



Administrative Policy Statement KENTUCKY MEDICARE DUAL

Policy Name	Policy Number	Date Effective
COVID-19 Vaccination	PAD-0086-KY-MDP	11/1/2022
Policy Type		
Medical	ADMINISTRATIVE	Pharmacy
		Reimbursement

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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 for individuals 12 years and older and Moderna vaccine for prevention of COVID-19 for individuals 18 years and older. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the following vaccines for the prevention of COVID-19: Pfizer-BioNTech for individuals 6 months and older, Moderna for individuals 6 months and older, Janssen for individuals 18 years and older for whom other COVID-19 vaccines are inaccessible or clinically inappropriate, and Novavax for individuals 12 years and older as of October 2022. The CDC recommends that the J&J COVID-19 vaccine only be considered in certain situations, due to safety concerns. The Pfizer-BioNTech, Moderna, and Novavax vaccines are offered as a two-dose series. The Janssen vaccine is offered as a single-dose vaccine. The EUA allows a third primary dose of Pfizer-BioNTech and Moderna vaccines for immunocompromised individuals and allows booster doses of Pfizer-BioNTech, Moderna, and Janssen. Pfizer-BioNTech Bivalent boosters are available for individuals 5 years and older and Moderna Bivalent boosters are available for individuals 6 years and older. 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, Novavax, and Janssen COVID-19 vaccines for the prevention of COVID-19 in the US. The interim recommendations are derived from the EUA 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 to provide background on the use of the vaccines in accordance with the ACIP interim recommendations, fact sheets, and the EUA fact sheets of the available COVID-19 vaccines.

The following recommendations are derived from the latest guidelines and scientific based literature available:

- **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 through 11 years old, the vaccine consists of 2 doses (10 µg, 0.2mL each) administered intramuscularly, 3 weeks apart. For individuals 6 months through 4 years old, the vaccine consists of 2 doses (3 µg, 0.2mL each) administered intramuscularly, 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose. Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use to prevent COVID-19 in individuals 5 years of age and older as a single booster



dose administered at least 2 months after either completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. For the Pfizer-BioNTech Bivalent formulation, a 0.2 mL dose (10 μ g) is administered IM to individuals age 5-11 years old and a 0.3 mL dose (30 μ g) is administered to individuals 12 years and older.

- Pfizer-BioNTech's COVID-19 vaccinations come in multiple formulations including one for adult/adolescents in a vial with a purple cap, two for adult/adolescents in a vial with a grey cap, two for pediatric use (5 – 11 year olds) in a vial with an orange cap, and another for pediatric use (6 months – 4 year olds) in a vial with a maroon cap. Formulations specific for adults/adolescents can not be used to prepare pediatric doses and vice versa.
- 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 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 FDA has since updated bivalent booster recommendation to be administered at least 2 months after initial series or initial booster in individuals 5 years of age and older.
- On October 29, 2021, the FDA expanded the EUA to include children aged 5 through 11 years of age.
- On January 3, 2022, the FDA expanded the EUA to include a single booster dose in individuals 12 and older which has since been updated.
- On June 17, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) amendments for the mRNA-1273 (Moderna) COVID-19 vaccine for use in children aged 6 months–5 years, administered as 2 doses (25 μ g, 0.25 mL each), 4 weeks apart, and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine for use in children aged 6 months–4 years, administered as 3 doses (3 μ g, 0.2 mL each), at intervals of 3 weeks between doses 1 and 2 and ≥ 8 weeks between doses 2 and 3.



- On October 12, 2022, the FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent vaccines to authorize their use as a single booster dose in younger age groups. The Pfizer-BioNTech COVID-19 bivalent vaccine was authorized for administration as a single booster dose at least 2 months following completion of primary or booster vaccination in children 5 years of age and older.
- 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: 0.5 mL (100 µg) each for individuals 12 years and older, 0.5 mL (50 µg) each for individuals 6-11 years old, or 0.25 mL (25 µg) each for children 6 months – 5 years old administered intramuscularly, 4 weeks apart. Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 6 years of age and older as a single booster dose administered at least 2 months after either completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. For the Moderna Bivalent formulation, a 0.25 mL dose (25 µg) is administered IM to individuals age 6-11 years old and a 0.5 mL dose (50 µg) is administered to individuals 12 years and older.
 - The Moderna COVID-19 vaccinations come in multiple different formulations including one for adult/adolescents 12 years and older in a vial with a red cap & light blue border, one for individuals 6 years and older in a vial with a dark blue cap & grey border, one for pediatric use (6 – 11 year olds) in a vial with a dark blue cap with a purple border, and another for pediatric use (6 months – 5 year olds) in a vial with a dark blue cap & magenta border. Formulations specific for adults/adolescents can not be used to prepare pediatric doses and vice versa.
 - 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 FDA has since updated bivalent booster recommendation to being administered at least 2 months after initial series or initial booster in individuals 6 years of age and older.
- On June 17, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) amendments for the mRNA-1273 (Moderna) COVID-19 vaccine for use in children aged 6 months–5 years, administered as 2 doses (25 µg, 0.25 mL each), 4 weeks apart, and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine for use in children aged 6 months–4 years, administered as 3 doses (3 µg, 0.2 mL each), at intervals of 3 weeks between doses 1 and 2 and ≥8 weeks between doses 2 and 3.
- On October 12, 2022, the FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent vaccines to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 bivalent vaccine is authorized for administration as a single booster dose at least 2 months following completion of primary or booster vaccination in children 6 years of age and older.
- 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.
 - 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 and a single booster dose at least 2 months after completing primary vaccination in individuals 18 years of age and older.
 - 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).
- Janssen COVID-19 vaccine should be considered for individuals 18 years and older for whom other COVID-19 vaccines are inaccessible or clinically inappropriate. The CDC recommends that the J&J COVID-19 vaccine only be considered in certain situations, due to safety concerns such as TTS.
- 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.
- 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.
- **Novavax COVID-19 Vaccine:** Vaccination with the Novavax COVID-19 vaccine consists of 2 doses (0.5 mL each) administered intramuscularly, 3 weeks apart for age 12 years and older. The vaccine is authorized for emergency use as a two-dose primary series.
 - On July 19th, 2022, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Novavax COVID-19 vaccine in persons aged 18 and older as a primary 2-dose series for vaccination in the prevention of COVID-19. Use of all COVID-19 vaccines authorized under an EUA, including the Novavax COVID-19 vaccine, 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 Novavax COVID-19 vaccine under an EUA and might change as more evidence becomes available.
 - FDA since updated recommendations to include individuals aged 12 years of age and older.
 - Before vaccination, the EUA Fact Sheet should be provided to recipients and caregivers. Providers should counsel Novavax COVID-



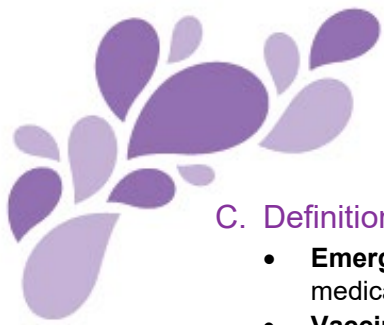
19 vaccine recipients about expected systemic and local reactogenicity.

- Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant, immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov

Guidance for COVID-19 Vaccination Boosters

- Individuals age 5 years and older (or 6 years and older for Moderna) may get the updated (bivalent) booster. Individuals should no longer receive an original (monovalent) Pfizer-BioNTech or Moderna booster.
- For individuals with prior COVID-19 infection, experts have recommended that individuals get a booster dose at least 3 months after symptoms began, or if asymptomatic, after the first positive test.
- Children under 5 years of age are not yet eligible to receive any booster.
- 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. Novavax is not currently authorized to be used as a booster and is only authorized for primary dose series.
- 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. The FDA has since updated the booster recommendations several times with the most recent recommendation on October 12, 2022.
 - On October 12, 2022, the FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent vaccines to authorize their use as a single booster dose in younger age groups. The Pfizer-BioNTech COVID-19 bivalent vaccine was authorized for administration as a single booster dose at least 2 months following completion of primary or booster vaccination in children 5 years of age and older. The Moderna COVID-19 bivalent vaccine is authorized for administration as a single booster dose at least 2 months following completion of primary or booster vaccination in children 6 years of age and older.

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 \geq 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 6 months or greater;
 - B. Moderna: age 6 months or greater;
 - C. Janssen: age 18 years or greater;
 - D. Novavax: age 12 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 for primary vaccination;
 - D. Novavax: 2 doses, 21 days apart;
 - E. People ages 6 months through 64 years, and especially males ages 12 through 39 years, may consider getting the 2nd primary Pfizer-BioNTech, Moderna, or Novavax 8 weeks after the 1st dose.
- 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 error is associated with an adverse event (AE) or not.
 - 2. Serious AEs regardless of causality. Serious AEs are defined as:
 - a. Death;
 - b. A life-threatening 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
- 0004A – 4th dose administration

Moderna COVID-19 Vaccine

- 91301 – vaccine
- 0011A – 1st dose administration
- 0012A – 2nd dose administration
- 0013A – 3rd dose administration
- 0014A – 4th dose administration

Janssen COVID-19 Vaccine

- 91303 – vaccine
- 0031A – administration

Novavax COVID-19 Vaccine

- 91304- vaccine
- 0041A- 1st dose administration
- 0042A- 2nd dose administration

Quantity Limit: Only one vaccine is allowed per member for primary series. Member may receive a different booster vaccine than received for their primary series.

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

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

Novavax 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
	10/20/2022	Policy revised to update for newly authorized Novavax primary series, bivalent Pfizer and Moderna booster shots and updated age recommendations for primary and booster series.
Date Effective	11/1/2022	
Date Archived		

H. References

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

