

CLINICAL ALERT

AUGUST | 2022

PharMerica

FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose

Issue

Today (August 31, 2022) the FDA authorized **BIVALENT** formulations of the **Moderna COVID-19 Vaccine** and **Pfizer-BioNTech COVID-19 Vaccine** for use as a **single booster dose \geq 2 months following primary or booster vaccination**.

These vaccines' Emergency Use Authorizations ([EUAs](#)) are amended to reflect the update.

What are BIVALENT vaccines?

The BIVALENT vaccines (aka UPDATED BOOSTERS) contain 2 mRNA components of the SARS-CoV-2 virus:

- 1 strain of the original SARS-CoV-2, *and*
- 1 strain in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2.

Why were BIVALENT vaccines authorized as boosters?

The BIVALENT vaccines were developed to provide an immune response that is *both* broadly protective against COVID-19 and to provide better protection against COVID-19 caused by the omicron variant.

The BA.4 and BA.5 lineages of the omicron variant are currently causing most cases of COVID-19 in the U.S. and are predicted to circulate this fall and winter.

Based on the data supporting each of these authorizations, the BIVALENT COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variant.

Who is eligible to receive a single BIVALENT dose?

Moderna COVID-19 Vaccine, BIVALENT: Individuals ≥ 18 years of age are eligible for a single booster dose ≥ 2 months since they completed primary vaccination or received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Pfizer-BioNTech COVID-19 Vaccine, BIVALENT: Individuals ≥ 12 years of age are eligible for a single booster dose ≥ 2 months since they completed primary vaccination or received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

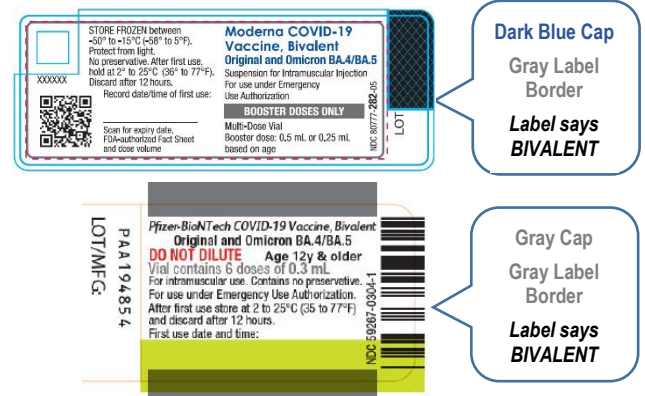
What about currently available "monovalent" COVID-19 vaccines?

With today's authorization, the monovalent mRNA COVID-19 vaccines are **NO LONGER** authorized as **BOOSTER** doses for individuals 12 years of age and older. Individuals due for a booster dose should wait until the BIVALENT booster is available (while currently *FDA-authorized*, now awaiting CDC review for *recommendation* and *schedule* considerations).

Monovalent mRNA COVID-19 vaccines are **STILL** authorized for primary vaccination, per their current EUA specifications.

Additional Resources

- [FDA Press Release](#)
- [Moderna COVID-19 Vaccine Fact Sheets and FAQs](#)
- [Pfizer-BioNTech COVID-19 Vaccine Fact Sheets and FAQs](#)



Information provided herein is purposefully abbreviated for clarity.

Please refer to products' FDA Labels / EUA Fact Sheets for Providers for full prescribing information.