Frustrations, Denials, Long Drives: Immunocompromised People Can't Access a Lifesaving COVID-19 Drug

People with cancer, those with advanced HIV and organ transplant recipients may be eligible for Pemgarda pre-exposure prophylaxis to prevent or reduce the severity of COVID.

August 9, 2024 By Erin Durkin and The Sick Times

Key points you should know:

- Pemgarda received emergency authorization from the FDA in March as a preventive medication, or pre-exposure prophylaxis, for COVID-19.
- It's intended for moderately to severely immunocompromised people, who may not mount a strong response toCOVID-19 vaccines.
- Many patients who are interested in Pemgarda have been unable to get it because of lack of awareness among doctors, a limited number of infusion centers administering it, eligibility criteria, and insurance denials.
- The drug's manufacturer says it is working to increase awareness of Pemgarda and support broader access.

***

A new drug approved months ago to help prevent COVID-19 infections could be a game changer for high-risk people — if they can get their hands on it. But many say they have struggled to access the medication.

Pemgarda received emergency authorization from the Food and Drug Administration (FDA) in March as a preventive medication, or pre-exposure prophylaxis (PreP), for moderately and severely immunocompromised Americans.

The drug is a monoclonal antibody given through an infusion, which takes about an hour. Its manufacturer, Invivyd, estimates Pemgarda reduces the risk of a symptomatic COVID-19 infection

by 70%. Doctors must monitor patients after the infusion because of a risk of anaphylaxis, which happened with 0.6% of participants in a clinical trial.

Pemgarda costs $5,775 per dose and is given every three months. The manufacturer has also applied for permission from the FDA to use it as a treatment for acute COVID-19.

More than a dozen people told The Sick Times they have been unable to get Pemgarda — blocked by lack of awareness among doctors, an absence of infusion centers giving the drug near their home, strict eligibility criteria, or insurance denials. A few said they were able to receive it but had to jump through a series of hoops to do so.

“It’s pathetic. I am the exact profile of the person who should be receiving this medication,” said Amy Mitchell, 43, who has common variable immune deficiency and has had COVID-19 seven times. “If I can’t get it, who can?”

Mitchell, who lives in southwest Ohio and has had long COVID since March 2020, scrambled to get Pemgarda as soon as it was released. “I was just counting down the days,” she said. Her symptoms improved with Evusheld, a different monoclonal antibody drug pulled off the market in 2023, so she was eager to try the new treatment.

She had no luck with the first few doctors she asked. But after months of inquiries, one infectious disease doctor was willing to prescribe it.

She was scheduled for an infusion in June — only to have it canceled at the last minute when her insurance company refused to cover it. The company, CareSource, denied multiple requests for prior authorization, saying the drug was considered experimental.

Hurdles to treatment

“There’s been a lot of logistical hurdles about how to get this infusion to patients,” said Dr. Scott Roberts, a Yale Medicine infectious disease specialist. Many hospital systems did not stock Pemgarda right away, he said, and facilities offering it are still few and far between. It hasn’t been clear which medical specialty is supposed to prescribe it.

Some patients said they’ve asked their doctors about Pemgarda and the doctors either had never heard of it, said it wasn’t their area of expertise, or had no idea how to order it.

Anna Caro, 48, of Connecticut, spoke to an infectious disease doctor and two immunologists about getting Pemgarda, but each said they weren’t the right person to prescribe it. Caro has undergone treatment for a brain tumor. She is unable to receive more COVID-19 vaccines, after a bad reaction to the first vaccine.

“What the hell am I supposed to do?” she said. “I want to be able to continue to work and do my job and not be forced to hide from public life, and it’s getting hard to do that.”

Caro previously received Evusheld, and when she got COVID-19 for the first time on that

medication her infection was mild. By contrast, when reinfected last fall without Evusheld, she was sick for eight months. “With Pemgarda I would be able to live a more normal life, and not have to worry every time I leave my house,” she said.

Deborah Wilhelm, 72, who was diagnosed with chronic lymphocytic leukemia, asked her oncologist and her primary care doctor about getting Pemgara but neither had heard of it. Both downplayed her concerns about COVID-19. “It’s ridiculous,” she said.

More education about this drug is needed for doctors who care for immunocompromised patients, said Dr. Amesh Adalja, senior scholar at the Johns Hopkins Center for Health Security. “Many of them don’t even know that Pemgarda exists,” he said. In the meantime, patients who have had trouble getting the drug might want to consult an infectious disease specialist.

Invivyd claims it is getting the word out to more doctors about Pemgarda. “Sometimes the patients are actually a little bit ahead of the [healthcare providers] in this regard,” Mark Wingertzahn, a senior vice president, said on a conference call with investors in May. “We really do want to inform the HCPs.”

Invivyd has created an online locator tool listing infusion centers with Pemgarda, which several patients said was crucial in allowing them to track down the drug. But the number of centers is limited, and people may live hours from the nearest location.

Ellen Lee Schwartz, 58, who has cerebral palsy and a history of cancer, said there are no infusion centers in the Charlotte, North Carolina area where she lives. The closest is over two hours away, and she can’t drive because of her medical condition. Her doctors have also been unwilling to prescribe Pemgarda because it is not administered by their own medical system.

“If it’s supposed to be for vulnerable people who really need it, then Invivyd really should have made it so that is was distributed more widely,” she said. “They’re playing against themselves if they have a product that really works that nobody can access.”

For Sara Anne Willette, 45, who has common variable immune deficiency, getting Pemgarda would require a six-hour drive from her New Jersey home, which would likely cause a flareup of her condition. “It’s not even in my state, which is infuriating,” she said. “I shouldn’t have to put my health at more risk of destabilizing to get a PreP drug.”

Invivyd declined to say how many doses of the drug have been ordered. The locator tool does not include all facilities giving Pemgarda, since institutions have to opt in to be listed, according to spokesperson Olipriya Das. “Invivyd has deployed field teams to raise awareness about Pemgarda and is actively working to educate about Pemgarda and answer questions institutions may have,” Das said.

There are more than 9 million immunocompromised people in the United States, but Invivyd is initially targeting the 485,000 most severely immunocompromised, who include cancer patients and organ transplant recipients, executives said on a conference call.

Other groups who qualify under the Emergency Use Authorization include those with primary immunodeficiency, advanced HIV, and people taking immunosuppressive drugs. People who are immunocompromised for other reasons may also qualify, but different doctors may interpret the eligibility criteria differently.

“It’s very gray,” Roberts said, noting conditions like age and diabetes are to some degree immunocompromising. ”There’s going to be confusion” from both patients and clinicians about who qualifies, he said.

Seeking protection from reinfections

Many people with long COVID — some of whom have suffered damage to their immune systems from the virus — are interested in getting Pemgarda to protect against reinfections. Some also believe it could help their symptoms, based on case studies showing improvements from other monoclonal antibodies. Researchers at the University of San Francisco are also currently testing the monoclonal antibody AER002 in a clinical trial for long COVID.

Christy Collins, 39, who has long COVID and lives in the Boston area, was told by her infectious disease doctor that she does not qualify for Pemgarda. “We obviously now have some kind of immune deficiency. Maybe we didn’t before, but it’s obvious we do now,” she said. “We should have a path to get prophylaxis.”

When Olenka Sayko, 35, asked her long COVID doctor about Pemgarda, he said none of his patients had been able to access it. He recommended she try a large academic medical center. So she contacted two doctors at Mount Sinai, near where she lives in New York, but has not heard back.

“It’s just really frustrating because once again the onus seems to be on profoundly sick people having to exert a lot of their limited energy to try to help themselves,” she said.

Some major insurers, including Medicare and Medicaid, already cover Pemgarda. But others have rejected requests to pay for the drug, patients told The Sick Times.

Deb Mashni, 64, is on immunosuppressants for a rare autoimmune disease, and received Pemgarda as part of the clinical trial. During that time, her daughter visited her for Christmas and tested positive for COVID-19 the next day, but Mashni did not get sick. Her rheumatologist was happy to prescribe Pemgarda after it was authorized, but her insurance company does not cover it.

“It’s just exhausting to keep hearing no,” Mashni said. “I avoid seeing people. I stay home with my dog or my husband most of the time, because it’s not worth it to get sick,” she said.

Some immunocompromised people have had more success in getting Pemgarda, though not without significant effort. Ruth Fischer, 57, an organ transplant patient in the Philadelphia area, was excited when Pemgarda was approved, believing it could be a “game changer” for her.

She called all her medical providers, but none of them offered Pemgarda. She called other medical institutions from Baltimore to New York and got the same response.

Then she used Invivyd's locator tool and found an infusion center in State College, a 3.5 hour drive from her home, and received a prescription from her transplant team. But her insurance declined to cover it because the facility was out of network. Her first appeal was denied, but her second appeal was granted, and she finally got the infusion in July.

"It was worth it to me," she said. She stopped working due to the pandemic, walked away from volunteer and creative communities, and doesn't see friends, go to cultural events, or fly. "Since COVID-19 began I have been living a very limited life," she said. "It means I could maybe start stepping out of my bubble a little bit."

But she knows many patients won't be able to navigate the system the way she has as a former healthcare administrator. "It actually makes me very angry," she said.

Erin Durkin is a journalist in New York City. She has worked for Politico, the New York Daily News, and The Guardian.

This article was published by The Sick Times, a website chronicling the long COVID crisis, on July 30, 2024. It is republished with permission.
