

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

Important Updates Regarding Johnson & Johnson's Janssen COVID-19 Vaccine, the Florida COVID-19 Vaccine Weekly Pre-Book Request, and the Emergency Use Authorization Revocation for Bamlanivimab Single-Use

April 26, 2021

FDA and CDC Lift Recommended Pause on Johnson & Johnson's Janssen COVID-19 Vaccine

Following a thorough safety review, including two meetings of the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the U.S. Food and Drug Administration (FDA) and the CDC have determined that the recommended pause regarding the use of the Johnson & Johnson's Janssen COVID-19 Vaccine should be lifted and use of the COVID-19 vaccine should resume.

Health care providers administering the vaccine must review the Johnson & Johnson's Janssen COVID-19 Vaccine [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#). Health care providers must also provide and explain the Johnson & Johnson [Fact Sheet for Recipients and Caregivers](#). Both fact sheets have been revised to include information about the risk of the thrombosis with thrombocytopenia syndrome, which has occurred in a small number of people who have received Johnson & Johnson's Janssen COVID-19 Vaccine.

For more information regarding the latest guidelines, please use the links below:

- [FDA News Release](#)
- [CDC Health Alert for Health Care Providers](#)
- [Johnson & Johnson Granting EUA Amendment \(April 23, 2021\)](#)

Florida COVID-19 Vaccine Weekly Pre-Book Request

COVID-19 enrolled providers may now request Janssen in their weekly COVID-19 pre-book request in Florida SHOTS. Please remember to submit your pre-book requests each week by Noon every Wednesday, EST. Requests will not carry over to the following week. For more information contact the Vaccines for Children (VFC) Program at FloridaVFC@flhealth.gov.

If you have specific questions, you may contact the VFC Program via email at FloridaVFC@flhealth.gov, or via phone at 1-877-888-7468, then press Option 1.

General VFC Program information and forms can be found on our website at <http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/index.html>.

FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab Single-Use

At the request of Eli Lilly and Company, the FDA has revoked the Emergency Use Authorization (EUA) for bamlanivimab, when administered alone, for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients who are at high risk of disease progression or hospitalization. REGEN-COV as well as bamlanivimab and etesevimab (administered together) continue to be available under EUA. For more information on this action, please click [here](#).