APhA

Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacy

Pharmacy Models for Expanding Access to COVID-19 Monoclonal Antibody Treatments

June 10, 2021

For Every Pharmacist. For All of Pharmacy.

pharmacist.com

Sandra Leal, PharmD, MPH, FAPhA, CDCES
Executive Vice President
Tabula Rasa Healthcare

President
American Pharmacists Association

Host and Moderator

Today's Webinar

Discuss pharmacy models for increasing awareness of and access to monoclonal antibody therapies for the treatment of COVID-19 infection.

Conducted in collaboration with the American Society of Consultant Pharmacists (ASCP).

ascp
Empowering Pharmacists.
Transforming Aging.

Chad Worz, PharmD, BCGP
Chief Executive
American Society of Consultant Pharmacists

Guest Speaker

Kimberly Sasser Croley, PharmD, BCGP, LDE
Clinical Pharmacist
Laurel Senior Living Communities

Guest Speaker

Mitch Rothholz, RPh, MBA
Chief of Governance & State Affiliates
American Pharmacists Association

Executive Director
American Pharmacists Association Foundation

Subject Matter Expert: Q&A

Dan Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

Subject Matter Expert: Q&A

Ilisa G. Bernstein, PharmD, JD, FAPhA
Senior Vice President
Pharmacy Practice and Government Affairs
American Pharmacists Association

Subject Matter Expert: Q&A

Disclosures

Mitchel C. Rothholz, RPh, MBA, has provided the following disclosures:

- Merck: Advisory board member, Spouse employer
- Pfizer: Advisory board member

All other individuals involved in the development of this material declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria. APhA's editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For a complete list of APhA staff disclosures, please visit the APhA website at www.pharmacist.com/apha-disclosures.

Learning Objectives

1. Describe the clinical considerations for monoclonal antibody therapies authorized for treatment of COVID-19 infection under emergency use.
2. Identify patients eligible to receive monoclonal antibody therapy and access to treatment.
3. Describe pharmacy practice models that can be implemented to increase awareness of and access to monoclonal antibody therapies.

Within how many days after symptom onset should an eligible patient receive monoclonal antibody therapy?

a) 3 days
b) 7 days
c) 10 days
d) 14 days

Which of the following patients would be eligible for monoclonal antibody therapy?

a) 10-year-old patient with asthma experiencing moderate COVID-19 symptoms
b) 61-year-old patient with diabetes and hypertension experiencing moderate COVID-19 symptoms
c) 80-year-old patient with heart disease experiencing severe COVID-19 symptoms
d) 65 year-old hospitalized patient requiring oxygen

Which of the following is NOT an example of how a pharmacist can increase access to monoclonal antibody therapies?

a) Educate local physicians and community members about the benefits
b) Refer patients who may be eligible to their physician after a positive COVID-19 test in the pharmacy
c) Administer monoclonal antibody therapies in appropriate settings
d) Prescribe monoclonal antibody therapies to eligible patients

Format for Today's Webinar

1:00pm: Introductions

1:05pm: Discussion with Chad Worz and Kim Sasser Croley

1:25pm: Open Forum Discussion: Share Your Questions & Thoughts

1:50pm: Review of APhA's Ongoing Activities & What's Coming

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible!
- Refer to the **Handout** in the GoToWebinar toolbar to access today's slides and links to resources.
- This webinar recording will be available in 24 hours.
- CE is only available during the live webinar.

Discussion with Chad Worz and Kim Sasser Croley

Discuss pharmacy models for increasing awareness of and access to monoclonal antibody therapies for the treatment of COVID-19 infection.

ascp
Empowering Pharmacists. Transforming Aging.

HHS Project SPEED

- Special Projects for Equitable and Efficient Distribution (SPEED) Program

- NHIA Project Speed
  - 172 individual pharmacy locations representing 36 organizations were enrolled in the program
  - Skilled nursing facilities received 288 (67.61%) doses, while residents of assisted living facilities received 122 (28.63%)

Long-term Care Pharmacy Access

- ASCP paved the way for any willing long term care pharmacy to order the products and helped facilitate less burdensome reporting requirements to hasten delivery to people in need.
- HHS has since allowed for direct ordering by long term care pharmacies - Click here to sign up.
- Lilly, Regeneron and the new GSK products have ample supply and are available to order.
- ASCP enrolled over 700 LTC pharmacies, helping to acquire over 15,000 doses, 5,000 of which were administered as of early February.
- Since direct ordering and reporting, an additional 5,000 doses have been ordered and 2,500 administered.

ascp
Empowering Pharmacists.
Transforming Aging.

ASCP Resources

- Monoclonal Antibody Treatment in Senior Care Environment - Readiness Document from ASCP and AMDA
  - ASCP resources for the patient eligibility, prescribing considerations, reimbursement and nursing home administration resources are here: https://www.ascp.com/page/mab
- All COVID-19 Resources www.ascp.com/disaster

ascp
Empowering Pharmacists. Transforming Aging.

WALL
OF
HONOR

Pharmacy Crew

Monoclonal Antibody Therapy

- Administer after a positive COVID-19 test
- AND within 10 days of mild to moderate COVID-19 symptom onset

Treatment	Dosage	Infusion Time	Observation Time
Bamlanivimab/ Etesevimab	700mg/ 1,400mg	~20-60mins	1hr
Casirivimab/ Imdevimab	600mg/ 600mg	60mins	1hr
Sotrovimab	500mg	30mins	1hr

References:
Casirivimab/Imdevimab FDA Fact Sheet for Health Care Providers
Bamlanivimab/Etesevimab FDA Fact Sheet for Health Care Providers
Sotrovimab FDA Fact Sheet for Health Care Providers

Patient Eligibility

- Prescription required

APhA COVID-19 RESOURCES: KNOW THE FACTS

Pharmacists' Referrals for Monoclonal Antibody Treatment

Assessing patients for potential COVID-19 treatment with monoclonal antibodies

The Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for monoclonal antibodies for the treatment of mild to moderate COVID-19 disease. **These treatments must be administered at an infusion center within 10 days of symptom onset; pharmacists can play an important role in bringing awareness to these important treatment options.** The purpose of this resource is to provide pharmacists with information about monoclonal antibody treatments and patient eligibility so that pharmacists are prepared to make these potentially life-saving referrals.

Which monoclonal antibody treatments are authorized by the FDA?

Three monoclonal antibody (mAb) therapies—bamlanivimab/etesevimab, casirivimab/imdevimab, and sotrovimab—have received EUAs. Monoclonal antibody treatments use exogenously generated antibodies to neutralize the SARS-CoV-2 virus's ability to infect cells, which can reduce the severity of COVID-19 symptoms in patients who have confirmed COVID-19 infections. Bamlanivimab/etesevimab has reportedly reduced hospitalizations by up to 70%; however, because these medications must be administered by infusion, they are often overlooked and underutilized.

Bamlanivimab alone is no longer authorized for use by the FDA due to reports of SARS-COV-2 variants resistant to monotherapy.

- **Bamlanivimab/Etesevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.
- **Casirivimab/Imdevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.
- **Sotrovimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.

What is the pharmacist's role in patient access to monoclonal antibody treatments?

Pharmacists in community-based settings can help increase patient awareness of these treatment options, assess for patient eligibility, and refer patients to their provider for treatment. Pharmacists are uniquely positioned to identify patients who may benefit from these underutilized and time-sensitive treatments through point-of-care COVID-19 testing, counseling, and/or clinical assessment. Pharmacists can help route patients to an appropriate provider and provide the location of an infusion clinic to initiate therapy.

How can patients access monoclonal antibodies?

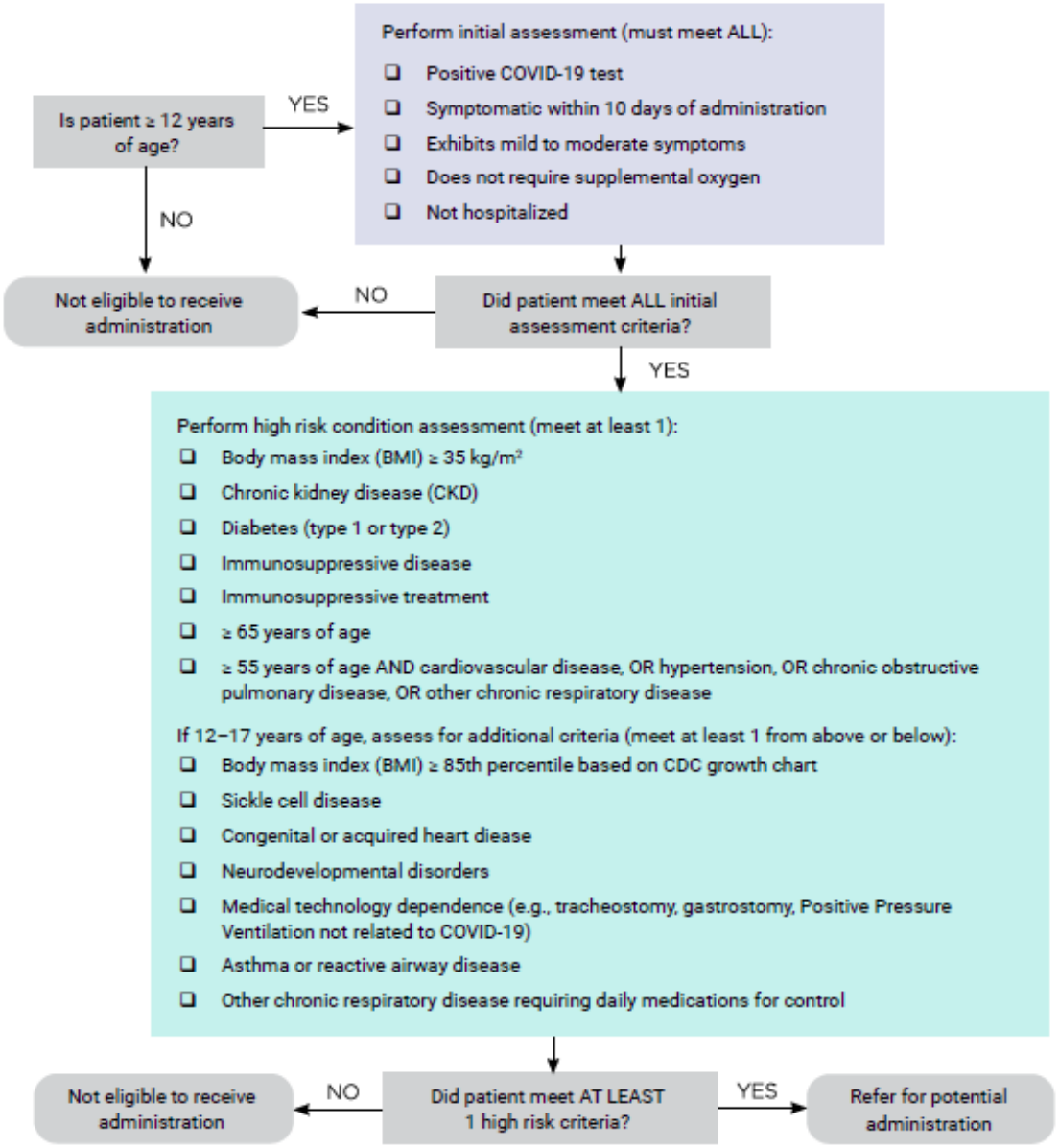
- Positive COVID-19 test
- Symptom onset within 10 days
- High risk

→ Referral to a medical provider → Find a nearby location for infusion services

Locate nearby infusion centers at: https://protect-public.hhs.gov/pages/therapeutics-distribution

UPDATED JUNE 4, 2021. COPYRIGHT © 2021, AMERICAN PHARMACISTS ASSOCIATION. ALL RIGHTS RESERVED.

Reference this eligibility chart and more information in APhA's [Pharmacists' Referrals for Monoclonal Antibody Treatment Resource]



References:
Casirivimab/Imdevimab FDA Fact Sheet for Health Care Providers
Bamlanivimab/Etesevimab FDA Fact Sheet for Health Care Providers
Sotrovimab FDA Fact Sheet for Health Care Providers

Billing for COVID-19 Monoclonal Antibody Treatment

- Monclonal Antibody Treatments are considered vaccines under an FDA EUA
- Currently product is provided by the federal government free of charge
- Providers are reimbursed a fee for administration by infusion

CPT Code	Product	CMS Rate
M0245	Bamlanivir/Etesevimab	$450 – Institution/clinic
M0246	Bamlanivir/Etesevimab	$750 – Home
M0243	Casirivimab/Imdevimab	$450 – Institution/clinic
M0244	Casirivimab/Imdevimab	$750 – Home

https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf

Open Forum Discussion: Share Your Questions & Thoughts

Review of APhA's Ongoing Activities & What's Coming

APhA

Recognizing Pharmacists As Providers

Evidence shows that pharmacists make a significant impact on patients' health outcomes and overall health and reduce health care costs. Provider status would align reimbursement with the services pharmacists are trained to provide and give underserved patients more access to crucial care.

Provider Status Legislation Would

- allow pharmacists in underserved areas to bill Medicare Part B for services within pharmacists' state scope of practice delivered to Medicare beneficiaries
- and be reimbursed at 85% of the physician fee schedule.

Provider Status Legislation Would Not

- apply to all Medicare Part B beneficiaries, or
- grant pharmacists new practice authorities. It would only increase access to already-authorized services.

Contact Congress Today!

Use APhA's pre-written, editable advocacy alert to ask your U.S. Senators and Representative to cosponsor the Pharmacy and Medically Underserved Areas Enhancement Act, H.R. 2759/S. 1362 , or thank them if they have already signed on.

https://pharmacist.com/Advocacy/Issues/Medicare-Provider-Status-Recognition

APhA

MEDICARE PAYMENT *for COVID-19 Vaccination Administration in the Home*

CMS Announces Additional Payment for At-Home COVID-19 Vaccination Administration

- CMS announced that Medicare is incentivizing providers and will pay an additional $35 per dose for COVID-19 vaccine administration in a beneficiary's home
- Increased from ~$40 to ~$75 per vaccine dose
- Two-dose vaccine totals $150 for the administration of both doses
- Find out more about: Billing for the Additional Payment for Administering the Vaccine in the Patient's Home.

APhA

EXAMPLES OF PAYMENT FOR VACCINE ADMINISTRATION IN DIFFERENT LOCATIONS

Location	Payment for vaccine administration	Payment for additional in-home rate	Expected Patient Cost-Sharing
A private residence	✓	✓	No Charge to Patient
Temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter)	✓	✓	No Charge to Patient
An apartment in an apartment complex or a unit in an assisted living facility or group home	✓	✓	No Charge to Patient
A Medicare patient's home that's made provider-based to a hospital during the COVID-19 public health emergency	✓	✓	No Charge to Patient
Communal space of a multi-unit living arrangement	✓	X	No Charge to Patient
Inpatient Hospital, Medicare skilled nursing facility[2], or Medicaid nursing facility	✓	X	No Charge to Patient
Outpatient Hospital, Physician Office, or Clinic	✓	X	No Charge to Patient
Patient Assisted living facility participating in the CDC's Pharmacy Partnership for Long-Term Care Program[3] when their residents are vaccinated through this program	✓	X	No Charge to Patient

https://www.cms.gov/files/document/vaccine-home.pdf

THE WHITE HOUSE
WASHINGTON

APhA

RSVP for the White House Pharmacy Thank You Call

- The White House COVID-19 response team is inviting all APhA member pharmacists to participate in a conference call.
- The speakers will share the Administration's thanks for the contributions pharmacist and pharmacy teams have made in our national vaccination effort, and the work you are doing each day to reach the American public.
- The speakers will also take time to share the Biden Administration's plans as we head into the National Month of Action and ask for your continued partnership to mobilize an all-of-America sprint to get more people vaccinated by July 4th.

Monday, June 14 from 2:00 – 2:30 PM
Individuals may RSVP here.

APhA

Visit the COVID-19 Practice Resource Library

Updated:

- **Pharmacists' Referrals for Monoclonal Antibody Treatment**
- **Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know**
- **HRSA COVID-19 Uninsured Program and Coverage Assistance Fund: Updates for Pharmacy**

APhA APhA COVID-19 RESOURCES: KNOW THE FACTS

Pharmacists' Referrals for Monoclonal Antibody Treatment

Assessing patients for potential COVID-19 treatment with monoclonal antibodies

The Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for monoclonal antibodies for the treatment of mild to moderate COVID-19 disease. **These treatments must be administered at an infusion center within 10 days of symptom onset; pharmacists can play an important role in bringing awareness to these important treatment options.** The purpose of this resource is to provide pharmacists with information about monoclonal antibody treatments and patient eligibility so that pharmacists are prepared to make these potentially life-saving referrals.

Which monoclonal antibody treatments are authorized by the FDA?

Three monoclonal antibody (mAb) therapies—bamlanivimab/etesevimab, casirivimab/imdevimab, and sotrovimab—have received EUAs. Monoclonal antibody treatments use exogenously generated antibodies to neutralize the SARS-CoV-2 virus's ability to infect cells, which can reduce the severity of COVID-19 symptoms in patients who have confirmed COVID-19 infections. Bamlanivimab/etesevimab has reportedly reduced hospitalizations by

- **Bamlanivimab/Etesevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.
- **Casirivimab/Imdevimab:** Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.

- Positive COVID-19 test
- Symptom onset within 10 days
- High risk

Locate nearby infusion centers at: https://protect-pub

UPDATED JUNE 4, 2021. COPYRIGHT © 2021, AMERICAN

APhA APhA COVID-19 RESOURCES: KNOW THE FACTS

HRSA COVID-19 Uninsured Program and Coverage Assistance Fund

Updates for Pharmacy

Pharmacies can be reimbursed for the provision of COVID-19 services, testing, treatment, and vaccine administration to uninsured individuals through the HRSA COVID-19 Uninsured Program. Providers must attest that individuals have no insurance coverage. For individuals who have insurance but whose insurance does not cover COVID-19 services or covers the services with patient cost sharing, providers can collect reimbursement Coverage Assistance Fund.

tions specifically for pharmacies.

sured Program

ead for UnitedHealth Group, who administers the Health Resources and Services D-19 Uninsured Program, to learn how pharmacies can avoid delays in enrollment OVID-19 services. **Pharmacies can be reimbursed for COVID-19 service claims within the previous 12 months. So, it is important to collect necessary patient't yet fully enrolled in the program.**

is program functions like a medical benefit, rather than a pharmacy benefit, and that e same as the Medicare rates for each service. Pharmacies will need to enroll in the their medical intermediary to submit claims for reimbursement.

e detailed for pharmacies. Visit the HRSA COVID-19 Uninsured Program webpage for ursement instructions.

obtain a One Healthcare ID **(formally Optum ID).** Sign in to access the

cy's Taxpayer Identification Number (TIN). It is important to select "CARES Act—ram," NOT "Medical," as your market type to ensure the validation process moves to identify one program administrator to manage access to the program portal. The can be transferred at any time. This step can take 1–2 days to process

H payments to be reimbursed AND complete your provider roster. Once your TIN ove on to both of the following steps at the same time to speed up the enrollment concurrently, it could take a few days to about a week for this information to be ram. Helpful video explanations are available for how to set up Optum Pay and rovider roster.

RIGHT © 2021, AMERICAN PHARMACISTS ASSOCIATION. ALL RIGHTS RESERVED.

APhA APhA COVID-19 RESOURCES: KNOW THE FACTS

Reimbursement for Administration of COVID-19 Vaccine(s)—What We Know

Pharmacists play a key role in ensuring the vaccine(s) are accessible to the public. This resource provides an overview of what is known about COVID-19 vaccine reimbursement at this time and outlines steps that pharmacists can take to be positioned as COVID-19 vaccine providers.

Summary of CMS's Plan for COVID-19 Vaccine Reimbursement

The Centers for Medicare and Medicaid (CMS) is leading COVID-19 vaccine reimbursement efforts by setting a standard for reimbursement rates and working with state and private health insurers to lay the groundwork for reasonable reimbursement nationwide. CMS's COVID-19 webpage outlines information and action that health care providers can take to ensure coverage and reimbursement for COVID-19 vaccine **administration**.

Helpful Toolkits

Pharmacists can review the Medicare toolkit for health care providers. This toolkit gives health care providers the information needed to enroll, administer, and bill COVID-19 vaccines for Medicare patients. Toolkits are also available for Medicaid and private insurers.

What should pharmacists know about vaccine reimbursement as outlined by CMS?

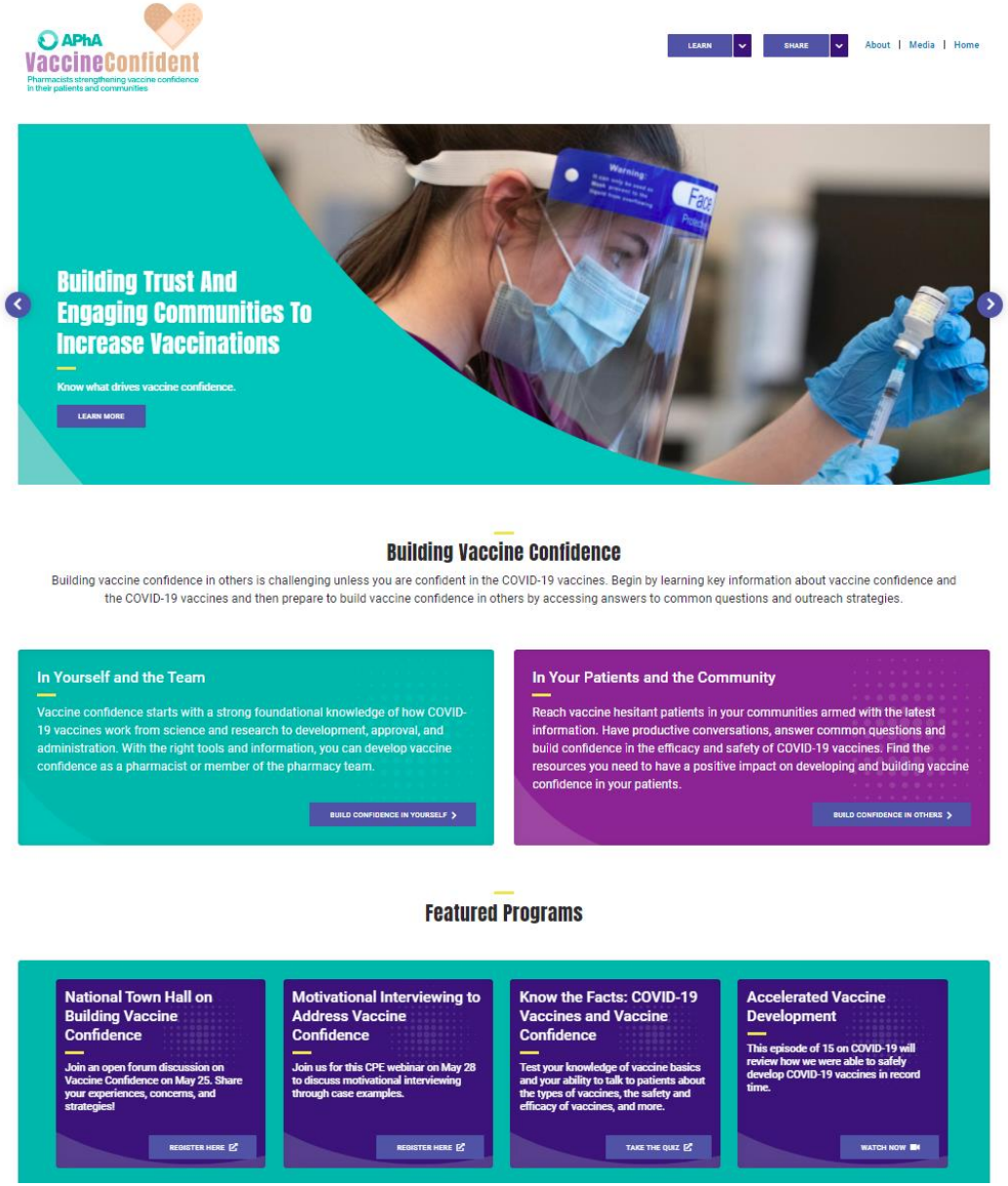
CMS addresses reimbursement for the vaccine product(s) approved or authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) and reimbursement to the provider for their **administration**. The federal government has purchased a supply of vaccine product that will be distributed through federal and state channels and allocated at no cost to providers during the public health emergency (PHE). **CMS makes it clear that the federal government intends for public and private health insurers to cover the cost of vaccine administration, both in-network and out-of-network, with no cost sharing for patients—meaning that patients do not have to pay out-of-pocket costs to receive a COVID-19 vaccine(s).**

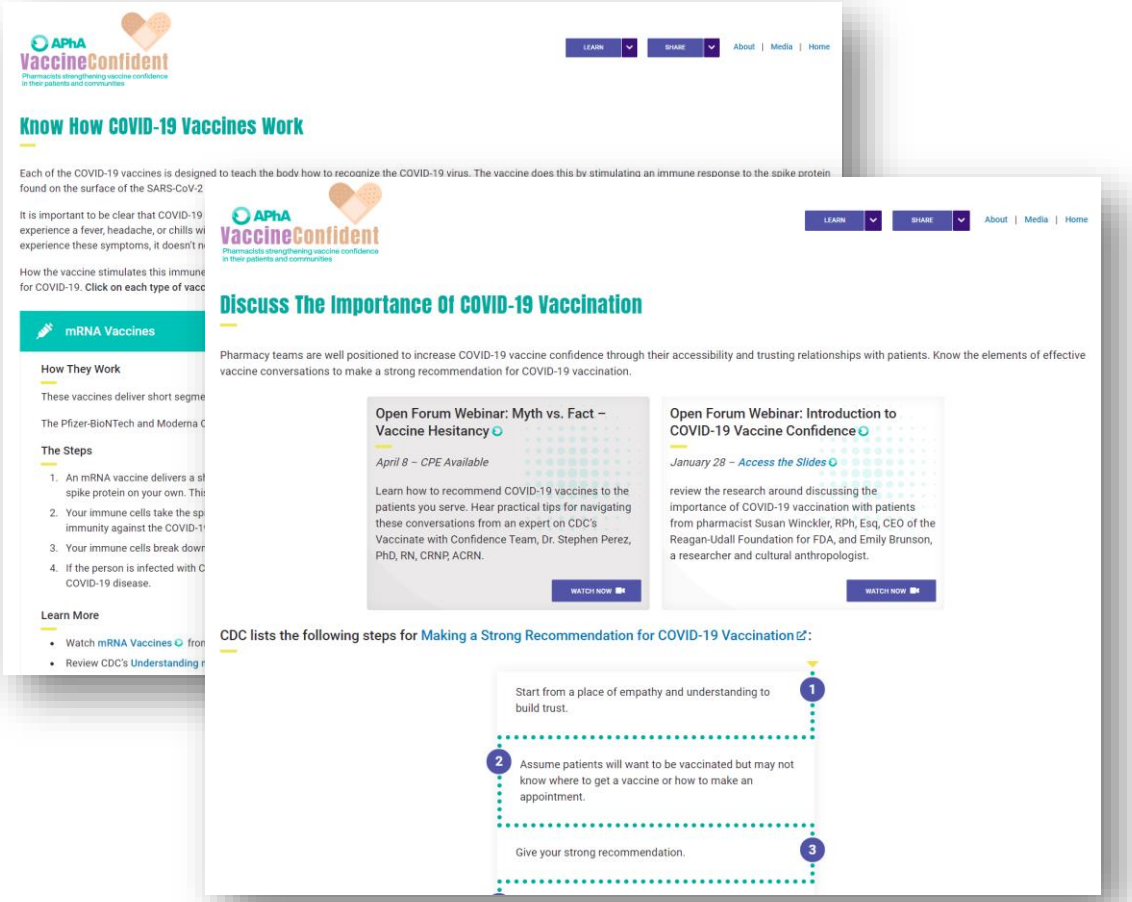
Vaccine Payment = Cost of the Vaccine Product + Fee for COVID-19 Vaccine Administration
(free to providers) (reimbursed by payer)

How is the COVID-19 vaccine product reimbursed?

Initially, the federal government is supplying the vaccine(s) and absorbing 100% of the **product** costs so **there is no product cost to providers and others who administer COVID-19 vaccine.** CMS has stated that sometime in the future, however, reimbursement will be based on 95% of the average wholesale price (or "reasonable cost").

UPDATED JUNE 4, 2021. COPYRIGHT © 2021, AMERICAN PHARMACISTS ASSOCIATION. ALL RIGHTS RESERVED.





Visit APhA's Vaccine Confident website for information about how to build confidence in the COVID-19 vaccines!
https://vaccineconfident.pharmacist.com/

APhA VaccineConfident

Education During COVID-19(CPE Videos)

APhA

APhA

SHOW YOU KNOW

Hesitancy vs. Confidence of COVID-19 Vaccination

Take this short quiz to evaluate your knowledge of why certain patient groups, such as the Black, Indigenous, and People of Color (BIPOC) community and pregnant patients may experience vaccine hesitancy.

Access APhA's Library of COVID-19 Education (CPE)

APhA

Post on ENGAGE

Pharmacy's Response to COVID-19

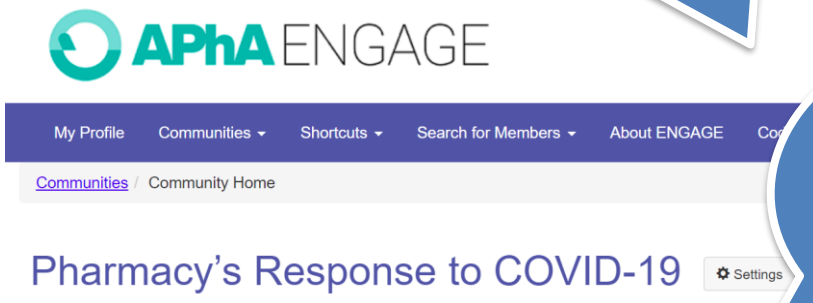
POST your questions

SHARE your lessons learned

SUPPORT your colleagues

ACCESS the latest information

How are you making your patients aware of monoclonal antibody therapy?



What challenges are you facing?

Not a member? **Join today!**

APhA

Join Us!

Thursday, June 24, 1:00-2:00 pm ET

Register here!

Today's webinar will be available within 24 hours

https://aphanet.pharmacist.com/coronavirus/weekly-webinars

34

Within how many days after symptom onset should an eligible patient receive monoclonal antibody therapy?

a) 3 days
b) 7 days
c) 10 days
d) 14 days

Which of the following patients would be eligible for monoclonal antibody therapy?

a) 10-year-old patient with asthma experiencing moderate COVID-19 symptoms
b) 61-year-old patient with diabetes and hypertension experiencing moderate COVID-19 symptoms
c) 80-year-old patient with heart disease experiencing severe COVID-19 symptoms
d) 65-year-old hospitalized patient requiring oxygen

Which of the following is NOT an example of how a pharmacist can increase access to monoclonal antibody therapies?

a) Educate local physicians and community members about the benefits
b) Refer patients who may be eligible to their physician after a positive COVID-19 test in the pharmacy
c) Administer monoclonal antibody therapies in appropriate settings
d) Prescribe monoclonal antibody therapies to eligible patients

How to Claim CE

1. After the webinar ends, return to the “My Training” page on pharmacist.com (http://elearning.pharmacist.com/my-training)
2. Log in using your pharmacist.com username and password
3. Click on the “Pharmacy Models for Expanding Access to COVID-19 Monoclonal Antibody Treatments” session listed in your enrollments
4. Click on “Pharmacy Models for Expanding Access to COVID-19 Monoclonal Antibody Treatments” under the “Activities” heading
5. Enter the attendance code
6. Complete the evaluation
7. Claim credit