

## Frequently Asked Questions for Monoclonal Antibody (REGEN-COV) use in the PALTC Setting

(Notes from Meeting with Pharmerica regarding mAb for LTC, and CMO Hospital Meeting w HHS guest, Michael Anderson on 8/10/2021, compiled by HMDA)

- **WHO should get monoclonal Ab treatment?**

- Are there criteria for the treatment of early symptoms in COVID positive patient?
  - COVID +, experiencing mild-mod symptoms
  - 12 years and older, > 40 kg,
  - Vaccinated or unvaccinated
  - High risk of progression to severe disease (including hospitalization/death), based on clinical judgement.
  - Within 10 days of the start of COVID Symptoms
- Post-Exposure Prophylaxis (PEP): 12 years and older, > 40 kg, not fully vaccinated, immunosuppressed, close contact as defined by CDC, particularly for people living in In congregate settings (NHs, prisons, etc). Note: This is not Pre-Exposure Prophylaxis.
- Should I give my unvaccinated NH resident a vaccine instead of a dose of monoclonal antibody?
  - If the goal is immediate protection from likely exposure, it is more important to get the mAb into them ASAP to protect them. This provides external antibodies to buy them time. They can get the vaccine later (after 90 days).
  - Note that if give Mab first, you have to wait 90 days, so Ab titers are low enough so they won't "attack the vaccine" and render it useless (CDC guidance).

- **SETTING**

- What are good settings for administering the SC formulation?
  - Designed for outpatient setting, thus able to be given at urgent care, infusion centers, mobile vans, Nursing homes, dialysis centers, CHCs, drive-by tents, homes, etc.
- Can't we just send NH residents out to the hospital infusion center to get the monoclonal antibody?
  - Not currently. Hospitals are extremely busy and have limited capacity

- **TRAINING**

- What resources/ training are available for nursing home staff training for administering sub Q or IV infusion?
  - You can review the Pharmerica Policies & Procedures, and read the Regeneron EUA fact sheet.
  - There is also a OmniCare (CVS) Nursing Procedure 6-page guide which is easy to follow
  - HHS has a 2-page infographic with lots of hyperlinks which are useful
  - HHS has some one-pager instructions, and Toolkit
  - HHS willing to do training to a large group if we pull them together

- **ORDERING**

- Is a physician signature required to order Regeneron SC or IV?
  - No, a telephone order will suffice (which can be signed later)
- Can we order SC dose from LTC Pharmacies? Or just the IV formulation?
  - The SC form was approved in June 2021, so yes, we can now order the SC form.
- What is the time window for giving the Regeneron?
  - Within 10 days of COVID positive test, and ideally as soon as possible in order to prevent worsening of symptoms.
- How soon after we order can we expect to have Regeneron to be delivered?

- Pharmerica needs to order it from the mainland. It will arrive in 2 days.
  - Pharmerica has pre-ordered and obtained 10 vials of [Regen-COV 600mg/600mg/10ml SDV vials](#). to have on hand for immediate use, then will order more as needed.
- If a facility has no formal contract with Pharmerica, can they still order Regeneron from them?
  - Yes.
- **RECONSTITUTION AND STORAGE**
  - If we order Regeneron SC, is there any need to reconstitute it?
    - No, just draw it up in your syringe, and administer 2.5 mL at 4 different sites.
  - If we order Regeneron IV, who reconstitutes it?
    - Pharmerica will reconstitute it (requires a hood).
  - Don't shake the vials!
  - Once we receive the medicine, how long can you store it?
    - Can only store refrigerated up to 4 hours.
  - Each vial provides enough for TWO patients. So if you only have ONE person in a day, you should discard the rest after 4 hours. However, HHS would rather have you waste a dose, than not administer it at all. There is plenty of supply.
- **ADMINISTRATION & MONITORING**
  - Who can administer? (e.g. RN, Pharmacist, LPN)
    - Anyone who can administer SC meds, and monitor.
  - Who should be monitoring?
    - Whoever monitors must have the capability to break into the e-kit in case of anaphylaxis, and ability to call 911.
  - How long to monitor?
    - One hour (not half an hour).
  - Can we monitor several people at one time?
    - Yes, if you have several people who receive the mAb, if they are all in the same room, they can be monitored by the same person simultaneously, and make this more efficient.
  - Do you know of any Nursing home experiences (with regards to ease of administration, monitoring, and safety) on the mainland who have done this?
    - Most of the experience is with IV Regeneron.
    - Extremely well tolerated.
    - Allergic/ anaphylaxis ADE are very rare.
    - Anecdotal stories from California- No side effects, and they saw a big improvement of symptoms within a day or two.
  - Repeat doses of Regen-COV for PEP
    - The first dose is 600 mg. If there is ongoing exposure, then subsequent doses are 300 mg and should be given Q4 weeks for the duration of the ongoing exposure.
- **COST**
  - Is there a cost to the facility if it orders Regeneron IV?
    - Yes and No. The drug itself is free, but there are IV and tubing supplies and the cost of reconstituting it. Pharmerica will charge \$99. And Pharmerica will NOT assist with IV access, infusion or monitoring. However, HHS said that CMS will reimburse home infusions.
    - Beginning 5/6/2021, if given in patient's home or residents (this includes NH), Medicare will pay approximately \$750 for administration fees regardless of IV or SC administration.

- Therapeutic Coverage Infographic for Medicare Part B Payment:  
<https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf>
- FAQs on Medicare FFS billing: <https://www.cms.gov/files/document/03092020-covid-19-fags-508.pdf>
- Facilities have the option of “contracting out” the IV access and monitoring for providing Regeneron IV to outside entities (e.g. home infusion companies, etc). However those entities can ask for CMS reimbursement, not the facility. (and the facility would still be left with the \$99 charge to Pharmerica).
- Is there a cost to the facility for ordering Regeneron SC?
  - No. the drug itself is free.
  - No. In fact, the facility can get CMS reimbursement for injection and monitoring.
- I would imagine that someone who was symptomatic and COVID + would be transferred to a COVID unit on a SNF unit for quarantine/isolation x 14 days. Will facilities still be able to request CMS reimbursement for Regeneron administration?
  - Yes. Facilities can be reimbursed for the usual Medicare SNF rates, as well as separately ask for Regeneron reimbursement.

Other Questions?

For more information on Coverage for Monoclonal Antibody COVID-19 Infusions:

<https://www.cms.gov/covid-19-vaccines-and-monoclonal-antibodies>

Email [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov) to get access to weekly “office hours” for Q&A.

## Weekly office call sessions

### Weekly mAbs Administration Sites and Stakeholders Call Sessions

- **State, Local, Tribal, and Territorial Public Health Officials:**  
Wednesdays (2:00-2:45PM ET)
- **Healthcare Systems and State Hospital Associations**  
Wednesdays (3:15-4:00PM ET)
- **Office Call Sessions: HHS / ASPR Allocation, Distribution, Administration of COVID-19 Therapeutics**  
Thursdays (2:00-2:30PM ET)

Please email [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov) to request Zoom links for these calls