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FDA Nears Decision Authorizing Covid-19 Treatment With Convalescent Plasma

Antibody-rich blood plasma would be one of the first coronavirus treatments to receive approval, which could pave way for wider use

Plasma was donated in April at a Seattle facility. A decision from the FDA could come as soon as next week.

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By Amy Dockser Marcus and Thomas M. Burton

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The Food and Drug Administration is nearing a decision to authorize emergency use of antibody-rich blood plasma from recovered Covid-19 patients for treating those infected

with the coronavirus, people familiar with the matter said.

The authorization could come as soon as next week, according to the people, though the agency could also decide to delay a decision.

The designation could open the way for faster and wider access to one of the most promising treatments for Covid-19 patients. Only a Gilead Sciences Inc. GILD -0.98% ▼ antiviral drug known as remdesivir carries the designation.

The FDA can authorize a drug's use in an emergency such as a pandemic after finding the treatment is safe and there is evidence of probable benefit. The designation might also prompt federal health officials to approve payment for the treatment under Medicare and Medicaid.

The FDA didn't immediately respond to a request for comment.

There is a long history of using convalescent plasma to treat people during past outbreaks, including Ebola and influenza.

Because of a lack of proven drugs, some doctors and hospitals have been treating hospitalized Covid-19 patients with convalescent plasma under compassionate use and as part of studies.

More than 48,000 Covid-19 patients have received convalescent plasma through an expanded-access program sponsored by the FDA and led by the Mayo Clinic in Rochester, Minn., which is also studying whether the treatment works safely.

Michael Joyner of the Mayo Clinic, the principal investigator of the expanded-access study, said in an interview earlier this month that hospitals in virus hot spots giving

convalescent plasma are struggling to treat patients while filing case reports and keeping up with data reporting.

An FDA emergency-use authorization could cut red tape for the hospitals and allow faster access to the therapy.

Preliminary studies have found convalescent plasma is generally safe to use and appears to improve the survival of hospitalized patients.

Researchers are also exploring whether earlier use of convalescent plasma could reduce the severity of illness and cut the number of hospitalizations.

This week researchers at the University of Pittsburgh, Michigan Medicine, Medical University of South Carolina and Stanford Medicine said they received federal funding for a 600-subject study that will in part look at such earlier use in patients starting to show symptoms.

As part of the trial, Covid-19 patients who showed up at a hospital with milder cases will be sent home after receiving either convalescent plasma or saline, then monitored to see whether the plasma prevented people from getting sicker or needing to return to the hospital.

If the plasma's outpatient use proves effective, "We may rely on this while we wait for a vaccine," said Clifton Callaway, executive vice chair of emergency medicine at the University of Pittsburgh and one of the principal investigators on the trial.

William Hartman, a doctor at the University of Wisconsin, Madison, who is treating hospitalized Covid-19 patients with convalescent plasma, said FDA emergency-use authorization may prompt more hospitals to give the treatment earlier.

"I think the data are pretty clear that using it as early as possible has advantages, and we should explore that possibility," he said.

Dr. Hartman and colleagues studied 31 severely ill Covid-19 patients who were hospitalized and received convalescent plasma as part of the expanded access study. The study's results, which were posted on a public server but haven't yet undergone peer review, indicated that most of the transfused patients with severe disease didn't have to go to the intensive-care unit or receive mechanical ventilation.

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