Tixagevimab–Cilgavimab: COVID-19 Pre-Exposure Prophylaxis

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Tixagevimab–cilgavimab is the only nonvaccine drug currently authorized in the United States for the prevention of COVID-19 infection in individuals who are moderately to severely immunocompromised or unable to receive COVID-19 vaccination. Tixagevimab–cilgavimab is composed of two monoclonal antibodies, tixagevimab and cilgavimab, which bind to the spike protein of the SARS-CoV-2 virus. This blocks the ability of the virus to infect cells.

Tixagevimab–cilgavimab is administered as two intramuscular injections consisting of tixagevimab 300 mg (3 ml) and cilgavimab 300 mg (3 ml). After patient injections, the nurse monitors the patient for one hour in the clinic. Tixagevimab–cilgavimab has been well tolerated, with mild headache, fatigue, and cough being the most commonly reported side effects.

AT A GLANCE

- Immunocompromised individuals may have inadequate antibody response to COVID-19 vaccination.
- Tixagevimab–cilgavimab is authorized for prevention of COVID-19 in immunocompromised individuals or in those who cannot receive a COVID-19 vaccine.
- Tixagevimab–cilgavimab is administered as two 3 ml intramuscular injections.

KEYWORDS
COVID-19; tixagevimab–cilgavimab; immunocompromised; monoclonal antibodies

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In March 2020, the World Health Organization declared COVID-19, caused by the the SARS-CoV-2 virus, a global pandemic. By March 2022, the virus had spread to 223 countries, with more than 472 million cases and more than six million reported deaths (Cascella et al., 2022). From the outset of the pandemic, researchers worldwide have focused on the prevention and treatment of COVID-19 infection. Considerable progress has been made in understanding the illness and its management. This has resulted in the development of several vaccines and therapeutic agents for the prevention and treatment of COVID-19. In addition, research continues into pre-exposure prophylaxis for individuals who are immunocompromised.

Approximately seven million adults in the United States are immunocompromised, comprising 2.7% of the total population (Harpaz et al., 2016). Figure 1 lists medical conditions and treatments that are associated with a moderately to severely immunocompromised state. Individuals who are immunocompromised are more likely to have an inadequate antibody response to COVID-19 vaccination (Kmietowicz, 2021). These individuals could benefit from pre-exposure prophylaxis against the COVID-19 virus because they are more likely to become severely ill and require hospitalization, have prolonged infection and viral shedding, and transmit COVID-19 to close contacts (Avanzato et al., 2020; Helleberg et al., 2020; Nakajima et al., 2021). This article provides an overview of tixagevimab–cilgavimab, the only nonvaccine drug currently authorized in the United States for the prevention of COVID-19 infection (Jackson, 2022).

Tixagevimab–Cilgavimab

Mechanism of Action

Tixagevimab and cilgavimab are recombinant human immunoglobulin G monoclonal antibodies that simultaneously bind to nonoverlapping regions of the receptor-binding domain of the SARS-CoV-2 virus spike protein. The spike protein mediates the interaction of the SARS-CoV-2 virus with the human ACE2 receptor, which is required for the virus to attach and become active (U.S. Food and Drug Administration [FDA], 2022a). The combination of tixagevimab and cilgavimab binding to the SARS-CoV-2 spike protein prevents the virus from entering and infecting cells in the human body (Jackson, 2022).

Clinical Experience

In December 2021, the FDA issued emergency use authorization (EUA) for tixagevimab–cilgavimab based on data analysis from two pivotal phase 3 trials,