



COVID-19 Vaccine Provider Guidance

Summary Sheet Updates

Updated April 30, 2021

Our goal is to vaccinate as many people as quickly, fairly, and easily as possible everywhere in North Carolina with COVID-19 vaccine. This includes expanding into primary care practices and other specialty practices to make vaccines easy to get to North Carolinians in settings they trust.

Everyone who wants a safe and effective COVID-19 vaccination is eligible: North Carolina's COVID-19 vaccine eligibility opened to everyone ages 16 and older on April 7, 2021.

Key Updates:

Johnson & Johnson (Janssen) COVID-19 Vaccine Pause Lifted and Updates on Guidance for Use:

“On April 13, 2021, CDC and FDA recommended a pause in the use of the Johnson & Johnson (Janssen) COVID-19 vaccine after reports of six U.S. cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare thromboembolic syndrome, among Janssen COVID-19 vaccine recipients. Two emergency ACIP meetings were rapidly convened to review reported cases of thrombosis with thrombocytopenia syndrome (TTS) and to consider updated recommendations for use of the Janssen COVID-19 vaccine in the United States. On April 23, 2021, after a discussion of the benefits and risks of resuming vaccination, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥ 18 years under the FDA's EUA, which now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18–49 years. Patient and provider education about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged < 50 years, as well as the availability of alternative COVID-19 vaccines, is required to guide vaccine decision-making and ensure early recognition and clinical management of TTS.”

(Source: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm>)

(Further details are included in Sections 12.2.6 and 12.6)

For Healthcare Providers

- Review the revised [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#), which has been revised to include a warning about the risk TTS.
- Read the official CDC health alert, [Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](#), which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia.
- Report adverse events to the [Vaccine Adverse Event Reporting System](#). (see Section 12.10.1)

For Vaccine Providers

- Vaccine providers may resume use of the Janssen COVID-19 Vaccine.



- Review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\), external icon](#) which has been revised to include a warning about the risk of TTS that has occurred in a small number of people who have received the Janssen COVID-19 Vaccine.
- CDC encourages vaccine providers to promote the use of v-safe among vaccine recipients using CDC's free [print resources](#). See information on CDC's webpage: [CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume](#)

If you have any questions, please submit a ticket to the *CVMS Help Desk Portal* or call the COVID-19 Vaccine Provider Help Center at (877) 873-6247 and select option 1 for COVID-19 questions (Monday – Friday 7:00 AM – 7:00 PM ET and Saturday – Sunday 10:00 AM – 6:00 PM ET).

Request-Based Vaccine Allocation: As we move forward to the next phases of our recovery from COVID-19, we are working to ensure COVID-19 vaccine is everywhere and easy to access for everyone in the state. Now that supply is strong, North Carolina has shifted to a new vaccine allocation process, where ***providers can request the number of first and second doses***, with an opportunity each week to request more doses. To request additional doses, a provider should have administered at least 50% of the allocated vaccine. (See Section 17.1)

There is no longer the 7-day requirement to use up all the first doses. We also realize that using all doses in the multi-dose vial can be a challenge in some settings. Every effort should be made to minimize leaving unused doses in a COVID vaccine vial but getting people vaccinated should be prioritized over ensuring that every dose is used in an open vial. (See Section 17.1 and Section 15.5)

Enrolling new providers: Increasing supplies of vaccines now allow for more providers to participate in vaccine administration, including settings that see a smaller volume of people needing to be vaccinated, such as primary care and smaller community-based vaccination events. Currently enrolled providers are encouraged to please route providers not yet enrolled to the CVMS Provider Enrollment Portal and share the latest provider enrollment training information. Please share the [CVMS Enrollment and Activation Process Roadmap](#) for a condensed one-pager of all steps a new provider location needs to take. (See Section 9.0)

Offering walk-in appointments: Providers are encouraged to accommodate walk-in vaccination requests and to offer vaccines as part of regular patient visits to provide the greatest flexibility and access to people wanting the vaccine. Walk-in vaccinations can also help you use your vaccine allocation. (See Section 17.10 for tips).

Social Vulnerability Census Tract Map: There is a new [map](#) that can help North Carolina reach its goal of vaccinating as many North Carolinians as quickly and fairly as possible. This map shows census tracts in North Carolina with the highest rates of social vulnerability and the lowest rates of COVID-19 vaccination. NC DHHS encourages vaccine providers and partners to use this map to help determine where to conduct outreach efforts and where to locate vaccination sites and mobile



units. Census tracts to focus on are those that have high social vulnerability (red areas) and lower vaccination rates (smallest turquoise circles). Census tracts are subdivisions of counties. The map is now available on YourSpotYourShot.nc.gov.

Consent for vaccination in individuals under age 18 years: Informed consent for medical treatment must be obtained prior to anyone being vaccinated with any of the COVID-19 vaccines. The Pfizer vaccine is currently authorized for people 16 and above, and we anticipate future authorization of COVID-19 vaccines for lower age groups. NC General Statute 90-21.5 gives minors the legal authority to consent for the prevention, diagnosis and treatment of reportable communicable disease and COVID-19 is a reportable disease under NCGS 130A-135 pursuant to rules of the Public Health Commission (10A NCAC 41A .0101 .0107). Therefore, pursuant to NC General Statute 90-21.5, it is permissible for teenagers to consent for themselves, if they are judged to have decisional capacity, meaning that they are able to understand and make decisions about their health. The emergency use authorization status of vaccines does not impact the ability of teenagers to consent for themselves. Now is a good time to work with your local school districts on school located opportunities for qualifying high school students, their families, and school staff. (See Subsections 11.2.2 and 11.2.3)

Guidance related to people vaccinated with COVID-19 vaccine not authorized in the United States: Some people may have received a COVID-19 vaccine that is not currently authorized in the United States (i.e. Astrazeneca or Sinovac). No data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized in the United States after receipt of a non-FDA-authorized COVID-19 vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently authorized in the United States may be offered revaccination with an FDA-authorized vaccine. (See Subsection 5.4)