Wyoming Department of Health

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State Health Advisory Supplement
COVID-19 Bivalent Booster Vaccine Authorized and Recommended for Individuals Aged 12 years and Older
Coronavirus Disease 2019 Supplemental Advisory #14.9
Wyoming Department of Health
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The U.S. Food and Drug Administration (FDA) has authorized, and the Centers for Disease Control and Prevention (CDC) now recommends, bivalent mRNA COVID-19 booster vaccines for individuals aged 12 and older. These bivalent boosters replace the formerly available monovalent mRNA booster vaccines for this age group; monovalent mRNA vaccines are no longer authorized to be used as booster doses for individuals aged 12 and older.

Pfizer-BioNTech COVID-19 vaccine, bivalent, is authorized for use in individuals aged 12 years and older. Moderna COVID-19 vaccine, bivalent, is authorized for use in individuals aged 18 years and older. These bivalent mRNA vaccines are authorized as a single booster dose administered at least 2 months after either of the following:

- Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, OR
- Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals ages 12 years and older, meaning monovalent booster doses can no longer be given to individuals ages 12 years and older, even if the person had not previously received a monovalent booster dose. Monovalent mRNA COVID-19 vaccines remain available as a primary series for this age group.

Everyone aged 12 years and older is recommended to receive one age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or last monovalent booster dose. Individuals cannot get a bivalent booster dose without first completing a primary series. Age-appropriate homologous and heterologous booster vaccines are allowed without preference.

At this time, there are no changes to the COVID-19 vaccine schedule for children ages 6 months through 11 years. Children ages 5 through 11 years who received a primary Pfizer series are recommended to receive one monovalent Pfizer booster dose at least 5 months after the final dose in the primary series. Booster doses are not authorized for children under the age of 5 or for children under the age of 12 who received a Moderna primary series.

The healthcare provider fact sheets for both Pfizer and Moderna bivalent booster vaccines can be found at the links below:
Pfizer: https://www.fda.gov/media/161327/download
Moderna: https://eua.modernatx.com/covid19vaccine-eua/Dear_HCP_Booster.pdf

A summary of current vaccine and booster recommendations is found in the table below:

	Primary Series			
	Pfizer, Monovalent	Moderna, Monovalent	Janssen[1]	Novavax
Eligibility for primary series	Ages 6mo+[2]	Ages 6mo+[2]	Ages 18+	Ages 12+
Timing between first and second doses in primary series	Ages 6mo+: 3-8 weeks[3]	Ages 6mo+: 4-8 weeks[3]	Not applicable	Ages 12+: 3-8 weeks[3]
Timing between second and third doses in primary series	Ages 6mo-4yrs: At least 8 weeks Ages 5+: N/A	Not applicable	Not applicable	Not applicable
Additional Primary Dose for individuals with moderate to severe immunocompromised 4	Ages 6mo-4yrs: Not authorized Ages 5+: Given at least 4 weeks after second dose of primary series	Ages 6mo+: Given at least 4 weeks after the second dose of the primary series	Ages 18+ Must be a mRNA vaccine Given at least 4 weeks after the Janssen dose	Not applicable
Booster Dose	Ages 6mo-4yrs: Booster dose not authorized Ages 5-11yrs: One Pfizer, monovalent booster dose at least 5 months after last dose in primary series Ages 12-17: One Pfizer,	Ages 6mos-11yrs: Booster dose not authorized Ages 12-17 yrs: One Pfizer, bivalent booster dose at least 2 months after last dose in primary series Ages 18+: One Pfizer,	Ages 18+: One Pfizer, bivalent or one Moderna, bivalent booster dose at least 2 months after last dose in primary series or last booster dose	Ages 12-17: One Pfizer, bivalent booster dose at least 2 months after last does in primary series Ages 18+: One Pfizer, bivalent or one Moderna, bivalent booster dose at least 2 months after last

	bivalent booster dose at least 2 months after last does in primary series or last booster dose Ages 18+: One Pfizer, bivalent or one Moderna, bivalent booster dose at least 2 months after last dose in primary series or last booster dose	bivalent or one Moderna, bivalent booster dose at least 2 months after last dose in primary series or last booster dose		dose in primary series
Second booster dose	No longer applicable	No longer applicable	No longer applicable	Not applicable

1. Due to the risk of thrombosis with thrombocytopenia syndrome, Janssen vaccine should only be given if there is a contraindication to the mRNA vaccines (Pfizer and Moderna), if an individual would otherwise remain unvaccinated for COVID-19 vaccines unless they received the Janssen vaccine, or if an individual wants to receive the Janssen vaccine despite the safety concerns.
2. There is different formulation and dosing of the Pfizer vaccine for 5-11 year olds and children aged 6mos-4 years compared with the formulation and dosing of the Pfizer vaccine for individuals 12+. There is different formulation and dosing of the Moderna vaccine for children aged 6mos-5 years compared with the formulation and dosing of the Modernal vaccine for individuals 18+. Dosing for additional primary doses and booster doses should be age-appropriate.
3. A 3-week interval for Pfizer or Novavax and a 4-week interval for Moderna is recommended for individuals who are moderately to severely immunocompromised, adults aged 65 years and older, and in situations when the fullest possible protection needs to be achieved sooner (i.e., concern about COVID community levels or individuals at higher risk of severe disease
An 8-week interval may be optimal for people who are not moderately to severely immunocompromised and aged 6 mos-64 years, especially for males aged 12-39 years
4. Dosing of the single additional primary dose is the same as for the primary series. Dosing should be age-appropriate.

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumors and hematologic malignancies
- Receipt of solid organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (within two years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Complete clinical considerations for COVID-19 vaccines from the CDC can be found here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccinating-exposure

CLINICAL RESOURCES

Clinical management guidance is available from the CDC (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html), the NIH (https://www.covid19treatmentguidelines.nih.gov/), and the IDSA (https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/). CDC's Clinical Outreach and Communication Activity (COCA) calls and webinars offer the most up to date information and guidance for clinicians. COCA calls can be accessed at https://emergency.cdc.gov/coca/calls/index.asp). The Wyoming Medical Society website contains clinical resources from the University of Washington, including treatment guidelines and algorithms: https://www.wyomed.org/resources/covid-19/.

CONTACT INFORMATION

For questions about the COVID-19 vaccines, providers should visit the WDH Immunization Unit website at https://health.wyo.gov/publichealth/immunization/wyoming-covid-19-vaccine-information/ or email WDH.immunization@wyo.gov.

For questions about monoclonal antibody therapies, please contact wdh.covid19@wyo.gov.

Wyoming healthcare providers and facilities are reminded to check COVID-19 resources available from WDH and CDC. Healthcare providers or facilities can contact WDH through the following channels:

- Please email questions about preparedness, PPE, infection control, or other non-urgent topics to wdh.covid19@wyo.gov.

- Please contact WPHL with questions about specimen collection, storage, or shipping at 307-777-7431 or WPHL@wyo.gov.
- **Please use the WDH Public Health Emergency Line (1-888-996-9104) for urgent questions. This line is intended ONLY for healthcare providers. Do not share this number with the public.**

Please refer questions from the general public to 211 or to the WDH email box (wdh.covid19@wyo.gov**).**