



Frequently Asked Questions

This list of Frequently Asked Questions (FAQ) provides current information on the newly updated COVID-19 vaccine and related topics such as how to order the vaccine, how to properly administer and store the vaccine, how to handle leftover vaccine, the Vaccines for Children Program (VFC), the NC Bridge Access Program and the discontinuation of the COVID-19 program.

COVID-19 VACCINE UPDATES

Q: Are the new COVID-19 vaccines under an EUA or fully FDA approved?

A: These vaccines are FDA approved or under an EUA:

- Comirnaty 2023-2024 formulation is fully approved for 12 years and older
- Pfizer-BioNTech 2023-2024 formulation under an EUA for ages 6 months through 11 years
- Spikevax 2023-2024 formulation is fully approved for 12 years and older
- Moderna 2023-2024 formulation is under an EUA for ages 6 months through 11 years

Note: "2023-2024 formulation" and "updated vaccine" are used interchangeably to indicate the new COVID-19 vaccine for this fall.

Q: Where can I find the updated CDC approved COVID-19 vaccine recommendations?

A: The updated COVID-19 vaccine recommendations can now be found on the page for [CDC COVID-19 Interim Clinical Considerations](#). CDC recommends everyone 6 months and older have an updated COVID-19 vaccine. If you have questions regarding COVID-19 vaccine guidance, please call the NC Immunization Branch Nurse on Call line at 919-707-5575.

Q: Where can I find the COVID-19 vaccine fact sheets?

A: Vaccine information can be found here:

- [Fact sheet](#) for Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older.

- [Fact sheet](#) for Moderna COVID-19 Vaccine (2023-2024 Formula): individuals ages 6 months and older.
- [Comirnaty package insert](#)
- [Spikevax package insert](#)

Q: Where can I find COVID-19 product information?

A: Click here to access [CDC COVID-19 Vaccine Product Information](#) with information on the following:

- Product type dosage guidance
- Storage and handling information for each product
- Preparation and administration guidance
- Contraindications and precautions
- When to report to VAERS
- Refrigerator/freezer labels
- Pre-vaccination Screening Checklists (multiple languages)
- Requirements, trainings, and resources
- Vaccine Storage and Handling Toolkit

Q: What should be done if there is not a VIS for a particular vaccine?

A: It is possible, particularly for a newly approved vaccine, that the vaccine could become available before a VIS can be produced. The law does not require that a vaccine be withheld if a VIS for it does not yet exist. Until a VIS is available for a particular vaccine, a provider may use the manufacturer’s package insert, written FAQs, or any other document – or produce their own information materials – to inform patients about the benefits and risks of that vaccine. Once a VIS is available it should be used; but providers should not delay use of a vaccine because of the absence of a VIS.

Q: Can the updated COVID-19 vaccines be used interchangeably?

A: The following patients are recommended to receive doses from the same manufacturer:

- Children ages 6 months–4 years (all doses)
- People ages 5 years and older who are moderately or severely immunocompromised (initial 3-dose vaccination series)

However, a different age-appropriate COVID-19 vaccine may be administered under these conditions:

- The same vaccine not available
- Previous dose is unknown
- The person would otherwise not complete the vaccination series
- The person started but is unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication.

Q: Can I still give Novavax vaccine?

A: People 12 years and older who are unable or choose not to get an updated Pfizer-BioNTech or Moderna COVID-19 vaccine can consider Novavax to be up to date. Guidance for Novavax is found [here](#).

Q: Where can I find the NC DHHS Press Release?

A: You can read the press release [here](#).

Q. Is written consent needed for COVID-19 vaccine?

A: COVID -19 is no longer a reportable communicable disease and therefore, not covered under NC’s Minor Consent Law. However, changes to that statute now requires a health care provider to “obtain written consent from a parent or legal guardian prior to administering any vaccine that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration to an individual under 18 years of age.”

Currently, the Moderna updated vaccine for ages 6 months through 11 years is still under an EUA and will require parental or legal guardian written consent. Also, the Pfizer updated vaccine for ages 6 months through 11 years is still under an EUA and requires parental or legal guardian written consent. Comirnaty and Spikevax vaccine are fully FDA approved and do not require parental or legal guardian written consent.

Q: Can I continue to use my current supply of bivalent vaccine?

A: No. You must immediately stop administering any bivalent mRNA COVID-19 vaccine you have in supply and dispose of them properly by wasting remaining doses according to your agency’s disposal policy and document the wastage in NCIR. Administration of non-authorized products is considered a vaccine administration error and must be reported to the [Vaccine Adverse Events Reporting System](#) (VAERS).

Q: Will I be penalized for wasting COVID-19vaccine?

A: No. Given the uncertainty with COVID-19 vaccine demand and potential for packaging size concerns, providers will not be penalized for COVID-19 vaccine wastage due to expiration or beyond-use-date limitations.

Q. What should I do with the remaining ancillary supplies?

A. Providers may use inventory of ancillary supplies provided by the U.S. Government at no cost to you through the CDC COVID-19 Vaccination Program for administration of your commercially purchased vaccines. The expiration date printed on the exterior box of the CDC ancillary kit does not apply to all of the items contained in the kit. The expiry date found on the external label is based on the earliest expiry of any of the kit's components.

Providers may exercise discretion and continue using unexpired kit components (e.g., needles and syringes) until they expire. Dispose of expired components in accordance with state and local requirements.

Unexpired ancillary kits or the items contained within **cannot be sold**, but can be shared domestically, at no charge, with other immunization programs. Ancillary kits cannot be donated outside of the United States or to organizations that will use the supplies outside of the US per federal funding requirements.

Q: How will COVID-19 products ship?

A: The Moderna, Pfizer, and Novavax products will ship as described below:

- Moderna will ship as a frozen product. Storage and handling will be the same as previous Moderna products.
- Pfizer will ship at ULT. Wholesalers (for privately purchased vaccine) may ship at refrigerated temperatures so providers should order accordingly as vaccines will arrive approximately 10 weeks prior to beyond use date. Storage and handling will be the same as bivalent Pfizer products.
- Novavax will ship as a refrigerated product. Shipping and handling will be the same as the original Novavax product.

Resource for Storage and Handling Information: [CDC Vaccine Storage and Handling Toolkit](#)

Q: Do nursing homes and pharmacies need to continue to log purchases in our inventory and transfer to facilities through NCIR?

A: Since the current program has dissolved and you are no longer receiving vaccines through us at the Immunization Branch, you will not be required to utilize the NCIR for administration documentation or inventory management (including transfers, wasted, expired), unless you are an immunizing pharmacist (or enrolled in one of our other programs, such as the Vaccines for Children program). Immunizing pharmacists will continue to have to record vaccine administrations in NCIR as required by law (but they will not have to manage inventory). If you would like to continue using NCIR to manage your private inventory, you will be given the option. We have some providers who like to use the system to manage their private stock administrations.

ORDERING COVID-19 VACCINE

Q: How do I order private COVID-19 vaccine?

A: You can order vaccine from these manufacturers:

Manufacturer	Instructions
Moderna	Order via McKesson, Cardinal or AmeriSource Bergen distributors or directly via Moderna at www.modernadirect.com or 1.866.663.3762. Courtney Bolen: Courtney.Bolen@modernatx.com
Pfizer	Order via wholesalers or directly via Pfizer at primecontacts.Pfizer.com or 1.800.666.7248.
Novavax	Order via dedicated distributor. Contact: Courtney Goober-Cgoober@Novavax.com

[You can find additional information for the commercial purchase of Novavax here.](#)

Q: Which Agreement Addendums (AAs) can be used by local health departments to purchase vaccines?

A: The following AAs can be used to purchase vaccines:

- AA110
- AA546 ***PLEASE NOTE:** After confirming with DHHS Budget Office this week, purchase may include uninsured, underinsured, and private purchase. Purchase of vaccines would be eligible as part of control and prevention activities as indicated within the AA. There are no specific federal restrictions on these funds that would be relevant to purchase of vaccines.

The following AAs **CANNOT** be used to purchase vaccines, but can be used to support operational costs, including staffing, equipment, etc. Please review each AA for additional information.

- AA543
- AA715
- AA716
- AA717 (forthcoming to support Bridge Access Program activities)

ADMINISTERING THE VACCINE

Q: How do I know what vaccine and dosage to give to what age child?

A: COVID-19 vaccine administration guidance can be found [here](#). Please call the Immunization Branch Nurse on Call if you have questions about COVID-19 clinical vaccine administration guidance at 919-707-5575.

Q: What do I do if I give the wrong vaccine?

A: Administration errors should be documented per your facility policy. Clinical guidance for administration errors can be found here: [Appendix B. Vaccine Administration Errors and Deviations](#). Please use quality improvement strategies to determine how the error occurred and put actions in place to prevent the error from occurring again. Administration of non-authorized products is considered a vaccine administration error and must be reported to the [Vaccine Adverse Events Reporting System](#) (VAERS). Please call the Immunization Branch Nurse on Call if you have questions about actions to take after an administration error has occurred at 919-707-5575.

Q: Are there special considerations for vaccinating people who are moderately or severely immunocompromised?

A: The number of recommended updated (2023–2024 Formula) mRNA vaccine doses for an individual who is moderately or severely immunocompromised is based on vaccination history and the vaccine manufacturer (Moderna, Novavax, or Pfizer-BioNTech). Guidance for people who are moderately or severely immunocompromised can be found [here](#).

Q: Can COVID-19 vaccines be administered with other vaccines at the same time?

A: Yes. There is no recommended waiting period between getting a COVID-19 vaccine and other vaccines. You can get a COVID-19 vaccine and other vaccines, including a flu vaccine, at the same time.

Q: Should we still give the CDC COVID-19 vaccination card after administration of the vaccine?

A: The CDC COVID-19 vaccination cards are no longer in use. Document the vaccine as you would any other vaccine you administer in the medical chart and on the vaccine record. If you use NCIR, you must document the administration in NCIR as well.

Q: Where can I find the Statewide Standing Orders?

A: The link for Info/Guidance for Health Care Providers including the Statewide Standing Orders for COVID-19 vaccines can be found [here](#).

VACCINES FOR CHILDREN PROGRAM

Q: Will the updated COVID-19 vaccine be included in the VFC program?

A: Yes. Like the introduction of other routine vaccines into the VFC program, providers are expected to begin ordering and administering COVID-19 vaccines to their VFC eligible patients as soon as possible. Vaccines for fully insured patients will need to be purchased following the traditional vaccine procurement pathways.

Q: Are VFC practices required to maintain a supply of state and private COVID-19 vaccine?

A: Yes. VFC practices are required to maintain a supply of COVID-19 vaccine for both VFC eligible children and privately insured patients based on your provider profile.

Q: If we do not provide the COVID-19 vaccine for patients 6 months to 11 years old with private insurance (we only see patients 12 years and up), do we have to provide vaccine for ages 6 months to 11 years for VFC?

A: VFC enrolled providers are required to stock and offer all ACIP recommended vaccines, including COVID-19 vaccines, according to the populations they serve. If you only see patients 12 years and older, you will only need to stock products for that age group.

Q: Are VFC providers required to enroll in an additional program to receive the vaccine for VFC eligible patients?

A: No.

Q: If I was enrolled in the CDC COVID-19 Vaccination Program, but not enrolled in the Vaccines for Children or Bridge Access Programs, can I continue to have access to NCIR?

A: Yes, if you are actively entering privately purchased vaccine administrations in the system. Read-only access is not available for healthcare providers.

Q: Can I borrow from my VFC stock of COVID-19 vaccine if my private order has not been shipped yet?

A: Yes. Bi-directional borrowing will be allowed. As private purchasing contracts and ordering systems are implemented, there may be delays for providers in procuring private stock COVID-19 vaccine. For this reason, borrowing of COVID-19 vaccine will be allowed. As with other routine VFC vaccines, borrowed doses must be repaid (dose for dose) within one month, following the VFC borrowing and replacement policy.

Q: Who is eligible to receive the VFC COVID-19 vaccine?

A: In October 2022, ACIP voted to include COVID-19 vaccines in the Vaccines for Children Program (VFC). VFC eligibility includes children birth through 18 years of age that meet at least one of the following criteria:

- Medicaid enrolled - a child who is eligible or enrolled in the Medicaid program.
- Uninsured - a child who has no medical insurance coverage
- American Indian or Alaskan Native
- Underinsured (can only be served by deputized providers such as LHD/FQHC/RHC).

Includes:

- Children who have commercial (private) health insurance, but the coverage does not include vaccines
- Children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only)
- Children whose insurance caps vaccine coverage at a certain amount - once that coverage amount is reached, these children are categorized as underinsured

**The [NC Coverage Criteria](#) will be updated soon.

Q: Will I be penalized for wasting vaccine if we can't use all that we order?

A: No. Given the uncertainty with COVID-19 vaccine demand and potential for packaging size concerns, providers will not be penalized for COVID-19 vaccine wastage due to expiration or beyond-use-date limitations. Future wastage of the updated 2023-2024 COVID-19 vaccine will follow normal VFC wastage/expiration procedures (i.e., unopened vials will need to be sent back to the centralized distributor).

Q. Is my practice required to carry every COVID-19 product?

A. Providers are not required to carry every COVID-19 product, but you want to make sure you are carrying the products for the ages of the populations you serve. For example, if you see children under the age of 12, you will need to carry either Moderna or Pfizer rather than solely Novavax as Novavax is only indicated for individuals 12 and older.

BRIDGE PROGRAM

Q: What is the Bridge Program?

A: On April 18th, 2023, the U.S. Department of Health and Human Services (HHS) announced the [HHS Bridge Access Program](#) for COVID-19 Vaccines and Treatments. The purpose of this program is to help maintain access to COVID-19 care (vaccines and therapeutics) for underinsured and uninsured adults 19 years of age and older, through existing public health infrastructure, HRSA-supported health centers (i.e., Health Centers), and participating pharmacies, via two major components:

- Provide support for the existing public sector vaccine safety net, implemented and maintained by state immunization programs and HRSA-supported health centers.
- Create a funded partnership with pharmacy chains that will enable them to continue offering free COVID-19 vaccinations and treatments.

Q: Which providers are eligible to enroll in the Bridge Program?

A: Providers that serve uninsured and underinsured adults, such as local health departments, federally qualified health centers, rural health clinics, and free and charitable clinics should enroll in the Bridge program.

Q: Is storage and handling the same for Bridge and VFC vaccines?

A: Bridge storage and handling requirements will be the same as VFC storage and handling requirements. There will need to be separation of stock between VFC and Bridge doses in both the physical inventory (i.e. clearly labeled for either VFC or Bridge Program use) as well as the NCIR virtual inventory.

Q: Who needs to sign the Bridge Program Agreement?

A: The lead physician or primary physician should sign the Bridge Program Agreement. The Health Director can sign the Agreement in the event the Medical Director is not available.

Q: Will Bridge Access Program providers be able to order vaccine through NCIR?

A: Yes, if enrolled. Only providers enrolled in the Bridge Access Program or the VFC program will be able to order the 2023-2024 COVID-19 vaccines for their eligible populations through NCIR. Vaccines for fully insured patients will need to be privately purchased.

Q: I am also a VFC provider. How am I able to distinguish my VFC doses from my Bridge doses in NCIR?

A: All dually enrolled Bridge and VFC providers will have a sub-site created in NCIR labeled “Bridge Access”. Upon receiving your Bridge vaccines, they will need to either be accepted into the Bridge Access site or transferred. Please refer to the Bridge Access Program NCIR Guidance [here](#).

Q: Can I use the borrowing and replacement policy for COVID-19 vaccines obtained through the Bridge Program?

A: No. Given the limited number of vaccine doses available for the Bridge Program, borrowing and replacement will not be allowed.

Q: Who is eligible to receive COVID-19 vaccines through the Bridge Program?

A: Persons who are 19 years of age and older AND:

- Are uninsured: no insurance, Medicaid or Medicare
- Are underinsured: has insurance but the insurance does not cover COVID-19 vaccines; a person whose medical insurance does not provide first-dollar coverage (i.e., copay-free coverage) of COVID-19 vaccinations

Providers must permit patients to attest to lack of insurance at the point of care. Providers cannot turn any patient away due to inability to pay or to verify insurance status.

Q. If my local health department is unable to bill an insurance company, can those patients be considered underinsured?

A. No, a clinic’s ability to bill insurance is not a factor when considering eligibility for the Bridge Access Program vaccine. If the patient has insurance that covers the vaccine, they are ineligible for COVID-19 vaccines under the Bridge Program.

Q: Will pharmacies receive doses of COVID-19 vaccine for uninsured patients?

A: The retail pharmacy component of the Bridge Program will provide COVID-19 vaccines at no cost to uninsured adults and adults whose insurance does not cover all COVID-19 vaccine costs. CDC has contracts with CVS, Walgreens, and eTrueNorth to supply vaccine doses to areas of lower access or vaccination coverage. eTrueNorth will assist independent or other non-Walgreens and non-CVS pharmacies with participation in this program. Immunizing pharmacists will continue to record vaccine administrations in NCIR as required by law, but they will not have to manage inventory directly in NCIR.

Q: How long will the Bridge Access Program be available?

A: The Bridge Access Program is a temporary measure to prevent loss of access to COVID-19 vaccines and treatment for underinsured and uninsured patients. The NC Bridge Access program is expected to run through December 2024.

Q. Are patients with Family Planning Medicaid eligible for COVID-19 vaccines as part of the Bridge Access Program?

A. NC Medicaid has confirmed that Family Planning Medicaid will not cover COVID-19 vaccines, therefore these adult patients (19 and older) can be considered underinsured and eligible for COVID-19 vaccines via the Bridge program.

DISCONTINUATION OF COVID-19 PROGRAM

Q: Is the COVID-19 program over?

A: Yes. The CDC COVID-19 Vaccine Provider Agreement has ended. The US government supplied COVID-19 vaccines ordered through this program are no longer authorized for use with the exception of Novavax.

Q: What does the end of the COVID-19 program mean for providers?

A: Providers should stop administering the mRNA bivalent products immediately and waste remaining doses following your agency's disposal policies, including appropriately documenting wastage in NCIR. Note that FDA has not yet authorized or approved an updated Novavax vaccine for 2023-2024. As a result, the existing Novavax vaccine may still be administered at this time if it is determined that the individual should not wait for a 2023-2024 Novavax COVID-19 vaccine. Providers with the ancestral Novavax doses must continue to follow the terms of the CDC COVID-19 Vaccination Program Provider Agreement until all remaining doses are either administered, wasted, expired or become no longer authorized by FDA.

For Further Questions contact the Help Desk at 1.877.USE.NCIR (873.6247) or email NCIRHelp@dhhs.nc.gov. For clinical questions, contact the Nurse on Call at 919.707.5575.

