THE WALL STREET JOURNAL

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HEALTH

Location Plays Big Role in Patient Access to First Covid-19 Drug

States, counties and hospitals use different ways to decide how to distribute remdesivir, a treatment for severely ill coronavirus patients



A lab technician inspects a vial of remdesivir at a Gilead Sciences facility in La Verne, Calif. PHOTO: GILEAD SCIENCES/REUTERS

By Melanie Evans and Joseph Walker

Updated May 22, 2020 10:25 am ET

Limited stock of the first drug shown to treat Covid-19 is arriving at hospitals, and location is a driving factor in whether a patient gets any as states, counties and hospitals use different approaches to allocate their shares.

Gilead Sciences Inc. GILD -0.86% ▼ is ramping up production of the drug, remdesivir, which moderately sped recovery for hospitalized patients in a federal study—though it isn't known whether the drug can prevent death from the disease, which is caused by the new coronavirus. The company is donating early supplies to the federal government in the U.S., which is allocating it to states.

Food and Drug Administration criteria for <u>remdesivir use</u> under its May 1 <u>emergency</u> <u>authorization</u> are broad, doctors say, and little published research points to who might benefit most. States and counties, which are allocating the drug to hospitals, are devising <u>widely</u> <u>different methods</u> of awarding the scarce supply. Hospitals, too, use different methods to decide who to treat. That means a patient who qualifies in one locale might be shut out in another.

"We're in a situation of scarcity and we have to find a fair way to allocate this scarce resource," said Doug White, a doctor and ethicist at the University of Pittsburgh.



Dr. Doug White says, 'We're in a situation of scarcity and we have to find a fair way to allocate this scarce resource.'

PHOTO: UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

Hospitals affiliated with the University of Pittsburgh decide who gets the drug by lottery—though not a totally random one. It is designed to slightly boost chances of patients from economically distressed neighborhoods. "Random lotteries will simply propagate disparities," said Dr. White, who helped develop the system.

It will also increase chances for essential workers, such as bus drivers, agricultural workers and grocery-store clerks, he said.

West Virginia hospitals will use the drug for patients first come, first served. UW Medicine in Seattle is requiring anonymous patient applications, to avoid possible bias.

Decisions about how best to use remdesivir are the latest example of the health-care system's <u>need to ration</u> critical goods and services amid the pandemic. To deal with scarcity, health-care providers typically rely on plans for how to ethically deploy resources, where the highest priority isn't the welfare of any one patient but rather the community, said Robert Truog, director of the Harvard Medical School Center for Bioethics. But maximizing benefits can conflict with their fair use, he said.

UPMC, the hospital system and health insurer affiliated with the University of Pittsburgh, doesn't have enough remdesivir for all patients who qualify for treatment. "Not by a long shot," Dr. White said.

States took over allocations to specific hospitals after the Department of Health and Human Services faced criticism for its initial distribution. HHS will have shipped 80% of Gilead's initial donation of about 607,000 doses to states by the end of the week, the agency said.

An HHS spokeswoman said this week that the government expects to receive more than 330,000 additional doses from Gilead, but the company declined to confirm any <u>increased donation</u>. "We are reviewing the incidence of disease and discussing with the U.S. government the amount of remdesivir potentially needed through the end of June," Gilead spokesman Chris Ridley said.

In a National Institute of Allergy and Infectious Diseases study, patients with Covid-19 who were given remdesivir recovered four days faster than those given a placebo. It is the first drug to show success in a late-stage clinical trial against the virus, which has infected more than 1.58 million and killed more than 94,700 in the U.S., data collected by Johns Hopkins University shows.



Shireesha Dhanireddy, an infectious-disease doctor, says of the Covid-19 drug: 'It's not an unlimited resource.'

PHOTO: UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

That study and another led the FDA to clear the drug for emergency use for hospitalized patients with low blood-oxygen or those who either need ventilators to breathe or supplemental oxygen through a respirator mask or nasal tubes.

That covers virtually all patients admitted to hospitals for Covid-19, say doctors. Because there isn't enough remdesivir to treat them all, doctors have called for the National Institutes of Health, which includes the NIAID, to release detailed study data, which they say will help to prioritize who should get the drug.

Doctors expect that analyzing granular study data will reveal patterns showing which variables —such as symptoms or length of illness—predict who will be helped by the drug.

"When you're allocating scarce resources without good information, it's really dicey," said Rochelle Walensky, chief of infectious diseases at Massachusetts General Hospital. "We haven't seen any data; it's been paralyzing."

West Virginia has received approximately 1,160 vials of remdesivir. It will divide stock equally across four regions of the state, said Dr. William Ramsey of the West Virginia University Health Sciences Center, who is chief logistics officer for the state's pandemic response.

Hospitals in each region will draw from local supply. Patients qualify for the drug if they meet FDA emergency-use criteria on a first-come, first-served basis.

California awarded its share by county, based on numbers of hospitalized Covid-19 patients.

In San Diego County, patients were eligible if they had symptoms for no more than 10 days or had been on a ventilator for no more than five, said Ghazala Sharieff, chief medical officer for Scripps Health. That excluded 18 at Scripps's hospitals who otherwise would be eligible, Dr. Sharieff said. Doctors identified 14 who met the county's criteria, while Scripps received doses for five patients, she said.

The county has changed its formula and will now award doses based on numbers of each hospitals' Covid-19 patients during the prior two weeks, Dr. Sharieff said.

A San Diego County spokeswoman said the county switched to proportional distribution from criteria based on FDA guidance for a six-dose course of treatment.

Some states have issued guidance that narrowed pools of eligible patients.

Beaumont Health, which has eight hospitals in Detroit and Southeast Michigan, received about 400 vials of remdesivir. It wasn't enough for the roughly 130 Covid-19 patients who met FDA criteria, said Paul Chittick, section head of infectious disease at Beaumont Hospital, Royal Oak.

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Michigan then issued new guidance calling for hospitals to use doses for patients with more severe oxygen needs, such as those with nose tubes or ventilators, Dr. Chittick said. Southfield, Mich.-based Beaumont has enough drugs for patients who qualify under the more restrictive criteria, he said.

Michigan's Department of Health and Human Services urged hospitals to treat severely ill patients and comply with ethical considerations to treat those who need it most, an agency spokesman said.

At UW Medicine, doctors fill out an anonymous application for the drug that includes only medical information needed for criteria set by the FDA and Washington state to avoid bias, said Shireesha Dhanireddy, an infectious-disease doctor on the committee that approves requests.

UW Medicine so far has enough doses, she said, but that may change with future allotments from the state. "It's not an unlimited resource," she said.

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