's website and to local providers that your pharmacy will offer this service.

Setting up your clinic:

- Large space with partitions or separate rooms (1 patient/room)
- Home visits are an option and may bring additional reimbursement
- Another option is to administer MAB in a small clinic space, then have patient wait in their car for the monitoring period. This helps being able to serve up to 3 patients per hour instead of 1 patient each hour if you have a small space.
- Reclining chairs can be purchased from Amazon ([link here](#)) for about ~150

NEW

Example clinic setup:



Patient Visit Logistics

Appointment Scheduling

- Using an online scheduling system that includes patient intake and consent forms is key to staying organized. It also helps if the treatment center is located in a different building than the pharmacy so that the pharmacy can access the information as timely as possible. Example application used that is HIPAA compliant is Acuity scheduling.
- From East Gate Pharmacy: Scheduling 5-6 patients at a time
 - Limiting factor: number of chairs
 - Can handle 40 patients a day, but have scheduled a maximum of 16 patients in a day

Time frame: Plan on 90 minutes per patient

- This requires frequent monitoring of vital signs throughout treatment. Required to monitor for at least 60 minutes after administration
- Patient will need time to complete paperwork, screening assessment, and initial vitals before administering MAB; thus schedule at least 90 minutes per patient.
- May need to hire additional staff

Example Workflow Once Patient Arrives

The Pharmacy at Wellington, Little Rock, AR

1. Patient completes paperwork
 - a. [consent form](#)
 - b. [Regen-Cov Fact Sheet](#) and the pharmacist is available to answer questions
 - c. Get copy of drivers license, insurance card and a copy of positive COVID test (if available)
2. Take an initial set of vitals including HR, BP, RR, temp., pulse ox. Pharmacist reviews vitals.
3. Draws up 4 SQ injections . Recommend using 5 mL syringes (not 3 mL syringe) for easier administration.
4. It takes roughly 30-45 seconds to administer each injection because the fluid is fairly viscous
5. After the 4 injections are given, take another set of vitals
6. Monitor for a minimum of 60 minutes (The duration of observation, regardless of route, is 60 minutes). Complete another set of vitals. Patient can then return home.

7. Follow-up with patients the next day. Most patients report feeling much better 24 hours later.

Monitoring Vitals

NEW

1. Frequency of monitoring (before, post-administration, and at 60 minutes) is directed in the Emergency Use Authorization through Regeneron
 - a. <https://www.fda.gov/media/143891/download>
2. The most relevant vitals are those indicative of an anaphylactic reaction
 - a. Hypotension - monitor BP
 - b. Bradycardic response - monitor HR
 - c. Monitor pulse ox
 - d. Monitor temperature

NEW

Enhancing the Patient Experience

- Ensure patients eat before they come and bring jacket/blanket because they may be fever-ish or cold
- Provide snacks, cold water, or white soda to help ease patients' nerves.

TEAM ROLES & RESPONSIBILITIES

Staffing Models

NEW

- Consider hiring additional staff. This can include other healthcare professionals who can assist in providing clinical services including nurses, LPN, EMT.
- Check state regulations on oversight of nurses or other mid-level practitioners. Some states have their nurses become pharmacy technicians or have a separate medical director sign off on administration of therapy.

BILLING

Medical billing is necessary for reimbursement

- Contact your clearinghouse to see if they can submit medical billing for this treatment
- Alternatively, you can hire a medical billing company to process claims.
- Keep in mind there may be cost sharing for non-Medicare patients.

Medicare Part B covers administration 100% with no cost share

- Medicare will pay approximately \$450 in most settings, or approximately \$750 in the beneficiary's home or residence
- [CPT Codes can be found here](#)
- Diagnosis Code: U07.1
- Procedure Code: M0243
- Site of Care: Outpatient

ADMINISTRATION

[Click here](#) for quick 1-pager review of administering SubQ

[REGEN-COV Dosing guide](#)

Adverse Reactions

- NEW** • East Gate Pharmacy prophylactically administers diphenhydramine 25mg by mouth for any patient with a notable drug allergy

Our partners at NCPA cover the clinical and continuing education to learn about the therapy.

Tip: Visit [NCPA's website](#) for treatment guidelines

TOOLS & TEMPLATES

Courtesy of Oregon Board of Pharmacy:

- [COVID-19 Comprehensive Communication](#) -MAB begins on page 7 and includes links to more templates.

Courtesy of The Pharmacy at Wellington, Little Rock, AR

- [Policies and Procedures](#)
- [Patient Consent Form](#)
- [Order Form](#)
- [Super Bill](#)

ADDITIONAL RESOURCES

1. [Monoclonal Antibody Playbook \(updated 2 September 21\)](#)
2. [HHS Combat COVID](#)