COMMONWEALTH of VIRGINIA

Department of Health

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COVID-19 Update for Virginia

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Dear Colleague:

Thank you for your continued partnership in responding to the COVID-19 pandemic. Please visit the Virginia Department of Health (VDH) website for current clinical and public health guidance, epidemiologic data, and other information. Updates on the following topics are included in this correspondence:

- CDC COVID-19 Community Levels
- COVID-19 Therapeutics Update
- Consideration of Increased Interval Between 1st and 2nd Doses of mRNA Vaccines
- Prioritization of COVID-19 Antigen Testing Supplies
- List of Medical Conditions that Put People at Higher Risk for Severe COVID-19

CDC COVID-19 Community Levels

The Centers for Disease Control and Prevention (CDC) presented a new method for assessing the impact of the COVID-19 pandemic on health and the healthcare system– COVID-19 Community Levels (a CDC science brief is also available). CDC looks at the combination of three metrics to determine the COVID-19 Community Level: new COVID-19 hospital admissions per 100,000 population in the past 7 days, the percent of staffed inpatient beds occupied by COVID-19 patients, and total new COVID-19 cases per 100,000 population in the past 7 days. New COVID-19 admissions and the percent of staffed inpatient beds occupied represent the current potential for strain on the health system. Data on new cases acts as an early warning indicator of potential increases in health system strain in the event of a COVID-19 surge. CDC's webpage provides county-level Community Level information; VDH is developing a companion dashboard that will provide Community Levels for larger geographic areas which will be available soon. Communities can consider the levels and other local context when making decisions on prevention strategies.

Please note that the CDC COVID-19 Community Levels do not apply in healthcare settings, such as hospitals and nursing homes. Instead, healthcare settings should continue to use community transmission rates and follow CDC's infection prevention and control recommendations for healthcare workers.

COVID-19 Therapeutics Update

The U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorization for EVUSHELD, changing the **initial** dosage from 300 mg (150 mg of tixagevimab and 150 mg of cilgavimab) to 600 mg (300 mg of tixagevimab and 300 mg of cilgavimab). EVUSHELD comes as a single box with two vials (150 mg of tixagevimab and 150 mg of cilgavimab). Therefore, two boxes will now be needed for a new patient. Per FDA, the dosing regimen was revised because available data indicate that a higher dose of EVUSHELD may be more likely to prevent infection by the COVID-19 Omicron subvariants BA.1 and BA.1.1 than the originally authorized EVUSHELD dose. Patients who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an **additional dose** of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels.

Two changes were made to the sotrovimab EUA package insert. First, sotrovimab is now authorized for use within **7 days** of symptom onset for patients with lab-confirmed COVID-19; this is a change from the previous time period of 10 days. Second, in the section on Antiviral Resistance (page 13 of the Full Prescribing Information), it's noted that the Omicron BA.2 subvariant has a 16-fold reduction in susceptibility to sotrovimab compared to the wild type Omicron variant. A comment in the package insert notes the clinical significance of this finding is unknown. According to a recent U.S. Department of Health and Human Services (HHS) call, this is under further study. Currently, the use of sotrovimab has not been curtailed or restricted by FDA or HHS.

Two federal programs allowing certain Federal Retail Pharmacy Partners (FRPP) to order oral antivirals directly from the federal government are live as of March 7, 2022. In the "Test to Treat" program, patients can be seen at certain chain pharmacies with a clinic inside (e.g., CVS Minute Clinics) where a healthcare provider can test patients for COVID-19, diagnose the illness, assess whether oral antiviral therapy is appropriate for patients and, if so, prescribe COVID-19 treatment. Providers should inquire if patients have received COVID-19 treatment outside of routine healthcare visits as access to this program has increased in many communities. The "Long-Term Care Pharmacy Partners" program increases access of oral antivirals to FRPP LTCF pharmacies. Oral antiviral allocations to Virginia will not be impacted.

Consideration of Increased Interval Between 1st and 2nd Doses of mRNA Vaccines

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), with the highest rate in young males (aged 12–29 years) after receipt of the second vaccine dose. Overall, the risk of myocarditis/pericarditis is very small and the benefits of mRNA vaccination continue to far outweigh the risks. In CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, it's noted that extending the interval between the first and second doses of the mRNA vaccine might reduce the risk of myocarditis/pericarditis and increase vaccine effectiveness. Therefore, for some people (especially males aged 12–39 years), an 8-week interval, instead of the usual 3- or 4-week interval depending on the vaccine used, between the first and second mRNA vaccine doses may

be optimal. It is the clinician's judgment about when the second mRNA vaccine dose should be administered. Extending the dosing interval is not appropriate for people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.

Prioritization of COVID-19 Antigen Testing Supplies

Because of a limited supply of COVID-19 antigen tests in the Commonwealth, on January 31, the Acting State Health Commissioner issued interim guidelines for the prioritization of the use of rapid COVID-19 tests. Due to a recent increase in antigen test supplies and lower demand for testing, the prioritization of test supplies is no longer needed. Please see VDH's COVID-19 Testing website.

List of Medical Conditions That Put People at Higher Risk for Severe COVID-19

CDC updated its document Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals based on a literature review as of October 7, 2021. Medical conditions are grouped by the strength of evidence associating them with severe COVID-19. The list is not exhaustive. People with Certain Medical Conditions is a companion page for the general public that you may wish to share with your patients.

Age is the strongest risk factor for severe COVID-19 outcomes. Among U.S. residents who had a COVID-19-related death, 81% were aged 65 or older. As seen on the webpage, many common chronic medical and mental health-related disorders, and disabilities have evidence supporting their association with severe COVID-19 outcomes. This information is particularly helpful when prescribing outpatient treatment for patients with COVID-19. All currently available drugs, whether FDA approved or authorized, for the treatment of outpatients with mild to moderate COVID-19 are indicated for patients who are at higher risk for progression to severe COVID-19.

Thank you for your continued partnership as we respond to the COVID-19 pandemic.

Sincerely,

Colin M. Greene, MD, MPH
Acting State Health Commissioner