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Stanford Blood Center Receives FDA Approval to Distribute Licensed COVID-19 Convalescent Plasma Nationwide

PALO ALTO, Calif. — October 15, 2025 — Stanford Blood Center (SBC) has received approval from the U.S. Food and Drug Administration (FDA) for national distribution of COVID-19 Convalescent Plasma (CCP) for the treatment of immunocompromised patients, making SBC the first blood center in California and only the second in the nation to secure this authorization under a Biologics License Application (BLA).

On August 27, 2025, the FDA revoked the Emergency Use Authorization (EUA) for CCP, noting that the emergency conditions that justified its initial use were no longer in effect. However, through the BLA pathway, SBC has now achieved full licensure to manufacture and distribute high-titer CCP nationally, ensuring continued access to this treatment for patients who remain vulnerable to severe COVID-19 illness.

“This FDA approval reaffirms our commitment to providing patients with what they need, when they need it, a core value of our organization,” said Harpreet Sandhu, Stanford Blood Center’s CEO. “By securing licensure, we are able to continue supporting immunocompromised patients across the nation who can benefit from convalescent plasma therapy.”

The new approval grants SBC the ability to collect and manufacture CCP at its locations and distribute the product to hospitals and blood centers in California and beyond, enabling greater collaboration and support nationwide. Treatment using CCP has been shown to be safe and effective, supporting FDA licensure. According to Dr. Suchi Pandey, SBC’s Chief Medical Officer, “Data from multiple studies, including clinical trials, demonstrate a mortality benefit and clinical improvement when high-titer CCP is administered to COVID-19 patients with underlying immunosuppression in either the outpatient or inpatient setting.”

SBC was one of the first U.S. blood centers to begin collecting CCP early in the COVID-19 pandemic and has played a key role in research and patient care efforts to evaluate and optimize its use. With this licensure, the organization will continue to manufacture high-titer CCP as part of its broader mission to advance transfusion medicine and provide lifesaving blood products to patients in need.

Individuals who have recently recovered from COVID-19 and are interested in learning more about donating for the program may email support@stanfordbloodcenter.org.

For more information, visit stanfordbloodcenter.org.

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About Stanford Blood Center

Stanford Blood Center (SBC) is an independent, community blood center that supplies blood products and testing services to multiple hospitals and is a recognized leader in the fields of transfusion and transplantation medicine. SBC was created at the Stanford University School of

Medicine in 1978 to meet the complex transfusion and transplant needs of Stanford Health Care and Stanford Medicine Children's Health, as well as provide clinical trial services and specialized blood products for researchers. Today, the center remains locally focused, serving community hospitals, patients and donors, while contributing to research and advancement that impact the world at large. More information is available at stanfordbloodcenter.org.