

September 7, 2022

**CORRECTED**  
**IMPORTANT PRESCRIBING INFORMATION**

**Subject: Moderna COVID-19 Vaccine, Bivalent –  
New Vial Presentation Available to Provide Booster Doses for Ages 18 Years  
and Older**

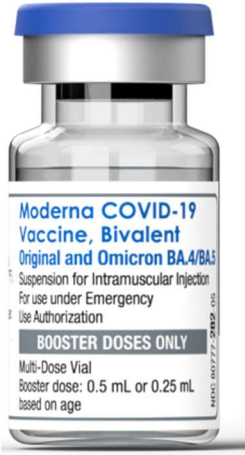
**Dear Healthcare Provider:**

On August 31, 2022, the U.S. Food and Drug Administration authorized emergency use of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Moderna COVID-19 Vaccine, Bivalent, which contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2. Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 18 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<sup>1</sup> COVID-19 vaccine, or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.


This letter is to alert you that Moderna COVID-19 Vaccine, Bivalent for individuals 18 years of age and older is supplied in a multiple-dose vial with a dark blue cap and a label with a gray border.

It is important to carefully read the labels to differentiate between this and other Moderna COVID-19 vaccines. The label for Moderna COVID-19 Vaccine, Bivalent is shown in the table below.

 <p><b>Gray border</b></p> <p>NDC 80777-282-05</p>	<p><b>Each single booster dose for ages 18 years and older is 0.5 mL</b></p>
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<sup>1</sup> Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below. A copy of the Fact Sheet for the Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 18 years of age and older is also attached to this letter.

Website	Telephone number
<p data-bbox="245 422 760 449"><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></p> 	<p data-bbox="1003 422 1243 485">1-866-MODERNA (1-866-663-3762)</p>

Vaccination providers must report certain information associated with the administration of the vaccine to VAERS in accordance with the authorized Fact Sheet.

Should you have any questions about the use of the 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](http://www.modernatx.com/covid19vaccine-eua) for additional resources.

This letter is not intended as a complete description of the benefits and risks related to the use of Moderna COVID-19 Vaccine, Bivalent. Please refer to the authorized Moderna COVID-19 Vaccine, Bivalent Fact Sheet.

Sincerely,

*Paul Burton*

Paul Burton, MD, PhD, FACC, MRCS Chief Medical Officer, Moderna

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