Authority to Provide COVID-19 Therapeutics

Pharmacists, Pharmacy Technicians, and Student Pharmacists and Interns

The federal government now allows eligible licensed pharmacists to order and administer COVID-19 therapeutics that Food and Drug Administration (FDA) has approved, authorized, cleared, or licensed. The amendment also authorizes pharmacy interns and pharmacy technicians to administer these COVID-19 therapeutics. This federal authority was made official when the U.S. Department of Health and Human Services (HHS) released its ninth <u>amendment</u> to the Public Readiness and Emergency Preparedness (PREP) Act on September 9, 2021.

What is a COVID-19 therapeutic?

To be considered a COVID-19 therapeutic, the therapy must be approved, <u>authorized</u>, or licensed by FDA. <u>Licensed pharmacists have the authority to order and</u> <u>administer a COVID-19 therapeutic only when it is administered by subcutaneous, intramuscular, or oral route.</u>

At this time, there is only one COVID-19 therapeutic that can be given subcutaneously. <u>REGEN-COV (casirivimab/imdevimab)</u> is a monoclonal antibody therapy with an emergency use authorization (EUA) for the treatment of COVID-19 infection and for post-exposure prophylaxis in certain individuals.

While other COVID-19 monoclonal antibody therapies and COVID-19 therapeutics are authorized or approved, they must be administered as an intravenous infusion. Under the PREP Act, pharmacists do not have the authority to order and administer these intravenously infused therapies.

Oral COVID-19 therapeutics are being studied; if authorized, approved, or licensed, pharmacists would have the authority to order the therapeutic for the treatment of COVID-19, likely with proof of a positive COVID-19 test.

What if my state scope of practice does not allow me to order and/or administer COVID-19 therapeutics?

During the public health emergency, the federal authority to order and/or administer COVID-19 therapeutics would apply even when a state law otherwise prohibits a qualified person from ordering, dispensing, or administering covered COVID-19 therapeutics.

What if my state scope of practice is more permissive than this federal authority?

When state scope of practice allows pharmacists, pharmacy technicians, or pharmacy interns greater authority to order and/or administer therapeutics, this more permissive state authority would remain. Individuals practicing in such states should continue to follow their state scope of practice.



Authority to Provide COVID-19 Therapeutics (continued)

Pharmacists, Pharmacy Technicians, and Student Pharmacists and Interns

What should I know about my authority to order and/or administer COVID-19 therapeutics?

	Pharmacists	Pharmacy Technicians	Pharmacy Interns
Active state	Licensed or registered per state requirements; must		Licensed or registered per state requirements or if
license	have CPhT from PTCB or NHA if no state requirements		inactive/expired/lapsed in good standing within 5 years; must be authorized if no state requirements
Authority	Order and administer	Administer	
Supervision Requirements	None	A readily available qualified pharmacist	A trained health care professional
COVID-19 Therapeutics Requirements	Must be ordered and administered subcutaneously, intramuscularly, or orally in accordance with FDA approval, authorization, or licensing.		
Training Requirements	Must complete an ACPE-approved practical training program that includes 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 by FDA approval, authorization, or licensing.		
	These requirements can be met by completing the following training programs:		
	 APhA's <u>Certificate Training Program for Pharmacy-based Immunization Delivery</u> meets the requirement for hands-on injection technique and general recognition and treatment of emergency reactions to COVID-19 therapeutics. 		
	 APhA's Monoclonal Antibodies: Assessment and Administration of COVID-19 Therapy training program reviews the clinical evaluation of indications and contraindications for COVID-19 therapeutics, adverse events, as well as and product-specific requirements or considerations related to FDA approval, authorization, clearance or licensing of COVID-19 therapeutics. 		
Basic CPR	Must have a current certificate in basic CPR. An online basic CPR certification program accredited by ACPE, the American Nurses Credentialing Center, or the		
Requirements	Accreditation Council for Continuing Medical Education satisfies this requirement.		
Recordkeeping	Must comply with recordkeeping and reporting	The supervising qualified pharmacist must	Same as pharmacists.
Requirements	requirements of the jurisdiction in which he or she	comply with recordkeeping and reporting	
	administers COVID-19 therapeutics, including informing the patient's primary care provider when available and complying with adverse-event reporting requirements.	requirements as described to the left.	
Additional Requirements	Must comply with any relevant requirements or conditions of use that apply to the administration of COVID-19 therapeutics.		

Disclaimer: Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.