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State Health Advisory
Updated Guidance for Coronavirus Disease 2019 (COVID-19)
Coronavirus Disease 2019 Advisory #13
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SITUATION SUMMARY

COVID-19 transmission is increasing throughout most of Wyoming resulting in increasing numbers of hospitalizations and deaths. It is estimated that the delta variant, which is more transmissible than previous strains, accounts for the vast majority of cases in Wyoming and our region. Testing is widely available and WDH has testing resources available for providers and healthcare facilities. The FDA authorization for monoclonal antibodies has expanded to include treatment or post-exposure prophylaxis for any outpatient 12 years of age and older who, in the

opinion of the provider, is at high risk for progression to severe disease. An additional dose of COVID-19 mRNA vaccines is now recommended for individuals with certain immunocompromising conditions. Booster doses of COVID-19 vaccines are likely to be recommended in the upcoming weeks. Quarantine recommendations have been adapted to account for fully vaccinated individuals.

Updated epidemiologic information can be found here: https://health.wyo.gov/publichealth/infectious-disease-epidemiology-unit/disease/novel-coronavirus/

COVID-19 TESTING

WDH recommends that all individuals with symptoms consistent with COVID-19 and individuals exposed to COVID-19 be tested for SARS-CoV-2. Screening testing among asymptomatic individuals who are not fully vaccinated can help prevent transmission in communal or work settings.

The Wyoming Public Health Laboratory (WPHL) continues to offer multiplex RT-PCR testing for SARS-CoV-2, influenza A, and influenza B. The WPHL accepts samples from patients who are symptomatic, close contacts of persons with SARS-CoV-2 infection, neonates born to women with COVID-19, and post-mortem swabs from individuals suspected to have COVID-19. WPHL recommends collection of nasopharyngeal swabs for COVID-19 testing. Oral swabs are also acceptable. While nasal swabs, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate specimens are accepted, the performance of the COVID-19 test has not been evaluated on these specimen types. WPHL also offers saliva-based COVID-19 testing using the SalivaDirect assay. All ordering is done through the Laboratory Web Portal (https://lwp-web.aimsplatform.com/wy/#/auth/login). Specimen collection and shipping supplies remain available. For more details about testing offered by the WPHL, please visit https://health.wyo.gov/publichealth/lab/wphl-covid-19-testing-information/.

WDH also offers community-based and employer-based testing throughout the state through several contractors.

WDH has rapid testing resources available to providers. WDH currently has an inventory of 76,000 BinaxNOW antigen tests, which are set to expire on November 11, 2021. We are currently distributing on a weekly average approximately 3,000 tests. Based on this, we believe only approximately 33,000 tests will be used by that expiration date. Any providers interested in BinaxNow antigen tests should contact Keith Harris at keith.harris1@wyo.gov.

ANTI-SARS-CoV-2 MONOCLONAL ANTIBODIES

In randomized, placebo-controlled trials of nonhospitalized patients who had mild to moderate COVID-19 symptoms and certain risk factors for disease progression, the use of anti-SARS-CoV-2 monoclonal antibody products reduced the risk of hospitalization and death. There are currently three FDA authorized anti-SARS0CoV-2 monoclonal antibody therapies. The combination of bamlanivimab plus etesevimab is not currently being distributed due to reduced susceptibility of circulating variants to this monoclonal antibody combination. Casirivimab plus imdevimab (REGEN-COV) continues to be distributed by the U.S. Department of Health and Human Services and can be used for both treatment of COVID-19 patients and post-exposure

prophylaxis. Sotrovimab is available for purchase through AmerisourceBergen and can be used for treatment of COVID-19 patients.

Treatment
Casirivimab plus imdevimab (REGEN-COV) and sotrovimab can be used for the treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive test results and who are at high risk for progression to severe COVID-19, including hospitalization or death. While the following conditions may place adult and pediatric patients at higher risk for progression to severe disease, use of the monoclonal antibodies is not limited to patients with these conditions.The determination of whether a patient is at high risk for progression to severe disease is at the discretion of the clinician.

- Older age (for example, age ≥ 65 years)
- Obesity or being overweight
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, moderate-severe asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)

Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Casirivimab plus imdevimab (REGEN-COV) and sotrovimab are not authorized for use in patients who:

- Are hospitalized due to COVID-19 (though if hospitalized for a diagnosis other than COVID-19, they can be used provided the patient has mild to moderate COVID-19 and is at high risk for progressing to severe disease), OR
- Require oxygen therapy due to COVID-19, OR
- Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Sotrovimab is administered via an intravenous infusion. Casirivimab plus imdevimab can be administered via intravenous infusion or subcutaneous injection. For treatment, intravenous infusion is strongly recommended, with subcutaneous injection available when intravenous infusion is not feasible and would lead to delay in treatment.

Additional information for healthcare providers on the use of sotrovimab and casirivimab plus imdevimab can be found in the FDA Emergency Use Authorization Fact Sheets for Healthcare Providers. Both fact sheets are linked below:

Casirivimab plus imdevimab: https://www.fda.gov/media/145611/download
Sotrovimab: https://www.fda.gov/media/149534/download

Post-Exposure Prophylaxis
Casirivimab plus imdevimab (REGEN-COV) is also authorized to be used for post-exposure prophylaxis of adult and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization and death, and are:

- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccinations (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per the Centers for Disease Control and Prevention (CDC) OR
    - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

Post-exposure prophylaxis is not a substitute for vaccination against COVID-19. Casirivimab plus imdevimab is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

While the conditions listed above under "Treatment" may place exposed adult and pediatric patients at higher risk for progression to severe disease, use of casirivimab plus imdevimab for post-exposure prophylaxis is not limited to patients with these conditions. The determination of whether a patient is at high risk for progression to severe disease is at the discretion of the clinician.

Intravenous and subcutaneous routes of administration can both be used for post-exposure prophylaxis.

Access to Anti-SARS-CoV-2 Monoclonal Antibodies
Casirivimab plus imdevimab can be ordered from the U.S. Department of Health and Human Services through their distributor AmerisourceBergen. Information about the direct order process can be found here: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/direct-order-process-covid19-mAb.aspx. The order form can be found here: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

Sotrovimab may be purchased through the distributor AmerisourceBergen. Details about how to purchase sotrovimab can be found here: https://www.sotrovimab.com/hcp/access/

OTHER THERAPIES AND CLINICAL MANAGEMENT GUIDANCE

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/.

COVID-19 VACCINE UPDATES

Additional doses of COVID-19 mRNA vaccines for moderately to severely immunocompromised individuals

On August 12, 2021, the FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people. On August 13, 2021 the Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for an additional dose under these circumstances. The age groups authorized to receive the additional doses are unchanged from those authorized to receive the primary vaccination series:

- Pfizer-BioNTech: aged ≥ 12 years
- Moderna: aged ≥ 18 years

An additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., as part of need assessment for an additional dose) has

not been established. Serologic testing or cellular immune testing outside of the context of research studies is not recommended at this time.

The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series. If the mRNA COVID-19 product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA vaccine doses.

Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion.

Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single dose Johnson & Johnson/Janssen COVID-19 vaccination series in immunocompromised people.

Additional doses of mRNA vaccines for patients who meet the above criteria are currently available in Wyoming.

Clinical considerations for the administration of COVID-19 vaccines from the CDC can be found here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html

Booster doses

The CDC has announced that the available data indicate that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, there is evidence of reduced protection against mild and moderate disease. The current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, booster shots will be needed to maximize vaccine-induced protection and prolong its durability.

Booster shots will likely become available this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's ACIP issuing booster dose recommendations based on a thorough review of the evidence.

It is likely that booster shots will be available beginning the week of September 20 and starting 8 months after an individual's second dose.

It is also anticipated that booster shots will likely be needed for people who received the Johnson & Johnson/Janssen (J&J) vaccine. More data on J&J vaccine should be available within the upcoming weeks.

Booster shots will be available in Wyoming once authorized by the FDA and recommended by the ACIP.

ISOLATION, QUARANTINE, AND COMMUNITY MITIGATION MEASURES

Isolation

Isolation recommendations for individuals diagnosed with COVID-19 are unchanged and are the same for individuals who are fully vaccinated and those who are not fully vaccinated.

For most adults with COVID-19 illness, isolation and precautions can be discontinued 10 days after symptom onset and after resolution of fever for at least 24 hours, without the use of fever-reducing medications, and with improvement of other symptoms. Some adults with severe illness may produce replication-competent virus beyond 10 days that may warrant extending duration of isolation and precautions for up to 20 days after symptom onset; severely immunocompromised patients may produce replication-competent virus beyond 20 days and require additional testing and consultation with infectious diseases specialists and infection control experts.

For adults who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of their first positive RT-PCR test result for SARS-CoV-2 RNA.

A test-based strategy for discontinuing isolation is not recommended for individuals who are not severely ill or severely immunocompromised. For adults who are severely ill or severely immunocompromised, a test-based strategy could be considered in consultation with infectious diseases experts.

Additional information on isolation precautions can be found here:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Quarantine

Quarantine recommendations have been modified to account for fully vaccinated individuals. An individual is considered fully vaccinated if it has been at least two weeks since their final dose in the vaccine series (i.e., two weeks after the second dose of mRNA vaccine or two weeks after the single dose of Johnson & Johnson/Janssen). An individual is considered exposed to COVID-19 if they have been within six feet of an infectious individual for at least 15 cumulative minutes over the course of a 24-hour period.

Individuals who have been fully vaccinated against COVID-19 do not need to quarantine with the exception of individuals in certain healthcare settings (see below). WDH recommends that fully vaccinated individuals get tested 3-5 days after exposure and wear a mask in public indoor settings for 14 days or until a negative test result is obtained at 3-5 days. If a fully vaccinated individual tests positive, he or she should isolate as above. Fully vaccinated individuals who live in a household with someone who is immunosuppressed, at increased risk of severe disease, or unvaccinated should consider masking at home for 14 days following a known exposure or a negative test result is obtained.

Exposed individuals who have tested positive for COVID-19 within the prior 90 days and remain asymptomatic do not need to quarantine or be tested. Unvaccinated persons who have tested antibody positive within 3 months before or immediately following an exposure to someone with

suspected or confirmed COVID-19 and who have remained asymptomatic since the current COVID-19 exposure do not need to quarantine, provided there is limited or no contact with persons at high risk for severe COVID-19 illness, including older adults and persons with certain medical conditions.

WDH recommends that all other individuals who are exposed to COVID-19 should quarantine for 14 days after the last exposure. CDC has published three options for reducing the length of quarantine following exposure to COVID-19. Options for shortening the quarantine period include:

- Ending quarantine **after** 10 days if the individual self-monitors daily and remains asymptomatic
- Ending quarantine **after** 7 days if the individuals self-monitors daily, remains asymptomatic, **AND** has a negative PCR test collected on day 5 or later. In no circumstances can quarantine be discontinued before 7 full days of quarantine have passed since exposure.
- Ending quarantine if the individual tests positive on a COVID-19 antibody test (IgG, IgM, total antibody) immediately following exposure. This option should be used for low risk situations only. High risk situations including contact with people at high risk of developing severe illness from COVID-19 such as older adults and people with certain underlying health conditions should be avoided.

Individuals who use one of the options above to shorten the quarantine period should continue to monitor for symptoms daily for the full 14 days. WDH recommends continuing to take measures such as avoiding crowds, social distancing, correct and consistent mask use, and hand and cough hygiene for the full 14 days. Some businesses, schools, or organizations may require a full 14-day quarantine period.

Fully vaccinated inpatients and residents in healthcare settings should continue to quarantine following prolonged close contact (within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period) with someone with SARS-CoV-2 infection; outpatients should be cared for using recommended transmission-based precautions.

Further information about quarantine can be found at the following links:

https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

Community mitigation measures

WDH recommends that individuals who are not fully vaccinated continue to wear masks and maintain social distancing in public indoor settings. WDH recommends that fully vaccinated individuals wear masks in public indoor settings in counties with substantial or high transmission. WDH publishes weekly county- and state-level metrics on this page: https://health.wyo.gov/publichealth/infectious-disease-epidemiology-unit/disease/novel-coronavirus/covid-19-orders-and-guidance/. WDH recommends that fully vaccinated individuals in the yellow, orange, or red zones according to WDH metrics wear masks in public indoor settings.

Based on CDC guidance, WDH recommends universal masking in K-12 schools regardless of vaccination status or community transmission levels.

CONTACT INFORMATION

Wyoming healthcare providers and facilities are reminded to check COVID-19 resources available from WDH https://health.wyo.gov/publichealth/infectious-disease-epidemiology-unit/disease/novel-coronavirus/ and CDC https://www.cdc.gov/coronavirus/2019-nCoV/. 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. This email address is monitored 7 days a week and replies will come within 24 hours.
- 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).