Administrative Policy Statement
NORTH CAROLINA MARKETPLACE

Policy Name	Policy Number	Date Effective
COVID-19 Vaccination	PAD-0078-NC-MPP	01/01/2023

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

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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 μg) is administered IM to individuals age 5-11 years old and a 0.3 mL dose (30 μg) is administered to indivudals 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-
  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 μg, 0.25 mL each), 4 weeks apart, and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine for

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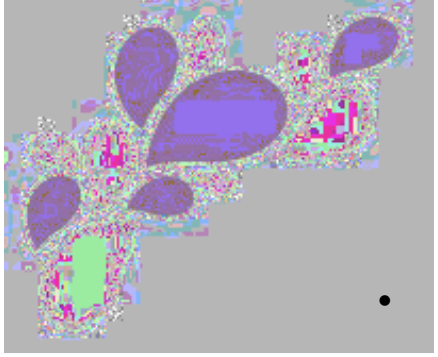


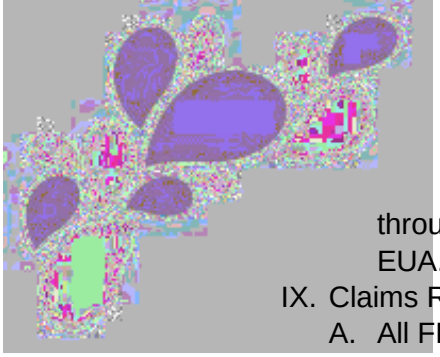
who are pregnant, immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov

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 State.3 (meas)-8 (ur)-18.4 (es)-8 (,)Eubl(o( )Tj3



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:

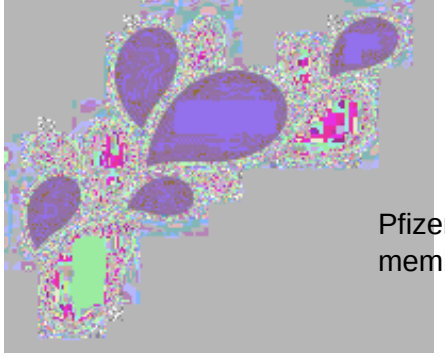
Pfizer-BioNTech COVID-19 Vaccine
- 91300 – vaccine
- 0001A – 1st dose administration
- 0002A – 2nd dose administration
- 0003A – 3rd dose administration
- 0004A – 4th dose administration

Moderna COVID-19 Vaccine
- 91301 – vaccine
- 0011A – 1st dose administration
- 0012A – 2nd dose administration
- 0013A – 3rd dose administration
- 0014A – 4th dose administration

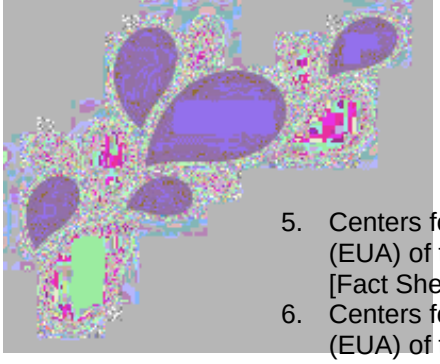
Janssen COVID-19 Vaccine
- 91303 – vaccine
- 0031A – administration

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 reveived for their primary series.



Pfizer-BioNTech and Moderna COVID-19 Vaccine: Four doses are allowed per membedere all0.002 Tc alle2.6 (ow)2.B9060 B6 Tc792 160c 0.007 Tw .6 (ow)2.-K0q72-1T5.7 (



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].
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9. U.S. Food & Drug Administration. Coronavirus Disease 2019 (COVID-19). Updated October 7, 2022. Accessed October 10, 2022. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19
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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.