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FDA Approves COVID-19 Antiviral Xocova as PEP. But Will It Be Accessible?

The post-exposure prophylaxis drug will be available in mid-July and will have a list price of $1,400.

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Key points you should know:

- Xocova was approved by the Food and Drug Administration (FDA) on May 29, following significant results from a robust clinical trial.
- The five day course of the drug, which helps prevent the SARS-CoV-2 virus from replicating, is approved as post-exposure prophylaxis, or PEP, meaning that you take it within 72 hours after exposure to COVID-19.
- Shionogi told The Sick Times that Xocova will be available in the U.S. in mid-July and will have a list price of $1,400.
- The drug is currently being studied for long COVID treatment and prevention. Those trials have not been completed yet.
- Experts say the drug is a significant addition to the toolkit of COVID-19 prevention strategies, but only if it’s accessible and paired with other prevention measures.

Last month, the Food and Drug Administration (FDA) approved the antiviral ensitrelvir to prevent COVID-19. The drug will be sold under the brand name Xocova.

Xocova is the first drug to be approved for post-exposure prophylaxis, or PEP, for COVID-19, meaning it is taken after exposure to COVID-19 to prevent the disease. It’s a “a great addition to our toolbox” for COVID-19 prevention, said epidemiologist Ziyad Al-Aly, director of the Clinical Epidemiology Center at the VA St. Louis Health Care System.

Since Xocova can reduce the risk of COVID-19, experts told The Sick Times it will be a useful medication for helping people with long COVID and related diseases reduce the risk of reinfections, which can exacerbate the chronic disease and trigger new ones.

The FDA approval was based on the significant results of the SCORPIO-PEP trial, which was published in the New England Journal of Medicine last month. The Phase III randomized controlled trial included over 2,000 participants, all of whom had potential COVID-19 exposures from other members of their households who had tested positive. In the study, the drug reduced the risk of symptomatic COVID-19 by 67% when treatment was started within 72 hours of an exposure.

As a secondary endpoint, the study also found a 34% reduction of transmission of COVID-19 as measured by PCR testing.

University of California, San Francisco (UCSF) infectious disease researcher Michael Peluso cautioned against overstating the trial's results in written comments to The Sick Times. He said SCORPIO-PEP "showed that ensitrelvir reduced the risk of symptomatic COVID-19 after household exposure, but it did not eliminate that risk." He added that the study was also not designed to determine whether the drug prevents long COVID. Preventing an infection or reducing its severity could plausibly reduce the risk of subsequent long COVID, he said, but that specific benefit still needs to be studied.

Xocova will be most impactful in the real world if people are able to quickly recognize a SARS-CoV-2 infection and easily access the drug, Peluso and Al-Aly both noted. The drug "needs to be taken within a very, very short window," Al-Aly said.

Shionogi told The Sick Times that the drug will be available in the U.S. in mid-July and that it will have a list price of $1,400. The drug is sold for around $310 in Japan, where it has been fully approved since 2024 to treat acute COVID-19, and as PEP for COVID-19 since March. The drug is not approved to treat COVID-19 in the U.S.

Xocova is also currently being studied for long COVID. One clinical trial is assessing whether taking it during an acute COVID-19 case can prevent the chronic disease, while another trial is studying the drug to see if it can help treat long COVID. Results for those trials are not yet available.

"A post-exposure prophylaxis option like ensitrelvir is a new, important option to have available as we continue in the sixth year of the COVID-19 pandemic, especially to people with long COVID," Alison Cohen, assistant professor of epidemiology and biostatistics at UCSF told the The Sick Times.

"Infection control measures, including air-cleaning interventions, masking, and having people self-isolate while contagious continue to also be important."

What is PEP and what is Xocova?

Xocova is a SARS-CoV-2 main protease inhibitor, meaning it stops the virus from replicating and

making more copies of itself by blocking an enzyme called the main protease, or Mpro. Blocking this replication can reduce the risk of developing COVID-19.

“Post-exposure prophylaxis means that this can be taken after a SARS-CoV-2 exposure and reduce the risk of that exposure leading to an infection,” Cohen said. The drug must be taken within 72 hours of exposure to COVID-19.

The antiviral Paxlovid, on the other hand, is approved to treat and reduce the serious risks of COVID-19 after a person develops and tests positive for COVID-19. And while the diabetes drug Metformin has been shown to reduce the risk of long COVID when taken after infection, it is not currently FDA-approved for COVID-19 or long COVID.

Pemgarda, a monoclonal antibody, is not FDA-approved, but is available through an emergency use authorization for pre-exposure prophylaxis, or PrEP, meaning that the infusion helps protect you from getting COVID-19 in the first place.

Other diseases, like HIV, hepatitis B, rabies, and mpox, have PEP treatments. Like Xocova, these treatments are prescribed in a short window following exposure to the viruses that cause these diseases.

The drug is a five-day oral treatment consisting of seven 125 milligram tablets. Three tablets are taken on the first day, then once per day through day five. The drug is approved for people 12 and older and should not be used by pregnant or breastfeeding people, Shionogi told The Sick Times.

The company also stated that people should check for potential interactions with drugs they are currently taking.

Accessibility is crucial for the drug’s real-world effectiveness

Like other COVID-19 antivirals, the drug is expensive in the U.S. It will hit the market at a list price of $1,400, according to Shionogi.

Some commercial insurance plans may fully cover that cost, while others may have copays. While the pharmaceutical company stated they will have an assistance program to help with those out-of-pocket copays, only people with commercial insurance that covers Xocova will qualify.

Shionogi said there is currently no assistance for people without insurance or people on non-commercial insurance, meaning it could cost a full $1,400 out of pocket. Federal and state insurance programs, including Medicare, Medicaid, VA, and Indian Health Service plans will not qualify for the copay program.

In a follow-up statement, Shionogi told The Sick Times that the company plans to “offer an assistance program beginning in mid-August for those who need financial assistance and meet program eligibility requirements, including an annual household income at/below 300% of the Federal Poverty Level, as well as other criteria which are still being determined.”

In the past, other COVID-19 treatments and vaccines have been less accessible to people most at risk of COVID-19 and long COVID, including people of color, who are disproportionately impacted by both COVID-19 and long COVID. A 2022 analysis by KFF Health News also found that Black, Hispanic, and Indigenous communities in the U.S. also had more limited access to COVID-19 antivirals than other communities.

“To truly reduce the burden of acute COVID and prevent long COVID, we must ensure that these interventions are affordable,” said Gabriel San Emeterio, co-founder of the advocacy organization Long COVID Justice.* San Emeterio stated that access to the drug must be widely publicized and integrated into multilayer prevention campaigns.

While the drug is an important new tool in reducing the risk of COVID-19, streamlining rapid access to it is essential to having an impact in communities most affected by the disease, San Emeterio added.

“Over the past decade, HIV post-exposure prophylaxis (PEP) has been a highly effective tool for preventing HIV acquisition when started within 72 hours of a potential exposure, but its success has depended as much on rapid access as on the medication itself,” they said. San Emeterio explained that there are programs for PEP for HIV that handle access urgently, including same-day prescription across multiple kinds of health centers, from hospitals to sexual health clinics.

“These streamlined access pathways are maximized when combined with broad public awareness, provider education, and affordability,” San Emeterio said. “People shouldn’t have to fight when they are sick with COVID for the chance to prevent severe illness and long COVID.”

Shionogi told The Sick Times that the company is working with pharmacies across the country to make Xocova broadly available this July, while “also engaging with primary care professionals, hospitals, urgent care centers, long-term care facilities, and telehealth providers to ensure frontline clinicians have the education and resources needed to determine appropriate use.”

Alongside healthcare centers and providers, Shionogi stated that they plan to expand awareness about Xocova through education, partnerships, and campaigns to “help reinforce the role of prevention and ensure appropriate patients understand their options following exposure.”

The company also said that they will continue to update the drug’s website, Xocova.com, with prescriber information and affordability resources. “We are in the process of evaluating a suitable program with the goal of helping support [people without insurance] and will share more details when available.”

Two studies are assessing Xocova for Long COVID prevention and treatment

Two current trials are further investigating Xocova for the prevention and treatment of long COVID.

The first, led by Shionogi, is the RESILIENCE clinical trial, which aims to assess if taking the drug

after a person tests positive for COVID-19 reduces the risk of long COVID. Some observational studies — not clinical trials — have looked at this for the antiviral Paxlovid. Recent studies have shown little protection.

RESILIENCE, a double-blind, randomized trial, aims to enroll 2,000 people with "mild COVID-19" and treat them with the standard five-day course of Xocova, or a placebo, within 72 hours of the onset of symptoms.

Researchers included a primary efficacy endpoint of specific symptoms, including fatigue and shortness of breath at one and three months post treatment and neurocognitive symptoms at three months post treatment. "We hypothesize that early treatment initiation may reduce the incidence of persistent symptoms and improve patient-reported outcomes," the study authors wrote in PLoS One. The study builds on Shionogi's prior research into Xocova as a COVID-19 treatment, including studies called ANCHOR-01 and ANCHOR-02.

Shionogi did not provide any updates on the RESILIENCE study or a publication timeline.

A second study at UCSF is evaluating if Xocova may be an effective and safe treatment for long COVID. The randomized, double-blind Phase III trial is called PREVAIL-LC; it enrolled 40 people with Long COVID who took the standard five-day course of the drug.

Peluso, the UCSF researcher who is coleading the trial, said that the study included exploratory clinical and laboratory outcomes intended to look for a signal that would justify larger or longer studies. "We have a major focus on understanding biomarkers and whether any of these are moveable, even with a relatively short course of an antiviral," he said. "The unique aspect of the study is really how deep a dive we will do biologically."

That biological research includes looking for changes in "research-based laboratory measures potentially related to persistent SARS-CoV-2 or post-COVID inflammation," he said, explaining that biospecimens including blood, lumbar punctures, and gut biopsies were collected in about half of the participants.

These findings, which may be published in the clinical trial study or separate analyses later on, may help guide researchers on the future directions of long COVID trials. One major task for researchers is defining subgroups of people within long COVID, including those who may be more likely to improve with antiviral treatment because their symptoms are driven by viral persistence.

Data collection for the study has been completed. Peluso and his colleagues are currently analyzing the results, and will release findings as soon as that process is complete, he told The Sick Times.

While the FDA approval as PEP for COVID-19 may make Xocova easier for other researchers to investigate for long COVID, there are still many barriers, Peluso said.

"Trials using longer courses, different doses, or treatment combinations for long COVID would still

be investigational and would require appropriate regulatory review, safety monitoring, funding, and coordination/collaboration with the manufacturer," he said. "But the FDA approval is a big step, so I am hoping that we see this drug become available for more clinical trials in long COVID."

Miles W. Griffis is a co-founder and the executive editor of The Sick Times.

*Editor's note: The Sick Times collaborated with Long COVID Justice to develop the Long COVID Essentials resource sheets. Our newsroom operates independently of financial supporters.

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