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Health Advisory: Updates on COVID-19 Therapeutics for Treatment and Prevention, 12 January 2023

Actions Requested

- **Be aware of the increasing prevalence in the United States of Omicron sublineages (including XBB.1.5) with resistance to** the monocolonal antibody therapies including the combination pre-exposure prophylaxis, tixagevimab plus cilgavimab (Evusheld™).
- **Be aware that antiviral therapeutics for acute COVID-19 are expected to remain effective against severe disease, hospitalization, and death caused by currently circulating Omicron sublineages, including the XBB.1.5 subvariant.**
    - Use of these antivirals should be prioritized as follows: ritonavir-boosted nirmatrelvir (Paxlovid™) followed by remdesivir (Velkury®); alternative therapy: Molnupiravir (Lagevrio™)
    - Healthcare partners should consult the COVID-19 therapeutic distribution locator on current availability of outpatient COVID-19 treatments and Test to Treat locations.
- **Educate patients about the importance of early testing if COVID-19 symptoms develop and prescribe COVID-19 treatment early for patients at higher risk for severe COVID-19.**
    - Patients at higher risk for severe COVID-19 are eligible for COVID-19 treatment if they develop mild or moderate illnesses.
    - Treatment initiation with these antivirals must begin within 5 to 7 days of symptom onset, depending on the therapy.
    - Consider the use of convalescent plasma for in- or outpatient treatment of immunocompromised persons when other options are not possible.
- **Stay up-to-date on appropriate treatment options for circulating SARS-CoV-2 variants:**
    - National Institutes of Health COVID-19 Treatment Guidelines
    - Treatment and prevention options through FDA Emergency Use Authorization
    - Currently circulating variants at CDC Data Tracker
- **Educate patients about the importance of prevention strategies including wearing masks, improving indoor ventilation and staying up to date with recommended COVID-19 vaccines.**
- **Consider influenza testing for patients at high risk for severe influenza.**
    - CDC has testing guidance for clinicians when SARS-CoV-2 and influenza viruses are co-circulating **because symptoms are similar**. Because co-infections can occur, a positive for only one of the viruses does not rule out infection with the other.
    - Guidance for antiviral treatment for influenza does not vary with SARS-CoV-2 coinfection.

Background

The Centers for Disease Control and Prevention (CDC) SARS-CoV-2 genomic surveillance provides estimates for the proportion of circulating variant infections and has identified a rise in the number of cases involving the Omicron subvariant XBB.1.5. Due to recent viral mutations, the previously authorized monoclonal antibody treatment, bebtelovimab, is no longer authorized for treatment in patients with COVID-19 in the US. Given the rise of XBB.1.5, the Food and Drug Administration (FDA)

issued an update stating that the monoclonal antibody combination, tixagevimab plus cilgavimab (Evusheld™) may not provide protection against developing COVID-19 for individuals who have received Evusheld and are later exposed to XBB.1.5. Currently, Evusheld is the only agent FDA currently authorized for SARS-CoV-2 pre-exposure prophylaxis (PrEP) in people who are not expected to mount an adequate immune response to COVID-19 vaccination or those with contraindications for COVID-19 vaccines.

Early outpatient treatment of mild-to-moderate COVID-19 with recommended therapies has been shown to prevent hospitalizations and deaths. Ritonavir-boosted nirmatrelvir (Paxlovid™) might also reduce the risk for post-COVID-19 conditions. Currently all three of the effective antiviral therapeutics are widely available for eligible people, but are not being widely used, particularly in populations disproportionately affected by COVID-19.

For more details, see the full CDC Health Alert Network (HAN) sent out in December. FDA will continue to monitor the frequency of circulating variants and should provide future updates as appropriate.

Resources

- CDC COVID Data Tracker: Variant Proportions
- Bebtelovimab Health Care Provider Fact Sheet 11042022 (fda.gov)
- FDA Announces Bebtelovimab is Not Currently Authorized in Any US Region | FDA
- CDC COVID-19 Treatments and Medications
- NIH COVID-19 Treatment Guidelines
- NIH COVID-19 Treatment Guidelines: Therapeutic Management of Nonhospitalized Adults with COVID-19
- Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 — United States, April–September 2022
- CDC HAN: Important Updates on COVID-19 Therapeutics for Treatment and Prevention