September 10, 2021

SUBCUTANEOUS ADMINISTRATION OF CASIRIVIMAB/IMDEVIMAB (REGEN-COV) BY PHARMACISTS

The Alabama Department of Public Health (ADPH) recognizes that treatment of coronavirus disease (COVID-19) with monoclonal antibodies can help prevent hospitalization or death. The emergency use authorization (EUA) for REGEN-COV was recently revised to include subcutaneous administration when intravenous infusion is not feasible or would delay treatment. Trained pharmacists can administer REGEN-COV by subcutaneous injection and can provide this treatment to patients in their community. The Public Readiness and Emergency Preparedness Act (PREP Act) has been amended to provide liability protection and expands the scope of authority for licensed pharmacists (pharmacists) to order and administer select COVID-19 therapeutics per the EUAs and for qualified pharmacy technicians (pharm techs), and licensed or registered pharmacy interns (interns) to administer COVID-19 therapeutics per the EUAs. Currently, the only COVID-19 therapeutic that pharmacist can order and/or administer is REGEN-COV approved for subcutaneous injection. Per PREP Act Declaration 9th Amendment, the following criteria must be met:

- The COVID-19 therapeutic must be authorized, approved, licensed, or cleared by the FDA.
- When a pharmacist orders a COVID-19 therapeutic, the therapeutic must be ordered for subcutaneous, intravenous, or oral administration and in accordance with the FDA approval, authorization, clearance, and licensing.
- Pharmacists, pharmacy techs, and interns are limited to subcutaneous, intramuscular, or oral administration in accordance with FDA approval, authorization, clearance, or licensing.
- The supervising pharmacist must be readily and immediately available to the pharm tech.
- The pharmacist, intern, and pharm tech must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE) and must include:
    - Hands-on injection technique,
    - Clinical evaluation of indications and contraindications of COVID-19 therapeutics,
    - The recognition and treatment of emergency reactions to COVID-19 therapeutics, and
    - Any additional training required in the FDA approval, authorization, clearance, or licensing.
- The pharmacist, intern, and pharm tech must have a current certificate in basic cardiopulmonary resuscitation.
- The pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events.
- The pharmacist, intern, and pharm tech must comply with any applicable requirements or conditions of use that apply to the administration of COVID-19 therapeutics.

REGEN-COV is available under EUA for:

1. Treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) who test positive for COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization and death.
2. Post-exposure prophylaxis for adult and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death, and are not fully vaccinated or who are not expected to mount an adequate immune response **and**

    -Have been exposed to an individual infected with SARS-CoV-2 **or**

-Who are at high risk of exposure to an individual infected with SARS-CoV-2 in the same institutional setting (for example, nursing home or prisons).

Before offering this service, pharmacists should review the EUA in detail and consider the requirements. Besides being properly **trained and proficient** in giving an injection subcutaneously, pharmacists should also consider:

- Screening criteria for patients: Only those patients described in the EUA are candidates for receiving REGEN-COV. A list of conditions that define the patient as high risk can be found in the EUA. Patients must be informed that the product is under EUA and not approved by the FDA for this indication.
- Infection Control: Space for treatment should be large enough to appropriately separate patients receiving monoclonal antibodies from customers and patient flow should not allow these patients to cross paths. Standard precautions must be observed, personal protection equipment (PPE) must be used to minimize risk of exposure, and contaminated syringes and PPE must be disposed of according to state and federal laws.
- Storage and Preparation: REGEN-COV should be stored in the refrigerator and removed approximately 20 minutes before injection to allow it to reach room temperature. It should be at room temperature for no more than 4 hours. No supplies or PPE are provided by ADPH.
- Monitoring: Patients should be observed during the injection and for an hour after the injection for signs of hypersensitivity reactions. The person observing patients should have no other duties that would interfere with immediate action if needed. An emergency kit must be immediately accessible, and the pharmacist must be able to respond to an anaphylactic reaction, including administering epinephrine and calling emergency medical services.

REGEN-COV is available at no charge through AmerisourceBergen. CMS allows pharmacies that are approved immunizers to bill for its administration but reimbursement by other payors should be confirmed by the pharmacy.

The pharmacist should be confident that the EUA will be followed and that the medication can be safely administered. Questions regarding the provisions of the EUA should be directed to the Pharmacy Division at ADPH (nancy.bishop@adph.state.al.us or 334-206-5226) and questions regarding statutes or rules should be directed to the Alabama Board of Pharmacy.