

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

Volume 64

Published online July 11, 2022

Advance  
Release  
Article

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### COVID-19 UPDATES

#### Dosing Interval for Tixagevimab/ Cilgavimab (*Evusheld*)

The FDA has amended its Emergency Use Authorization (EUA) for the investigational long-acting monoclonal antibodies tixagevimab and cilgavimab (*Evusheld* – AstraZeneca) to recommend repeat dosing every 6 months in patients who require ongoing protection against COVID-19.<sup>1</sup> *Evusheld* is authorized for IM pre-exposure prophylaxis of COVID-19 in persons  $\geq 12$  years old who weigh  $\geq 40$  kg and have either a history of a severe adverse reaction that prevents their vaccination against COVID-19 or moderate or severe immune compromise.<sup>2</sup>

The revision was based on pharmacologic modeling data, which suggest that tixagevimab and cilgavimab retain activity against currently circulating variants of SARS-CoV-2 (including the Omicron variants BA.2, BA.2.12.1, BA.4, and BA.5) for 6 months after administration of a 300-mg dose of each antibody.<sup>2</sup>

The recommended dosage of *Evusheld* is 300 mg of tixagevimab and 300 mg of cilgavimab given as two consecutive IM injections once every 6 months. Patients should be monitored for at least 1 hour after administration. *Evusheld* should not be used for treatment or post-exposure prophylaxis of COVID-19, or within 2 weeks after administration of a COVID-19 vaccine.<sup>2</sup> ■

1. FDA. FDA authorizes revisions to *Evusheld* dosing. June 29, 2022. Available at: <https://bit.ly/3K5AcNc>. Accessed July 11, 2022.
2. FDA. Fact sheet for health care providers: Emergency Use Authorization for *Evusheld* (tixagevimab co-packaged with cilgavimab). June 2022. Available at: <https://bit.ly/3IWpQjg>. Accessed July 11, 2022.

#### Prescription of *Paxlovid* by Pharmacists

The FDA has amended its Emergency Use Authorization (EUA) for *Paxlovid* (Pfizer), the investigational oral antiviral drug nirmatrelvir copackaged with oral ritonavir, to allow for it to be prescribed by licensed pharmacists in certain situations.<sup>1</sup> *Paxlovid* is authorized for oral treatment of mild to moderate COVID-19 in high-risk outpatients  $\geq 12$  years old who weigh at least 40 kg.<sup>2,3</sup> NIH guidelines list it as the treatment of choice for COVID-19 in high-risk adult outpatients.<sup>4</sup>

The amendment to the EUA allows pharmacists to provide *Paxlovid* to eligible patients for whom they can review measurements of renal and hepatic function (obtained within the last 12 months) and a list of prescription and nonprescription medications currently being taken.

*Paxlovid* is not recommended for use in patients with severe renal impairment (eGFR  $< 30$  mL/min) or severe hepatic impairment (Child-Pugh C); dosage adjustments are recommended in patients with moderate renal impairment (eGFR  $\geq 30$  to  $< 60$  mL/min).<sup>3</sup> The drug is contraindicated for use with strong CYP3A4 inducers,<sup>5</sup> or with drugs that are highly dependent on CYP3A for clearance and are associated with serious or life-threatening events at elevated serum concentrations (e.g., amiodarone, midazolam). According to the revised EUA, if other medications in the patient's regimen must be modified because of a potential interaction, the patient should be referred to their healthcare provider. ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes pharmacists to prescribe *Paxlovid* with certain limitations. July 6, 2022. Available at: <https://bit.ly/3RelGau>. Accessed July 11, 2022.

2. FDA. Fact sheet for health care providers: Emergency Use Authorization for Paxlovid. July 6, 2022. Available at: <https://bit.ly/3sTNGqh>. Accessed July 11, 2022.
3. Paxlovid for treatment of COVID-19. *Med Lett Drugs Ther* 2022; 64:9.
4. NIH. COVID-19 treatment guidelines. Therapeutic management of nonhospitalized adults with COVID-19. April 8, 2022. Available at: <https://bit.ly/3w5TdLB>. Accessed July 11, 2022.
5. Inhibitors and inducers of CYP enzymes, P-glycoprotein, and other transporters. *Med Lett Drugs Ther* 2021 October 20 (epub). Available at: [medicalletter.org/downloads/CYP\\_PGP\\_Tables.pdf](https://medicalletter.org/downloads/CYP_PGP_Tables.pdf).

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