Reimbursement for the Moderna COVID-19 Vaccine

Billing & Coding for EUA Period

AUTHORIZED USE

For certain indications, the Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by the FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. There are two presentations/formulations of the Moderna COVID-19 Vaccine authorized for use.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner. Moderna COVID-19 Vaccine is authorized to provide:

- a two-dose primary series to individuals 18 years of age and older;
- a third primary series dose to individuals 18 years of age and older with certain kinds of immunocompromise;
- a first booster dose to individuals 18 years of age and older who have completed a primary series with Moderna COVID-19 Vaccine or SPIKEVAX (COVID-19 Vaccine, mRNA);
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination;
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
- a second booster dose to individuals 18 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.

FDA has approved SPIKEVAX (COVID-19 Vaccine, mRNA) as a two-dose primary series one month apart for prevention of COVID-19 in individuals ages 18 years of age and older.*

This vaccine is available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program). To participate in the Vaccination Program, healthcare providers must enroll as providers and comply with the provider requirements. Vaccination providers in the Vaccination Program may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Moderna COVID-19 Vaccine Reimbursement Codes

Vaccine CPT Code*	Vaccine Administration CPT Codes†	NDCs by Presentation‡
91301 – 100 mcg/0.5 mL	0011A First Dose (100 mcg/0.5 mL) 0012A Second Dose (100 mcg/0.5 mL) 0013A Third Dose (100 mcg/0.5 mL)	Primary and Booster Dose Presentations with Maximum of 11 Doses Vial: 80777-273-10 Carton: 80777-273-99
91306 – 50 mcg/0.25 mL	0064A Booster (50 mcg/0.25 mL)	Primary and Booster Dose Presentations with Maximum of 15 Doses Vial: 80777-273-15 Carton: 80777-273-98
91309 – 50 mcg/0.5 mL	0094A Booster (50 mcg/0.5 mL)	Booster Dose Only Presentation with Maximum of 5 Doses Vial: 80777-275-05 Carton: 80777-275-99

*Use the vaccine CPT code that describes the dose administered (1st, 2nd, 3rd, or booster) and vial presentation used.

†Note, the administration CPT codes align with the associated dose (1st, 2nd, 3rd, or booster) and vial presentation used for administration. CPT administration codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the records.

‡Note, for NCPDP billing initial doses are billed as 0.5 mL, the booster dose from the primary and booster dose presentation is billed with 0.25 mL, and the **booster dose only** presentation is billed with 0.5 mL.

Other codes that may be needed for billing: ICD-10:Z23 Encounter for Immunization; CVX Code 207 for the primary and booster dose presentation and CVX code 221 for the booster dose only presentation.

For questions related to billing, contact Moderna Customer Care at:
1-866-MODERNA (1-866-663-3762)

For more information, please see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information, and Fact Sheet for Vaccine Recipients and Caregivers at **eua.modernatx.com/covid19vaccine-eua**.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

Please see the

- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Booster Dose Only Presentation)***
- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Primary Series and Booster Dose Presentation)***

For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

- **Limitations of Vaccine Effectiveness:** The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash.

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of Multisystem Inflammatory Syndrome (MIS) in adults
- cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. Reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

Report to ModernaTX, Inc. by calling 1-866-MODERNA (1-866-663-3762) or provide a copy of the VAERS form by faxing 1-866-599-1342 or emailing ModernaPV@modernatx.com.

Please see the

- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Booster Dose Only Presentation)***
- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Primary Series and Booster Dose Presentation)***

For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

*As described in the Letter of Authorization, the FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the two EUA-authorized presentations of the Moderna COVID-19 Vaccine (supplied in multiple-dose vials with red caps and multiple-dose vials with dark blue caps) can be used to provide a booster dose. The FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the EUA-authorized presentation of the Moderna COVID-19 Vaccine supplied in multiple-dose vials with red caps can be used interchangeably to provide primary series and booster doses without presenting any safety or effectiveness concerns.

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