Administrative Policy Statement
OHIO MEDICARE ADVANTAGE

Policy Name		Policy Number	Date Effective
COVID-19 Vaccination		PAD-0080-OH-MAP	02/28/2021
Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

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According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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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 an Emergency Use Authorization (EUA) for the following vaccines for the prevention of COVID-19: Pfizer-BioNTech, 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 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 and the EUA 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. On December 12, 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. 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 EUA is interim and will be updated as additional information becomes available.
    - Before vaccination, the 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**: On December 19, 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. 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 the Moderna COVID-19 vaccine under EUA 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 local and systemic reactogenicity.
    - The Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products; the safety and efficacy of a mixed-product series have not been evaluated.
    - ACIP does not state a product preference; a person may receive any recommended COVID-19 vaccine series. However, persons should complete the 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**: On February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for the Janssen COVID-19 vaccine as the first single-shot COVID-19 vaccine in individuals 18 years of age or older for 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 recommendation and clinical considerations are based on use of the Janssen COVID-19 vaccine under an EUA and might change as more evidence becomes available.
    - 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 local and systemic reactogenicity.
    - The Janssen COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products.
    - 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.

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. The **COVID-19 vaccines are carved out of Ohio Medicare Advantage** and are **reimbursed via Original Medicare Fee-for-Service (FFS)**. Please see the Conditions of Coverage section for additional information. CareSource is closely monitoring state and federal guidance regarding coverage and reimbursement and this policy will be updated if guidance is changed.

II. The remainder of this policy is to provide background on the use of the vaccines in accordance with the ACIP interim recommendations and the EUA fact sheets of the available COVID-19 vaccines.

A. 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.

B. 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.):
   1. 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) any 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.

C. The member's age must be within the age group that is authorized to receive the COVID-19 vaccination:
   1. Pfizer-BioNTech: age 16 years or greater;
   2. Moderna: age 18 years or greater;
   3. Janssen: age 18 years or greater.

D. The vaccination provider must follow the vaccine schedule as outlined in the EUA fact sheet:
   1. Pfizer-BioNTech: 2 doses, 21 days apart;
   2. Moderna: 2 doses, 28 days apart;
   3. Janssen: 1 dose only.

E. 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.

F. The vaccination provider must follow the storage and handling instruction of the vaccine as outlined in the EUA fact sheet of the individual vaccine.

G. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization System (IIS) or other designated system:
   1. 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.
   2. 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.

H. The vaccination provider is responsible for mandatory reporting of any significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
   1. The following adverse events are required to be reporting in addition to any other events if later revised by the CDC:
      01. Vaccine administration errors, whether or not associated with an adverse event (AE);
      02. 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 of Multisystem Inflammatory Syndrome;
         h. Cases of COVID-19 that result in hospitalization or death.
   2. 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.

3. 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.

III. Claims, Reimbursement and Member Cost Share
   A. Vaccine providers must administer the vaccine regardless of the member's ability to pay or verify health insurance coverage status.
   B. Vaccine providers may not seek any reimbursement, including through balance billing, from the vaccine recipient.
   C. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient.

E. Conditions of Coverage

The COVID-19 vaccines are not covered on the CareSource Medicare Advantage benefit plan and are only covered with Original Medicare per Centers of Medicare and Medicaid guidance. Please submit billing information directly to Original Medicare.

HCPCS and CPT Codes:

Pfizer-BioNTech COVID-19 Vaccine
- 91300 – vaccine
- 0001A – 1st dose administration
- 0002A – 2nd dose administration

Moderna COVID-19 Vaccine
- 91301 – vaccine
- 0011A – 1st dose administration
- 0012A – 2nd 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: Two doses are allowed per member.

Janssen COVID-19 Vaccine: Only one dose is 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. Claims,

		Reimbursement and Member Cost Share section was revised.
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, Scobie H, 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].

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