

CLINICAL **ADVISORY**

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PharMerica

FDA Authorizes Changes to Simplify Use of BIVALENT mRNA COVID-19 Vaccines; CDC updates Interim Clinical Considerations for COVID-19 Vaccination

Current Update

4-18-23: the [FDA amends the Emergency Use Authorizations](#) (EUAs) for Moderna and Pfizer BIVALENT mRNA vaccines:

- Authorizes BIVALENT Moderna and Pfizer-BioNTech COVID-19 vaccines to be used for all doses administered to individuals 6 months of age and older.
- Authorizes an additional authorized bivalent dose (booster) for certain populations.

The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

4-19-23: The CDC officially endorsed the FDA's recommendations to simplify the vaccine schedule.

Imminent Future: Formal updates to the [Interim Clinical Consideration for use of COVID-19 Vaccines in the U.S.](#) are pending

Key Takeaways

Most unvaccinated individuals may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.

Most individuals (depending on age) previously vaccinated with a monovalent COVID-19 vaccine who have not received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.

Most individuals who have received a single dose of the bivalent vaccine are not currently eligible for another dose.

Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional dose at least 4 months following their initial bivalent dose.

Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine (additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider). However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.

Action Steps

PharMerica Pharmacies

- Sequester all remaining Pfizer and Moderna MONOVALENT doses to prevent dispensing/administering these vaccines which, effective immediately, are no longer authorized for use in the U.S. and await further instruction from Internal Operations on documenting disposal of the vaccines.

Facilities

- Effective immediately, halt use of MONOVALENT COVID-19 vaccines.
- Refer to the [Interim Clinical Consideration for use of COVID-19 Vaccines in the U.S.](#) for forthcoming guidance updates.