

April 18, 2023

IMPORTANT PRESCRIBING INFORMATION

Moderna COVID-19 Vaccine, Bivalent labeled “BOOSTER DOSES ONLY” is authorized for ALL doses for individuals 6 months of age and older

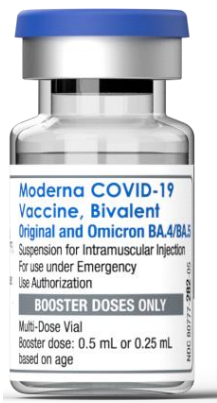
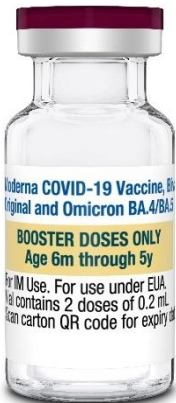
Dear Vaccination Provider:

The purpose of this letter is to inform vaccination providers of the following:

The April 18, 2023, revision to the Emergency Use Authorization of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) included:

- Use of Moderna COVID-19 Vaccine, Bivalent for **ALL** doses for administration to individuals 6 months of age and older.
- Removal of the authorization for use of the monovalent Moderna COVID-19 Vaccine in the U.S.
- Revision of Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to no longer refer to “Primary” or “Booster” doses.
- Simplification of the dosing regimen to a single dose for most individuals 6 years of age and older.


There are 2 presentations of Moderna COVID-19 Vaccine, Bivalent (see table). **Even though vials and cartons of both presentations are labeled “BOOSTER DOSES ONLY,” doses from these vials are authorized for individuals 6 months of age and older** as conveyed in the Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

Multiple-Dose Vial with Dark Blue Cap and Label with Gray Border ¹	Multiple-Dose Vial with Dark Pink Cap and Label with Yellow Box ¹
 <p>For ages 6 months through 5 years, a single dose for Dose 1 and Dose 2 is 0.25 mL each</p> <p>For ages 6 years through 11 years, a single dose is 0.25 mL</p> <p>For ages 12 years and older, a single dose is 0.5 mL</p>	 <p>For ages 6 months through 5 years, a single dose for Dose 3 is 0.2 mL</p>
NDC 80777-282-05	NDC 80777-283-02

¹ Refer to the Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for additional information, including dosing regimen, dose and schedule for individuals with certain kinds of immunocompromise.

Additional Resources

For additional information and to access the current Moderna COVID-19 Vaccine, Bivalent Fact Sheets, please scan the QR code or visit the website provided below. A copy of the Fact Sheet for Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 6 months of age and older is also attached to this letter.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

Should you have any questions about the use of Moderna COVID-19 Vaccine, Bivalent, you can either contact the Moderna Medical Information Contact Center at 1-866-MODERNA (1-866-663-3762) or visit www.modernatx.com/covid19vaccine-eua for additional resources.

Sincerely,

Paul Burton

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*Enclosure: Moderna COVID-19 Vaccine, Bivalent Fact Sheet for Healthcare Providers
Administering Vaccine (Vaccination Providers)*