Administrative Policy Statement
KENTUCKY MARKETPLACE

Policy Name	Policy Number	Date Effective
COVID-19 Vaccination	PAD-0077-KY-MPP	09/16/2021
Policy Type		
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

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Table of Contents

A. Subject

COVID-19 Vaccination

B. Background

The 2019 novel coronavirus, also known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes the disease known as coronavirus disease 2019 (COVID-19). The Food and Drug Administration (FDA) has issued full authorization for the Pfizer-BioNTech vaccine for prevention of COVID-19 in age 16 years and older. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EAU) for the following vaccines for the prevention of COVID-19: Pfizer-BioNTech in age 5 through 15 years old, Moderna, and Janssen as of February 2021. The Pfizer-BioNTech and Moderna vaccines are offered as a two-dose series. The Janssen vaccine is offered as a single-dose vaccine. The EUA allows the vaccines to be widely distributed in the United States.

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines for the prevention of COVID-19 in the U.S. The interim recommendations are derived from the EAU of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. Considerations will be updated as additional information becomes available or if additional vaccine products are authorized.

The purpose of this policy is the provide background on the use of the vaccines in accordance with the ACIP interim recommendations, fact sheets, and the EAU fact sheets of the available COVID-19 vaccines.

The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

Advisory Committee on Immunization Practices (ACIP):

- **Pfizer COVID-19 Vaccine:** Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 μg, 0.3 mL each) administered intramuscularly, 3 weeks apart for age 12 years and older. For children age 5-11 years old, the vaccine consists of 2 doses (10 μg, 0.2mL each) administered intramuscularly, 3 weeks apart. On December 11, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19. On May 10th, 2021, the FDA expanded the EUA to include adolescents 12 through 15 years of age. On October 29, 2021, the FDA expanded the EUA to include children aged 5 through 11 years of age. Pfizer-BioNTech's COVID-19 vaccinations come in two formulations, one for adult/adolescents in a vial with a purple cap, one for pediatric use in a vial with an orange cap. The current adult/adolescent formulation can not be used to prepare doses for children 5-11 years old.

- On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals of 16 years old and older. The licensed vaccine is now marked as Comirnaty, can be interchanged with the EUA-authorized formulation of the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years of age and older without presenting safety or efficacy concerns.
- On September 22, 2021, the FDA expanded the EUA to include a single booster dose of the Pfizer-BioNTech COVID-19 Vaccination booster dose, for all adults age 18 and older. On December 9, 2021, the FDA expanded this to include a single booster for age 16 and 17. The single booster must be administered at least 6 months after completion of the vaccination primary seies. The single booster dose is the same dosage as the initial vaccine (30 μg, 0.3 mL).
    - The FDA has since updated the booster recommendation to being administered at least 5 months after completion of the vaccination primary series.
- On January 3, 2022, the FDA expanded the EUA to include a single booster dose in individuals 12 and older. The singble booster must be administered at least 5 months after the completion of the vaccinaption primary series.
- The recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's interim recommendation for allocating initial supplies of COVID-19 vaccines. The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine under FDA approval as well as the interim EUA will be updated as additional information becomes available.
    - Before vaccination, the Fact Sheet or EUA Fact Sheet should be provided to recipients and caregivers. Providers should counsel Pfizer-BioNTech COVID-19 vaccine recipients about expected systemic and local reactogenicity.
    - Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant or immunocompromised or who have severe allergies) are available at www.cdc.gov

- **Moderna COVID-19 Vaccine:** Vaccination with the Moderna COVID-19 vaccine consists of 2 doses (0.5mL each) administered intramuscularly, 4 weeks apart. On December 18, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19.
    - On August 12, 2021, the FDA expanded the EUA to allow for an additional dose to be given to certain immunocompromised individuals. On October 20, 2021, the FDA amended the Moderna COVID-19 Vaccine EUA to allow for a single booster dose, for all adults age 18 and older, The single booster must be administered at

least 6 months after the completion of the primary series. The single booster dose is a smaller dosage than the initial vaccine (0.25 mL).
    - The FDA has since updated the booster recommendation to being administered at least 5 months after completion of the vaccination primary series.
  - Use of all COVID-19 vaccines authorized under an EUA, including the Moderna COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines (*3*). The ACIP recommendation for the use of Moderna COVID-19 vaccine under EAU is interim and will be updated as additional information becomes available. The interim recommendation and clinical considerations are based on use of the Moderna COVID-19 vaccine under an EUA and might change as more evidence becomes available.
    - Before vaccination, the EUA Fact Sheet should be provided to recipients and caregivers. Providers should counsel Moderna COVID-19 vaccine recipients about expected systemic and local reactogenicity.
    - ACIP does not state a product preference; a person may receive any recommended COVID-19 vaccine series. However, persons should complete the initial vaccination series with the same COVID-19 product they received for the first dose.
    - Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant, immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov
- **Janssen COVID-19 Vaccine:** Vaccination with the Janssen COVID-19 vaccine consists of a single dose (0.5mL) administered intramuscularly. On February 27, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Janssen COVID-19 vaccine as the first single-shot COVID-19 vaccine in individuals 18 years of age or older for the prevention of COVID-19. The use of the Janssen COVID-19 vaccine under the EUA should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines. The interim recommendations and clinical considerations are based on use of the Janssen COVID-19 vaccine under an EUA and might change as more evidence becomes available.
  - On October 20, 2021, the FDA expanded the EUA to include a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccination booster dose for adults age 18 and older. The single booster must be administered at least 2 months after completion of the primary vaccine dose. The single booster dose is the same dosage as the initial vaccine (0.5mL),
  - Before vaccination, the EUA Fact Sheet should be provided to the recipient and caregivers. Providers should counsel Janssen COVID-

19 vaccine recipients about any expected systemic and local reactogenicity.
- ACIP does not state a product preference; a person may receive any ACIP – recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.
- Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant. Immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov.

Guidance for COVID-19 Vaccination Boosters

- On October 21, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the COVID-19 Booster Shots.
  - For those who received a mRNA primary COVID-19 vaccination (Pfizer-BioNTech or Moderna), if eligible, should receive a single vaccine booster at least 6 months after completion of the primary series. Any FDA-approved or authorized COVID-19 vaccination can be used as a booster dose.
    - The FDA has since updated the booster recommendation for the mRNA vaccinations to being administered at least 5 months after completion of the primary series.
  - For those who received the Janssen COVID-19 vaccination as their primary vaccine, if eligible, should receive a single vaccine booster at least 2 months after receiving their dose. Any FDA-approved or authorized COVID-19 vaccination can be used as a booster dose.

Note: Additional Vaccines – Newly developed vaccines are still moving through the clinical trial process before submission for regulatory approval. CareSource is closely monitoring FDA approval of these vaccines.

C. Definitions

- **Emergency Use Authorization (EUA)** – A mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies.
- **Vaccine Adverse Event Reporting System (VAERS)** – A national early warning system to detect possible safety problems in vaccines used in the United States.
- **Immunization Information System (IIS)** – A confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a specific geopolitical area.

D. Policy

I. COVID-19 vaccination providers participating in the Centers for Disease Control and Prevention (CDC) COVID -19 Vaccination Program are required to sign a CDC

COVID-19 Vaccination Program Provider Agreement. Providers are responsible for adhering to all requirements outlined in the agreement.

II. Providers must follow the prioritization schedule as determined by the state's and/or the Department of Health's plan for distributing the vaccines (e.g., Phase 1a includes healthcare personnel, Phase 1b includes persons ≥ 75 years of age, etc.):
    A. COVID-19 vaccine providers are prohibited from selling USG-purchased COVID-19 vaccine, receiving any inducement (whether direct or indirect) for vaccinating (or providing COVID-19 vaccine to be used for vaccinating) and individual who is not currently eligible to receive COVID-19 vaccine as a member of a group currently authorized under prioritization specified by CDC/ACIP, the state/territory's governor or other relevant public health authority, or otherwise diverting COVID-19 vaccine from the CDC COVID-19 Vaccination Program.
III. The member's age must be within the age group that is authorized to receive the COVID-19 vaccination:
    A. Pfizer-BioNTech: age 5 years or greater;
    B. Moderna: age 18 years or greater;
    C. Janssen: age 18 years or greater.
IV. The vaccination provider must follow the vaccine schedule as outlined in the EUA fact sheet.
    A. Pfizer-BioNTech: 2 doses, 21 days apart; third dose 28 days apart for those who have undergone solid organ transplantation or have a diagnosis with an equivalent level of immunocompromise;
    B. Moderna: 2 doses, 28 days apart; third dose 28 days apart for those who have undergone solid organ transplantation or have a diagnosis with an equivalent level of immunocompromise;
    C. Janssen: 1 dose only.
V. The provider must communicate to the individual receiving the vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to receiving the vaccine.
VI. The vaccination provider must follow the storage and handling instruction of the vaccine as outlined in the EUA fact sheet of the individual vaccine.
VII. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization System (IIS) or other designated system:
    A. All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into VaccineFinder. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into VaccineFinder.
    B. COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration; and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., IIS) as soon as practicable and no later than 72 hours after administration.
VIII. The vaccination provider is responsible for mandatory reporting of any significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
    A. The following adverse events are required to be reported in addition to any other events if later revised by the CDC:
        1. Vaccine administration errors, whether associated with an adverse event (AE);
        2. Serious AEs regardless of causality. Serious AEs are defined as:

a. Death;
b. A life-threating AE;
c. Inpatient hospitalization or prolongation of existing hospitalization;
d. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
e. A congenital anomaly/birth defect;
f. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above;
g. Cases or Multisystem Inflammatory Syndrome;
h. Cases of COVID-19 that result in hospitalization or death.

B. Providers are encouraged to report to VAERS any additional clinically significant adverse event following vaccination, even if they are not sure if vaccination caused the event.
C. Providers should also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine being authorized under an EUA.

IX. Claims Reimbursement and Member Cost Share
A. All FDA-authorized COVID-19 vaccines will be covered at no cost for members during the public health emergency.
B. Vaccine providers must administer the vaccine regardless of the member's ability to pay or verify health insurance coverage status.
C. Vaccine providers may not seek reimbursement, including through balance billing, from the vaccine recipient.
D. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.
E. Providers may bill the CareSource medical benefit through our standard claim process.
F. Pharmacies should submit claims through their pharmacy claims platform through our pharmacy benefits manager, Express Scripts.

E. Conditions of Coverage

All FDA-approved or authorized COVID-19 vaccines do not require any prior-authorization and will be covered at no cost for members. Please refer to the Reimbursement Policy for more details.

HCPS and CPT Codes:

Pfizer-BioNTech COVID-19 Vaccine

- 91300 – vaccine
- 0001A – 1st dose administration
- 0002A – 2nd dose administration
- 0003A – 3rd dose administration

Moderna COVID-19 Vaccine

- 91301 – vaccine
- 0011A – 1st dose administration

- 0012A – 2nd dose administration
- 0013A – 3rd dose administration

Janssen COVID-19 Vaccine
- 91303 – vaccine
- 0031A – administration

Quantity Limit: Only one vaccine is allowed per member.

Pfizer-BioNTech and Moderna COVID-19 Vaccine: Three doses are allowed per member.

Janssen COVID-19 Vaccine: Two doses are allowed per member.

Quantity limit is subject to change as more vaccines become available for use.

F. Related Policies/Rules

COVID-19 Vaccine Reimbursement Policy

G. Review/Revision History

DATES		ACTION
Date Issued	**12/18/2020**	New Policy
Date Revised	**02/28/2021**	Policy revised to include information about Janssen COVID-19 vaccine.
	09/01/2021	Policy revised to update age for Pfizer vaccine, and update vaccine schedule for Pfizer and Moderna vaccine.
	11/30/2021	Policy revised to update age for Pfizer vaccine, Pfizer vaccination approval, vaccine schedules for all booster shots.
	12/09/2021	Policy revised to update for Pfizer vaccine booster age
	3/4/2022	Policy revised to update for new booster dose length
Date Effective	**02/28/2021**	
Date Archived		

H. References

1. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(50):1922-1924.
2. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine – United States, December 2020. *MMWR Morb Mortal Wkly Rep.* 2021;69(5152):1653-1656.
3. Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine – United States, February 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 2 March 2021.
4. Centers for Disease Control and Prevention (CDC). (2021). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) [Fact Sheet].

5. Centers for Disease Control and Prevention (CDC). (2020). Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) [Fact Sheet].
6. Centers for Disease Control and Prevention (CDC). (2021). Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) [Fact Sheet].
7. Ohio Department of Medicaid. COVID-19 vaccine administration billing guidelines.
8. Centers for Disease Control and Prevention (CDC). (2021). COVID-19 Vaccination Booster Shots. Updated November 9, 2021. Accessed November 12, 2021. https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html

The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.