

**State Health Advisory Supplement
COVID-19 Vaccine and Outpatient Therapeutics Summary
Coronavirus Disease 2019 Supplemental Advisory #14
Wyoming Department of Health
January 14, 2022**

SITUATION SUMMARY

The Centers for Disease Control and Prevention (CDC) has updated Pfizer COVID-19 vaccine recommendations to include a booster for individuals ages 12-15 years and an additional primary dose for immunocompromised individuals aged 12 to 15 years 28 days after completion of the primary series. The interval between completion of the primary series of Pfizer and Moderna and a recommended booster has been changed from 6 months to 5 months. This health advisory summarizes current COVID-19 vaccine recommendations. This health advisory also summarizes available outpatient COVID-19 therapeutics and provides guidance on their use when supplies are limited. Rapid testing supplies are currently limited in Wyoming and the Wyoming Department of Health (WDH) provides recommendations for use of rapid tests in scarce resource situations.

COVID-19 VACCINES

The U.S. Food and Drug Administration (FDA) has amended the Emergency Use Authorization (EUA) and the CDC has updated recommendations for the Pfizer COVID-19 vaccine as follows:

- Individuals aged 12-15 years should receive a booster dose. The dosage is the same as a single dose in the primary series.
- Booster doses may now be given 5 months rather than 6 months after the second dose of a primary Pfizer series to individuals eligible for a booster dose. Individuals aged 12-17 years are eligible for a Pfizer booster dose 5 months after completion of the primary Pfizer series. Adults aged 18 years and older are eligible for a booster dose with Pfizer, Moderna, or Janssen 5 months after completion of the primary Pfizer series.
- Individuals aged 5-11 years who are moderately to severely immunocompromised (see definition below) and have completed a primary Pfizer series may receive an additional dose of the Pfizer vaccine given at least 28 days after the second dose of the primary series.

In addition, the FDA has amended the EUA for the Moderna vaccine to allow a booster dose at 5 months after the completion of the primary series, rather than 6 months.

The chart below provides a summary of current COVID-19 vaccine recommendations, including additional doses for moderately to severely immunocompromised individuals and booster doses:

	Primary Series		
	Pfizer	Moderna	Janssen ¹
Eligibility for primary series	<ul style="list-style-type: none"> • Ages 5+² 	<ul style="list-style-type: none"> • Ages 18+ 	<ul style="list-style-type: none"> • Ages 18+
Additional Primary Dose ³	<ul style="list-style-type: none"> • Individuals aged 5+ who are moderately to severely immunocompromised⁴ • Given 28 days after second dose of primary series 	<ul style="list-style-type: none"> • Individuals aged 18+ who are moderately to severely immunocompromised⁴ • Given 28 days after the second dose of the primary series 	<ul style="list-style-type: none"> • No additional primary dose recommended
Booster Dose	<ul style="list-style-type: none"> • Individuals aged 12-17 can receive a booster dose of Pfizer given 5 months after the second dose in their primary series. Individuals aged 12-17 who received an additional primary dose can receive a booster given 5 months after the additional primary dose • Individuals aged 18+ can receive a booster dose of Pfizer, Moderna⁵, or Janssen given 5 months after the second dose in their primary series. Individuals aged 18+ who received an additional primary dose can receive a booster of Pfizer, Moderna⁵, or Janssen given 5 months after the additional primary dose • Booster doses are not authorized for individuals aged 5-11 years at this time 	<ul style="list-style-type: none"> • Individuals aged 18+ can receive a booster dose of Pfizer, Moderna⁵, or Janssen given 5 months after the second dose in their primary series. Individuals aged 18+ who received an additional primary dose can receive a booster dose of Pfizer, Moderna⁵, or Janssen given 5 months after the additional primary dose 	<ul style="list-style-type: none"> • Individuals aged 18+ can receive a booster dose of Pfizer, Moderna⁵, or Janssen given 2 months after the primary Janssen dose

1. mRNA vaccines (Pfizer and Moderna) are preferred over Janssen due to the thrombosis with thrombocytopenia syndrome associated with the Janssen vaccine.
2. The formulation and dosing of the Pfizer vaccine for 5-11 year olds is different from that for ages 12+. Dosing for additional primary doses and booster doses should be age-appropriate.
3. Dosing of the single additional primary dose is the same as for the primary series. For the Pfizer vaccine, dosing should be age-appropriate.
4. 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 $<200/\text{mm}^3$, 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.
5. The single booster dose of Moderna is half that given during the primary series. The single booster dose of Pfizer and Janssen is the same as for the primary series. For the Pfizer vaccine, dosing should be age-appropriate.

COVID-19 THERAPEUTICS WHEN RESOURCES ARE SCARCE

A side-by-side comparison of the currently available outpatient COVID-19 therapeutics, including efficacy, eligible populations, contraindications, and dosage can be found here: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx>

COVID-19 outpatient therapeutics include medications meant for patients with mild to moderate COVID-19 who are at high risk of disease progression. Supplies of COVID-19 outpatient therapeutics are currently scarce. WDH provides the following guidance, based on recommendations from the National Institutes of Health (NIH), the Utah Department of Health, and Massachusetts Department of Health, for prioritizing patients and selecting therapeutics while resources are scarce. Given the current prevalence of Omicron (estimated to be $>90\%$ in Wyoming), sotrovimab is the only effective monoclonal antibody available and is the only monoclonal considered in this guidance. However, since there is likely some delta variant still circulating, providers that have supplies of REGEN-COV and/or bamlanivimab/etesevimab can consider using them in patients when there are no other therapeutics available with awareness of the risk that they may not be effective.

The guidelines below group patients based on risk for development of severe illness and recommended therapeutics. Patients in the highest risk category should be prioritized for the most effective medications. If patients are determined to be equal in risk but there are insufficient supplies, a lottery system should be used. Providers should follow all requirements of the emergency use authorization for each medication, including limitations of use.

Patient Risk Level	Patient Characteristics (at least one of the listed conditions)	Recommended therapies, in order of preference, if given within 5 days of symptom onset	Recommended therapies, in order of preference, if given within 5-10 days of symptom onset
Highest	<ul style="list-style-type: none"> ● Age \geq 65 years ● Moderate to severe immunosuppression¹ ● Severe obesity (BMI \geq 35) 	<ol style="list-style-type: none"> 1. Paxlovid 2. Sotrovimab 3. Remdesivir² (off-label) 4. Molnupiravir, if above therapies are not available 	<ol style="list-style-type: none"> 1. Sotrovimab 2. Remdesivir² (off-label) if within 7 days of symptom onset
Highest	<ul style="list-style-type: none"> ● Pregnancy 	<p>Pregnancy increases the likelihood of severe illness with COVID-19. Pregnant women with COVID-19 are more likely to experience preterm birth and stillbirth and may be more likely to have other pregnancy complications. Data are insufficient for Paxlovid, Sotrovimab, and Remdesivir to determine whether there are drug-associated adverse maternal or fetal outcomes. Shared-decision making between clinicians and patients weighing potential benefits of therapy with unknown risks should be used to determine whether to initiate therapy. Molnupiravir is not recommended for use during pregnancy based on animal studies indicating potential teratogenic effects.</p>	
High	<ul style="list-style-type: none"> ● Obesity (BMI 30-34) ● Chronic kidney disease ● Diabetes ● Cardiovascular disease including hypertension and coronary artery disease ● Chronic lung disease ● Sickle cell disease ● Chronic neurologic disease including cerebrovascular disease and neurodevelopmental disease ● Dependence on medical technology 	<ol style="list-style-type: none"> 1. Remdesivir² (off-label) 2. Molnupiravir <p>If neither medication is available, Paxlovid or Sotrovimab may be used if available and if there is no demand from higher risk patients</p>	<ol style="list-style-type: none"> 1. Remdesivir² (off-label) if within 7 days of symptom onset 2. Sotrovimab if available and if there is no demand from higher risk patients

1. 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 $<200/\text{mm}^3$, 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.

If supplies are too scarce to be provided to all moderately to severely immunocompromised individuals because of logistical constraints or supply limitations, the NIH suggest prioritizing their use for those who are least likely to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection and who are at risk for severe outcomes, including but not limited to the following patients: Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab); patients receiving Bruton tyrosine kinase inhibitors; chimeric antigen receptor T cell recipients; post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication; patients with hematologic malignancies who are on active therapy; lung transplant recipients; patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant); solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents; patients with severe combined immunodeficiencies; patients with untreated HIV who have CD4 T lymphocyte cell count <50 cells/ mm^3

2. Remdesivir is only FDA-approved for treatment of inpatients. However, the NIH recommends off-label use for outpatients at high risk for severe illness when resources are scarce. The NIH recommends Remdesivir 200mg IV on day 1, followed by Remdesivir 100 mg IV daily on days 2 and 3, initiated as soon as possible and within 7 days of symptoms onset in those aged ≥ 12 years and weighing ≥ 40 kg.

As with any prioritization guidelines, clinical discretion remains critical when determining which patients are at the highest risk for severe illness and hospitalization and guidelines cannot cover every scenario. These are guidelines only and local jurisdictions and healthcare facilities that have developed their own protocols can continue to use those. Providers may also wish to consider a scoring system to stratify patients within the above categories based on a patient having multiple risk factors. If a scoring system is used, WDH encourages providing the same age-based points to all patients 80 and over.

Further information is provided by the NIH:

<https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies>

<https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/>

RAPID COVID-19 TESTING

Due to the substantial increase in transmission in Wyoming and the country, demand for testing, in particular rapid testing, has grown significantly. Many manufacturers are unable to completely fill rapid testing orders at this time.

WDH currently has a very limited number of rapid tests available. High-risk communal settings, early childhood education settings, and K-12 schools will be prioritized to receive these tests while supplies are available. Orders from other entities will not be filled until supplies increase.

WDH recommends that providers who use limited rapid testing supplies prioritize rapid testing for individuals for whom a rapid diagnosis will inform clinical treatment, specifically for individuals with severe illness and outpatients with conditions that put them at high risk for severe illness and could benefit from the available outpatient therapeutics. Rapid testing should also continue to be used in high risk communal settings such as long-term care facilities where a timely result will impact infection control measures. Where possible, other individuals should be offered laboratory-based testing.

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).