COM-2022-016

March 23, 2022

Dear provider of healthcare-related services,

We all have important roles in the front lines of the 2019 coronavirus disease (COVID-19) pandemic that we are facing. As the COVID-19 pandemic continues to evolve, PharmPix is making every possible effort to continue to provide our essential services to assure the use of appropriate medications by the appropriate patients at the right moment, while also caring for the safety of our employees, their families, and the community in general.

As new COVID-19 treatments emerge, the number of U.S. Food and Drug Administration (FDA) approvals for vaccines, drugs, and other non–vaccine biologic therapies continue to increase. It is also important as we get further into the on-going pandemic, that we continue to review the Emergency Use Authorizations (EUAs). In efforts to stay up to date with EUAs and FDA approvals, below you will find a table which summarizes the current EUA treatments, excluding vaccines, used in both outpatient and inpatient treatment settings. Please note, medical devices and products used for sedation in COVID-19 have been excluded.

Drug and Non-Vaccine Biological Products	Date of First Emergency Use Authorization Issuance	Emergency Use Authorization Indication(s)
Bebtelovimab	2/11/2022	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct severe acute respiratory syndrome (SARS-CoV-2) viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.
Molnupiravir	12/23/2021	Treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.
Paxlovid™ (nirmatrelvir and ritonavir tablets, co-packaged)	12/22/2021	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19, including hospitalization or death.
Evusheld™ (tixagevimab co-packaged with cilgavimab)	12/08/2021	Pre-exposure prophylaxis for prevention of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40kg): who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and - Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **OR** - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

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Actemra™ (tomcilizumab)	6/24/2021	Treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Sotrovimab	5/26/2021	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
Bamlanivimab and Etesevimab	2/09/2021	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients, including neonates, with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. **Additional Information:** On January 24, 2022, the FDA amended the EUA to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as Omicron that is not susceptible to the treatment (currently not authorized in any U.S. region).
REGEN-COV™ (casirivimab and imdevimab)	11/21/2020	Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death. For post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are: not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination **AND** have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per 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. **Additional Information:** On January 24, 2022, the FDA amended the EUA to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as Omicron that is not susceptible to the treatment (currently not authorized in any U.S. region).
Olumiant™ (baricitinib)	11/19/2020	Treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
COVID-19 convalescent plasma	8/23/2020	Treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting.
Veklury™ (remdesivir)	5/01/2020	Treatment of COVID-19 in pediatric patients weighing 3.5kg to less than 40kg or pediatric patients less than 12 years of age weighing at least 3.5kg, with positive results of direct SARS-CoV-2 viral testing, who are: - Hospitalized, or - Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. **Additional Information:** Veklury™ received FDA approval on October 22, 2020, for use in adult and pediatric patients 12 years of age and older

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		and weighing at least 40 kg for the treatment of COVID-19 requiring hospitalization. On January 21, 2022, the patient population was expanded to included non-hospitalized patients.

For detailed information regarding EUA product updates for COVID-19, visit the following:

- Emergency Use Authorization – Coronavirus Disease 2019 (COVID-19) EUA Information

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 220.

Kind regards,

Clinical Department

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