



NCDHHS COVID-19 RESPONSE

COVID-19 VACCINE PROVIDER GUIDANCE

Updated July 15, 2022

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1. What's New

- HHS Secretary Xavier Becerra [renewed the COVID-19 public health emergency declaration](#) to ensure that healthcare providers and state/territorial health departments have continued flexibility to respond to the pandemic. HHS will provide states and territories with at least 60 days' notice prior to the termination of the public health emergency declaration for COVID-19.
- Shelf Life and Expiry Lookup Reminders
 - **Pfizer Expiry Look-up Tool** Coming by the end of July. We will notify you when the page and tool are operational. Stay tuned to Office Hours and email for additional information and a link to the Pfizer expiry page.
 - **Pfizer purple cap** doses are expiring - you are encouraged to transition to the Pfizer GREY Cap product by August 31, 2022, and to dispose of all expired PURPLE Cap COVID-19 vaccines according to state and local regulations. Contact your Project Officer or VDSO if you need assistance or have questions.
 - **Moderna** Shelf-Life Extension Moderna COVID-19 vaccines are once again receiving a shelf-life extension by lot number. Vials have a QR code that provides the up-to-date expiration date from the manufacturer website. Check your Moderna lot number expiration dates regularly at [Vial Expiration Date Lookup](#).
 - **Novavax** Expiry Page Now Available! An Expiry Page is now available for the new Novavax COVID-19 Vaccine recently approved for emergency use by the FDA. Novavax was approved for a 9-month refrigerated shelf life, and all Novavax vaccine purchased by USG currently expires February 2023. Should this date be extended, the Novavax Expiry Page will contain all current expiration date information.
 - **Johnson and Johnson/Janssen** A large quantity of J&J COVID-19 vaccine is expiring in August 2022. We would like to remind you to check expiration dates at Janssen COVID-19 Vaccine Expiry Checker ([vaxcheck.jnj](#)). Again, please dispose of all expired vaccine in accordance with state and local regulations.
- Moderna Spikevax (18+ years, BLA Moderna COVID-19 vaccine product) expected to be available for ordering early August
- 2nd Boosters - only about 28% of adults ages 50 years and older with a first booster dose have received a second booster dose. Advise patients to **act now and get boosted** - data suggest that BA.4 and BA.5 spread more easily than previous Omicron lineages. They've been on the rise for weeks, and BA.5 has become the predominant lineage in the United States (see A Closer Look). So more people—even those who might have protection from past infection or vaccination—have gotten COVID-19, and COVID-19-associated hospitalization rates and death rates have risen among older adults. [Take a closer look](#).
- [CDC COVID-19 Vaccine Effectiveness Monthly Update](#) (updated July 14th)

- White House [strategy to manage BA.5](#) relies on ensuring that Americans continue to have easy and convenient access to the vaccines, treatments, tests, and other tools that protect against and treat COVID-19.

2. Getting Started

Welcome to the NCDHHS COVID-19 Provider Guidance!

The links and information below will help you find information related to COVID-19 vaccine administration and product logistics.

For patient-facing resources like the ones linked throughout this document, please see:

- [DHHS COVID-19 Communications Toolkit](#)
- [CDC Vaccine Recipient Information](#)

For the most up-to-date COVID-19 related information from NCDHHS, we invite you to attend the weekly Provider Webinar at 12:30 PM EST. [Click here to access and save the link](#) or use Meeting ID: 161 406 4331; Passcode 906994.

Looking for Stories or Best Practices in Vaccinating for COVID-19? See [COVID-19 Vaccine Community Features | CDC](#).

3. Guiding Principles

North Carolina's COVID-19 Vaccine Plan is guided by a set of core principles rooted in equity, inclusivity, transparency, data-driven decision-making, and responsibility.

Equity

All North Carolinians have equitable access to vaccines based on risk of exposure and risk of severe illness.

NCDHHS has a specific focus on building trust with historically marginalized populations (HMP). Longstanding and continuing racial and ethnic injustices in our health care system contribute to lack of trust in vaccines. We hope you will join us in partnering with trusted leaders and organizations to provide accurate information about the vaccine.



Inclusivity

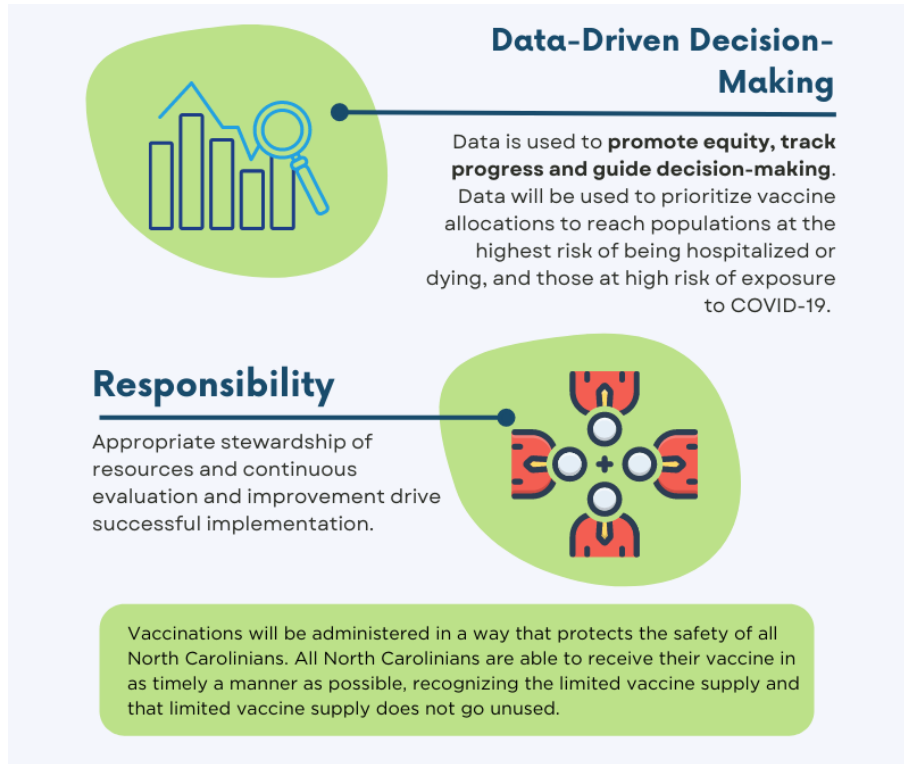
Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations.

Coordination is facilitated by state and local entities to ensure all priority populations can be reached. Vaccine and health care providers have a responsibility to take intentional action to reach and engage historically marginalized communities.

Transparency

Transparent, accurate, and frequent public communications is essential to building trust. All North Carolinians, including vaccine providers and the public, should understand what to expect in the vaccination campaign.





4. Overview of North Carolina’s COVID-19 Vaccine Plan

[Moving Forward Together](#) is the next phase of North Carolina’s COVID-19 pandemic response.

Please see the [NC Vaccine Strategy](#) page for full details from the beginning of the pandemic and an administration timeline.

5. General Vaccine Information

Current information can always be found in the [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines](#) and at the [DHHS Vaccination Information for Healthcare Professionals](#) page.

5a. Vaccine Eligibility

Please see the [CDC Eligibility Page](#) for detailed info, and the [Quick Reference Guide](#) for help. Important notes include:

- The vaccine is free everywhere in North Carolina.
 - See the [Medicaid billing guide](#)
- No photo or government ID is required.
 - See the Health Resources and Services Administration HRSA Fact Sheets:
- Everyone can be vaccinated, regardless of their immigration status. Getting vaccinated will not affect an individual's immigration status.
- People can self-attest (no proof is needed) that they are eligible for an additional dose of an mRNA COVID-19 vaccine.

5b. General Vaccine Messaging

COVID-19 primary series vaccination is recommended for everyone 6 months of age and older in the United States.

- Pfizer-BioNTech or Moderna COVID-19 Vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
- A booster dose of COVID-19 vaccine is recommended for everyone ages 5 years and older.

Additional Resources

- **NEW:** Resources about recommended [booster doses for everyone five years and older, if eligible](#).
- [COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals](#)
- NCDHHS [COVID-19 Communications Toolkit](#)
- NCDHHS [Patient Fast Facts Sheet](#)
- NCDHHS [Vaccine Video Library](#)
- CDC [Vaccine FAQ for Healthcare Professionals](#)
- CDC [Training and Education for Healthcare Professionals](#) Resources
- CDC [Resources for Health Departments](#)
- CDC [Learning Connection](#)
- Immunize.org COVID-19 vaccination [patient education materials](#)
- [COVID Playlist](#) contains 90+ regular and animated videos and graphics.

5c. Vaccine Hesitancy Resources

DID YOU KNOW?

Trusted providers are one of the **most effective levers** for improving vaccine acceptance



Your conversations with patients about COVID-19 vaccines in routine care can make a difference:

Personal Stories

Use your credibility as a healthcare provider to help guide the conversation. Don't be afraid to tell your personal vaccination story!

Tested & TRUE

Build trust in the vaccine development process, without getting bogged down in overly technical details or medical jargon.

Help Loved Ones

Frame the conversation around how getting the vaccine helps patient's loved ones.

Vaccine Hesitancy Resources

- [Boosting COVID-19 Vaccine Confidence: An Educational Toolkit for Providers](#)

- [COVID-19 State of Vaccine Confidence Insights Report](#)
- NCDHHS [Vaccine Discussion Guide for Healthcare Providers](#)
- CDC [Vaccine Confidence Resources](#)
- CDC [Interactive COVID-19 Vaccine Conversations Module for Healthcare Professionals](#)
- Yale [Vaccine Messaging Guide](#)
- CDC [“How to Address Misinformation”](#)
- CDC [Communication Resources for COVID-19 Vaccines](#)

5d. Booster Information

The definition of “Up To Date” definition now includes a 2nd booster

People ages 5 years and older are “[up to date](#)” with their COVID-19 vaccines when they have received all doses in the primary series and all booster doses recommended for them, when eligible.

- On May 20, 2022, CDC strengthened its second booster recommendations. People ages 50 years and older and people who are moderately or severely immunocompromised should get a second booster dose to be up to date.
- People ages 18 through 49 years who received a Janssen COVID-19 vaccine for both their primary and booster dose may get a second booster dose of either Pfizer-BioNTech or Moderna COVID-19 vaccine, but the second booster dose is not required to be considered up to date.

For the general population, a booster dose of COVID-19 vaccine is recommended for everyone ages 5 years and older according to the schedule below. There is no need for people to go back to the location where they received their original vaccines.

Additionally, certain immunocompromised individuals, people ages 50 and older, and all individuals who received Johnson & Johnson primary and booster doses are eligible for **another** mRNA booster to increase their protection. The additional dose must be administered at least 4 months after a previous dose of any vaccine product.

See the CDC’s [Booster Information](#) page for up-to-date guidance.

For immunocompromised persons, please see the CDC’s guidance for [COVID-19 vaccinations for people who are moderately or severely immunocompromised](#).

See the COVID-19 vaccination schedule for the [general population](#) and [immunocompromised individuals](#).

Additional Resources:

- NCDHHS [COVID-19 Vaccine Boosters](#)

6. Special Populations

6a. Cultural Humility

The National Institutes of Health (NIH) defines cultural humility as *“a lifelong process of self-reflection and self-critique whereby the individual not only learns about another's culture, but one starts with an examination of her/his own beliefs and cultural identities.”*

Cultural humility recognizes the correlation between a person’s health and their identities related to race and ethnicity, gender, sexual orientation, socioeconomic status, education, social needs, and others. These factors can influence:

- How patients perceive symptoms and health conditions
- When and how patients seek care
- Patients’ expectations of care and preferences regarding treatment
- Who patients believe should participate in making healthcare decisions

Additional Resources:

- [Cultural Humility vs. Cultural Competence — and Why Providers Need Both](#)
- [Cultural Humility Is Critical to Health Equity](#)
- [How to Improve Cultural Competence in Health Care](#)
- CDC [Conversations in Equity](#), a collection of blogs dedicated to increasing the awareness of health inequities.

6b. Historically Marginalized Populations (HMP)

Many individuals, groups, and communities have historically and systematically been denied access to services, resources and power relationships across economic, political, and cultural dimensions. This marginalization is a result of systemic and persistent racism, discrimination and other forms of oppression.

Historic marginalization can result in poor health outcomes and has contributed to the inequitable distribution of COVID-19 cases and fatalities within these communities.

It is important as a provider to be aware of historical implications that can be perceived as a barrier to access, acceptance, and overall vaccine confidence for these groups.

Additional Resources:

- **NEW:** Resources to address [equity in childhood COVID-19 vaccination](#).
- [Health Equity Guiding Principles for Inclusive Communication](#)
- [NCDHHS Historically Marginalized Populations Engagement Toolkit](#)

6c. Homebound Persons

Homebound persons are those that need the help of another person or medical equipment such as crutches, a walker, or a wheelchair to leave their home, or their medical provider believes that their health or illness could get worse if they leave their home. In North Carolina, there are estimated to be as many as over 97,000 homebound persons.

[See the CDC's guidance and best practices for vaccinating homebound persons](#)

Additional resources:

- NCDHHS [Accessibility Checklist](#)
- NCDHHS [At-home Vaccines](#)
- CDC [Guidance for Vaccinating Older Adults and People with Disabilities](#)
- [PREP act](#) and state authorizations for individuals to administer COVID-19 vaccines
- Liability protection: [PREP Act](#) and state [Executive Order 193](#), Section 3B
- [Partnering with Uber](#) to reach homebound persons

6d. Pregnant and Lactating Individuals

COVID-19 vaccination is strongly recommended for all people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future in order to prevent serious illness, deaths, and adverse pregnancy outcomes.

Pregnant people who are 12-17 years of age can receive age-appropriate, authorized COVID-19 vaccine products.

Vaccination for those who are pregnant or wanting to become pregnant is recommended by the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), the American Society for Reproductive Medicine (ASRM), and the Society for Male Reproduction and Urology.

See the American College of Obstetricians and Gynecologists [Practice Advisory for COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care](#) and the [CDC recommendations for pregnant and breastfeeding individuals](#).

Additional Resources:

- NCDHHS [COVID-19 Vaccination: Pregnancy, Fertility, and Breastfeeding](#)
- CDC [COVID-19 Vaccines While Pregnant or Breastfeeding](#)
- ACOG [patient videos on recommended vaccines during pregnancy](#)

Pregnancy-related Research:

- [Neurodevelopmental Outcomes at 1 Year in Infants of Mothers Who Tested Positive for SARS-CoV-2 During Pregnancy | Child Development | JAMA Network Open | JAMA Network](#)
- [Maternal Vaccination and Risk of Hospitalization for Covid-19 among Infants](#)
- [Covid-19 Vaccination during Pregnancy — Two for the Price of One | NEJM](#)
- [Association of COVID-19 Vaccination in Pregnancy with Adverse Peripartum Outcomes | Neonatology | JAMA | JAMA Network](#)

- [Association of SARS-CoV-2 Vaccination During Pregnancy with Pregnancy Outcomes | Neonatology | JAMA | JAMA Network](#)

6e. Long-term Care and Congregate Facilities

Additional Resources:

- NCDHHS [COVID-19 Infection Prevention Guidance for Long-Term Care Facilities](#)
- CDC [COVID-19 Risks and Vaccine Information for Older Adults](#)
- [FAQs About Medical Consent & Pfizer-BioNTech Booster Doses for Long-term Care](#)
- [Medical Management of Vaccine Reactions in Adults in a Community Setting](#)

6f. Immunocompromised Individuals

A 3-dose primary mRNA COVID-19 vaccine series is recommended for people ages 6 months and older who are moderately or severely immunocompromised, followed by a booster dose when age-appropriate.

See the CDC's [guidance for COVID-19 vaccinations for people who are moderately or severely immunocompromised](#) and [vaccination schedule for immunocompromised individuals](#).

Additional Resources

- AMA [“How to Talk with Immunocompromised Patients”](#)
- ACIP's [general best practices for vaccination of people with altered immunocompetence](#)
- CDC [Guidance for persons vaccinated as part of a clinical trial](#)

6g. Individuals Vaccinated Outside the United States

Please see [Appendix E of the CDC Clinical Considerations](#) for up-to-date information.

6h. Additional Special Populations Resources

- [Vaccinating Children with Disabilities](#)
- [Tips for Effective Communication with Individuals Who Have Hearing Loss at a Mass Vaccination Event](#)
- [Ensuring the Rights of People with Limited English Proficiency in Health Care During COVID-19](#)
- [Department of Homeland Security Statement on Equal Access to COVID-19 Vaccines and Vaccine Distribution Sites](#)

7. Pediatric Vaccines

NEW Video: Elmo's dad Louie talked to their pediatrician, and [learned that Elmo should get vaccinated](#)
NEW [Pediatricians and Family Physicians Toolkit](#)
NEW [6 mo and older COVID Vaccine Effective Messages one-pager](#)
NEW [Resources to promote the COVID-19 vaccine for children & teens](#), including fact sheets, social media graphics, template newsletters, and links to [additional materials in multiple languages](#).

Printable Job Aids:

- [Vaccine Administration: Intramuscular \(IM\) Injection Infants 11 months of age and younger](#)
- [Vaccine Administration: Intramuscular \(IM\) Injection Children 1 through 2 years of age](#)
- [Vaccine Administration: Intramuscular \(IM\) Injection Children 3 through 6 years of age](#)
- [Vaccine Administration: Intramuscular \(IM\) Injection Children 7 through 18 years of age](#)
- [Vaccine Administration: Needle Gauge and Length](#)

7a. Children 6 months – 4 years old

CDC recommends that all children ages 6 months and older should receive a primary series of either Pfizer or Moderna COVID-19 vaccines. Both products are safe and effective.

- Moderna
 - [Statewide Standing Order Moderna COVID-19 Vaccine Administration for 6 months through 5 years](#)
 - [EUA Fact Sheet](#)
- Pfizer
 - [Statewide Standing Order for Pfizer-BioNTech Covid-19 Vaccine Administration in Patients 6 months through 4 Years](#)
 - [EUA Fact Sheet](#)

See Updated [COVID-19 Vaccine Codes](#)

Additional Resources:

- [Fact sheets](#) available in nine languages that can be printed and shared.
- [Top 6 Questions from Children Under 5 Answered](#)
- [Pediatricians and Family Physicians Toolkit](#)
- [How to Talk with Parents and Caregivers about COVID-19 Vaccination](#)
- [Barriers to Equity in Childhood Vaccination](#)
- [Ingredients included in the COVID-19 Vaccines](#)
- [Needle length for all ages](#)
 - Healthcare professionals can use professional judgement; if a provider determines that a 5/8th-inch needle should be used, they can use one from their own inventory and replace it with the 1-inch needle from the ancillary kit.

- [Resources to Promote the COVID-19 Vaccine for Children & Teens](#)
- [State Strategies to Increase COVID-19 Vaccination Rates in Children](#)

7b. Children 5 and Older

All children over the age of 5 are eligible to receive an age-appropriate mRNA vaccine series, and a booster dose.

Considerations for ordering pediatric COVID-19 vaccines:

- Both Moderna and Pfizer pediatric vaccines have a minimum order quantity of 100 doses.
- Moderna can be stored frozen between -50 C and -15 C until the expiration date.
 - Moderna vials can be moved to the refrigerator as needed for a maximum of a 30-day shelf life (unpunctured).
- Pfizer vials may be stored in an ultra-cold temperature (ULT) freezer between -90 C and -10 C until the expiration date.
 - If you do not have an ULT freezer, Pfizer vials may be kept in the refrigerator for up to 10 weeks.
- Providers are encouraged to order small amounts more frequently i.e. “just in time”.

[See the CDC’s Clinical Considerations for offering pediatric vaccines](#)

Additional Resources:

- NCDHHS 5-11 [side effects flyer](#)
- [COVID-19 Pfizer BioNTech Vaccine EUA Fact Sheet for individuals 5 through 11 years of age](#)
- [How to Talk with Parents and Caregivers about COVID-19 Vaccination](#)
- [Needle length for all ages](#)

8. North Carolina Vaccination Legal Considerations

Starting August 20, 2021, a state law ([Session Law 2021-110 Section 9](#)) requires health care providers 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.”

Written consent from a parent or legal guardian is still required in order to receive Pfizer-BioNTech COVID-19 vaccine for the following children and teens because the age-appropriate Pfizer-BioNTech COVID-19 vaccine products are only available under emergency use authorization:

- Children and Teens (5 -17 years of age) who are eligible for a booster dose of a Pfizer-BioNTech COVID-19 vaccine.

Additional Resources:

- [FAQs about Consent from Minors](#)
- [Legal Issues Related to Minors, School Staff, and Volunteers](#)

9. Moderna COVID-19 Vaccines

Moderna COVID-19 Vaccine is FDA-approved or FDA-authorized in people ages 6 months and older.

- Some individuals may benefit from getting their second dose 8 weeks after their first dose, rather than the typical 4-week interval. See the [CDC Guidance for Individualized Vaccination Schedules](#) for more.
- See the [CDC Guidance for contraindications and precautions](#) and [Triage of People with a History of Allergies or Allergic Reactions](#) before administering vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

See the [Moderna: Administration Overview for Moderna COVID-19 Vaccine](#) and the [Moderna Storage and Handling Overview](#) for the most recent product info.

Moderna COVID-19 Vaccine Fact Sheets in English*

Moderna Training: <https://app.livestorm.co/moderna-na-medical/label-updates-moderna-covid-19-vaccine?aimlink=f672d41c9e21821e5a29713c58a2378b&aimtoken=NTk4ODU0NC01OWI4ZWYwYQ>

[Fact Sheet for Healthcare Providers](#) – Primary series 6 months through 5 years of age

[Fact Sheet for Recipients and Caregivers](#) – Primary series 6 months through 5 years of age

[Fact Sheet for Healthcare Providers](#) – Information on vaccines for children 6 through 11 years of age

[Fact Sheet for Recipients and Caregivers](#) – Information on vaccines for children 6 through 11

[Dear Healthcare Provider Letter](#) – Information on vaccines for children 6 through 11 years of age

[Fact Sheet for Healthcare Providers](#) – Information on vaccines for people 6-11 and 18 and older

[Fact Sheet for Healthcare Providers](#) – Information on vaccines for children 12 years of age and older

[Fact Sheet for Healthcare Providers](#) – Information on vaccines for those 18 years and older (boosters)

[Wall Chart](#) – Information on Moderna COVID-19 vaccine products

Additional Resources:

- [Communication Resources for COVID-19 Vaccines](#)
- [Moderna Online Training Module](#)
- [Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers, labels with purple borders](#) (booster dose only)
- [Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers, labels with light blue borders](#)
- [Interchangeability of COVID-19 Vaccine Products](#)
- [Long Covid Support](#)
- [COVID-19 Moderna Vaccine EUA Fact Sheet for Recipients](#)
- [Moderna Vial Expiration Date Look-up Tool](#)

Moderna Customer Service

- 1-866-MOD-ERNA or 1-866-663-3762
- Email: excursions@modernatx.com
- For ancillary kit issues, contact McKesson Specialty
 - Phone #: (833) 343-2703
 - Email: COVIDVaccineSupport@McKesson.com

10. Pfizer BioNTech COVID-19 Vaccines

- *Pfizer-BioNTech COVID-19 Vaccine* is FDA-approved or FDA-authorized in people ages 6 months and older. Some individuals may benefit from getting their second dose 8 weeks after their first dose, rather than the typical 3-week interval. See the CDC Guidance for Individualized Vaccination Schedules for more. <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>
- See the [CDC Guidance for contraindications and precautions](#) and [Triage of People with a History of Allergies or Allergic Reactions](#) before administering vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

Please see the [Pfizer BioNTech Fact Sheet for Healthcare Providers](#) and the [Pfizer Storage and Handling Checklist](#) for up-to-date information.

See the most recent [Pfizer shelf-life extension/expiry information](#)





The Food & Drug Administration has approved an amendment to the EUA for Pfizer Tris COVID-19 vaccine extending the shelf-life of the following Pfizer product formulations **from 9 to 12 months if kept in ultra-cold storage**:

- Pfizer Tris Pediatric vaccine (**Orange Cap** for ages 5 through 11, with diluent)
- Pfizer Adult Tris (**Gray Cap** for ages 12+, no diluent)
- Any remaining Pfizer purple cap (last viable lots now expire September 2022)

The image below demonstrates the handling and administration differences between available Pfizer products and **preliminary** information about the vaccine for children ages 6 months-4 years of age.

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Pfizer BioNTech COVID-19 Vaccine: Product Characteristics

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use	Dilute Before Use
Age Group	12 years and older	12 years and older	5 through 11 years	6 mos through 4 years ¹
Vial Cap Color and Label with Color Border	PURPLE 	GRAY 	ORANGE 	MAROON 
Dose	30 mcg	30 mcg	10 mcg	3 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL	0.2 mL
Amount of Diluent* Needed per Vial	1.8 mL	NO DILUTION	1.3 mL	2.2 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)

¹The vaccine is not authorized for use in individuals younger than 5 years of age.

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.



FOR TRAINING PURPOSES ONLY – THE VACCINE HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS YOUNGER THAN 5 YEARS OF AGE

Before administration of the vaccine, please see full Prescribing Information: 16+ years of age (DILUTE BEFORE USE/Purple Cap) and 16+ years of age (DO NOT DILUTE/Gray Cap) and EUA Fact Sheets for Vaccination Providers: 12+ years of age (DILUTE BEFORE USE/Purple Cap), 12+ years of age (DO NOT DILUTE/Gray Cap) and 5 through 11 years of age (DILUTE BEFORE USE/Orange Cap). For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

6

NEW: Can Comirnaty® and the Pfizer-BioNTech COVID-19 Vaccine be used interchangeably?

The vial contents for Comirnaty® and Pfizer adult EUA vaccine are identical and interchangeable (as determined by the FDA).

Pfizer COVID-19 Adult Vaccines BLA Product Release: Key Points

Licensed Pfizer BioNTech Covid-19 Vaccine, Comirnaty®, will be made available for ordering by all channels on June 6, 2022. Below are a set of key points related to this release to assist in responding to questions you may have. We encourage you to attend one of the Pfizer training webinars (see below) for additional information. Time is allotted during these webinars to address additional questions. The Pfizer-BioNTech COVID-19 vaccine for adults 18 years of age and older, approved through EUA remains available. The licensed Pfizer COVID-19 vaccine for adults (the Biologics License Application [BLA] labeled product known as Comirnaty®) will be available to order by all channels (jurisdictions, federal entities, pharmacies) on June 6, 2022.

The minimum order quantity and increment (300 doses) is the same for both vaccines. The EUA and BLA products both have a GRAY Cap. Each product will have a unique label and NDC. Both products have the same storage and handling guidelines. The vial contents are identical and interchangeable (as determined by the FDA). While the vial contents are identical, the license for Pfizer Comirnaty® applies to people 16 years of age and older. The EUA allows the Pfizer-BioNTech vaccine to be used for ages 12 through 15. For additional information, see Recipients and Caregivers 12 years of age and older (fda.gov). The Comirnaty® product will be included in thresholds on June 6th under a new NDC. o The Pfizer vaccine thresholds will have 50% EUA and 50% BLA for all channels. The USG has about 20M doses of the Pfizer BLA product in inventory. o Doses will be released under controlled thresholds until exhausted.

The EUA labeled product will be available during and likely after supplies of BLA-labeled product are exhausted. Both products will be co-circulating during this limited release. Support and education will be provided by Pfizer and the CDC to help stakeholders understand labeling to ensure that all vaccine is administered correctly. Providers are discouraged from stockpiling the Pfizer BLA-labeled product. When feasible, the PfizerBioNTech COVID-19 vaccine inventory for people 12 years of age and older (approved through the EUA) should be used prior to ordering additional vaccine to reduce possible waste due to expiry.

Additional Resources:

- [Information for Pfizer COVID-19 vaccines](#)
- [FAQ for Comirnaty](#)
- [Pfizer Online Training Module](#)
- [COVID-19 Pfizer BioNTech Vaccine EUA Fact Sheet for Health Care Providers, purple cap \(must dilute\)](#)
- [Fact Sheet for Healthcare Providers Administering Vaccine \(Gray Cap/Adult\)](#)
- [Fact Sheet for Healthcare Providers Administering Vaccine \(Orange Cap/PEDS\)](#)
- [Pfizer-BioNTech Fact Sheets and FAQs \(recipients/caregivers and healthcare providers\)](#)
- [Translations of the Pfizer-BioNTech Fact Sheets](#)

Pfizer BioNTech Customer Service

- Phone # (800) 666-7248
- Email: cvgovernment@pfizer.com
- For ancillary kit issues, contact McKesson MedSurg
 - Phone #: 833-272-6634
 - SNSSupport@McKesson.com

11. Johnson & Johnson/Janssen COVID-19 Vaccines

The FDA has [limited the use](#) of the Janssen COVID-19 vaccine to individuals 18+ for whom **other** COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18+ who **choose** to receive the Janssen vaccine because they would otherwise not receive a COVID-19 vaccine.

- Although mRNA vaccines are preferentially recommended in most situations over the Janssen COVID-19 Vaccine, the Janssen COVID-19 Vaccine may be considered in some situations.
- See the [CDC Guidance for contraindications and precautions](#) and [Triage of People with a History of Allergies or Allergic Reactions](#) before administering vaccine.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.

The Johnson & Johnson vaccine supply will be limited indefinitely. We understand this product serves a variety of populations with different needs, and supply will be strategically placed across the state to serve those populations.

See [Administration Overview for Johnson & Johnson's Janssen COVID-19 Vaccine](#) and the [Janssen Storage and Handling Overview](#).

Additional Resources:

- [J&J Expiration Date Lookup Tool](#)
- [Janssen Online Training](#)
- [CDC COVID-19 Vaccine Product Information Guide](#)

Janssen Customer Service

- 800-565-4008 (or) 1-908-455-9922
- Email: JSCCOVIDTEMPEXCURSION@its.jnj.com
- For ancillary kit issues, contact McKesson Specialty
 - Phone #: (833) 343-2703
 - Email: COVIDVaccineSupport@McKesson.com

12. Novavax COVID-19 Vaccine

Novavax Authorized Under EUA

On July 13th, [FDA Authorized Emergency Use of Novavax COVID-19 Vaccine](#) for ages 18+. The CDC has recommended this product as a primary series only, for adults ages 18+.

- Webinars/Office Hours to provide information on the COVID-19 vaccine Novavax will be offered in the upcoming weeks, following the schedule below. Please [use this link to register](#) and to view the schedule through Aug 23rd For more information, see novavax.com/contact or <https://www.novavaxcovidvaccine.com/> or contact Novavax Customer Service at 1-855-239-9174.

13.Safety Monitoring and Resources

CDC maintains a [website about COVID-19 vaccine expiration dates](#). This site requires you to [register](#) before accessing the information. This webpage is usually updated after the manufacturer pages, so for recent shelf-life extensions, you may want to refer to the manufacturer pages first.

- **Moderna Vaccine:** Moderna vaccine vials have a QR code that, when scanned, provides the up-to-date expiration date from the [manufacturer website](#).
- **J&J/Janssen COVID-19 Vaccine:** J&J/Janssen vials have a QR code on the label that you can scan to view current expiry dates at [Janssen COVID-19 Vaccine Expiry Checker \(vaxcheck.jnj\)](#). Or you can call customer service at 1-800-565-4008.
- **Pfizer-BioNTech COVID-19 Vaccines:** The Pfizer vaccine vial [expiration date fact sheet](#) was updated to include the orange, gray, and purple cap products*. These products have different presentations:

Expiry Information for Pfizer Vaccine Presentations		
Color of Vial Cap	Age Group	More Details
ORANGE Cap Vial	5 Through 11 Years	<i>Dilute Before Use</i> Shelf Life Extended from 9 to 12 Months
GRAY Cap Vial	12 Years and Older	<i>Do Not Dilute</i> Shelf Life Extended from 9 to 12 Months
PURPLE Cap Vial*	12 Years and Older	<i>Dilute Before Use</i> Expiration Date Extended from 9 to 12 months – See Table

Healthcare providers with complex patient vaccine questions not addressed by [CDC interim clinical considerations guidance](#), can obtain expert consultation from the Clinical Immunization Safety Assessment COVIDvax project by calling 800-CDC-INFO (800-232-4636) or submitting this [CDC-INFO webform](#).

The CDC and FDA are actively engaged in safety monitoring of COVID-19 vaccines with numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events after vaccination.

The Center for Biologics Evaluation and Research (CBER) at the FDA is monitoring safety of authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-

government healthcare data systems. In addition, CBER participates actively in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO). These efforts are in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers for authorized vaccines. A coordinated and overlapping approach using state-of-the-art technologies has been implemented. These systems can also potentially be leveraged to assess safety in specific subpopulations and to assess vaccine effectiveness, including against emerging variants.

These monitoring systems include:

- [Vaccine Adverse Event Reporting System \(VAERS\)](#)

An early warning system that helps CDC and FDA monitor problems following vaccination. Anyone can report suspected vaccine reactions and issues to VAERS.

VAERS can provide vaccine safety experts with valuable information to assess possible safety concerns. VAERS is especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine. VAERS is not designed to assess cause and effect so VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All *serious* reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA also use statistical models to help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed. VAERS staff obtain follow-up medical records for reports classified as *serious*. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. These reports are submitted directly to VAERS and not through the state. CDC, the FDA and NC DHHS encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. Information provided to VAERS which identifies a person who received the vaccine or vaccines will not be made available to the public. De-identified VAERS data are made available to each jurisdiction 4-6 weeks after the report is received. VAERS data available to the public include only the initial report data to VAERS. Updated data which contains data from medical records and corrections reported during follow-up are used by the federal government for analysis. However, for numerous reasons including data consistency, these amended data are not available to the public. CDC shares VAERS summary data for each jurisdiction for their awareness. Summary data is monitored weekly by North Carolina, which includes county as a variable.

- [CDC v-safe](#)

A smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.

V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-ups to anyone who reports medically-attended adverse events. Participants can enroll in v-safe after any dose of vaccine, and parents and guardians can enroll on behalf of their children.

- **[V-safe COVID-19 Vaccine Pregnancy Registry](#)**

As part of v-safe, information about pregnancy status at the time of vaccination and at defined follow up time points after vaccination is collected.

Given the lack of safety data from preEUA clinical trials of COVID-19 vaccines among pregnant persons, the v-safe pregnancy surveillance system will provide critical information to monitor the safety of COVID-19 vaccines administered under EUA and is intended to capture information about pregnant persons and their infants who have been vaccinated. This can inform clinical guidance regarding COVID-19 vaccination during pregnancy and can provide an additional method to detect adverse events that warrant further evaluation using existing safety and database systems.

- **[Clinical Immunization Safety Assessment \(CISA\) Project](#)**

A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.

- **[Vaccine Safety Datalink \(VSD\)](#)**

A collaboration between CDC and several health care organizations that allows ongoing monitoring and proactive searches of vaccine-related data.

- **[The BEST](#)**

Part of the [Sentinel initiative](#), that comprises large-scale claims data, electronic health records (EHR), and linked claims-EHR databases with a data lag of approximately three months.

The system makes use of multiple data sources and enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines. The linked claims-EHR database makes it possible to study the safety of vaccines in sub-populations with pre-existing conditions or in pregnant women.

- **[Medicare Claims Database](#)**

*During the current pandemic, FDA, CMS, and CDC have already used the Medicare data to **publish a study showing that frailty, comorbidities, and race/ethnicity were strong risk factors of COVID-19 hospitalization and death among the U.S. elderly.***

CBER has worked over the past several years with CMS to develop capabilities for routine and time-sensitive assessments of the safety of vaccines for people 65 years of age and older using the [Medicare Claims database](#). Because it was already in place, this system was immediately put into use for COVID-19 vaccine surveillance to monitor for adverse events.

Additional Resources

- [Safety Monitoring Systems Information Sheet](#)
- [VAERS fact sheet](#)
- [v-safe Fact Sheet](#)
- [How Vaccines are Tested, Licensed, and Monitored for Safety](#)
- [Reporting Adverse Events](#)
- [Birth Defects Study to Evaluate Pregnancy Exposures \(BD-STEPS\)](#)

14. Statewide Standing Orders

Please see the latest [Statewide Standing Orders](#) on the DHHS website.

15. Storage, Reporting, and Transfer

15a. Ordering and Managing Vaccine

Please see the [COVID-19 Ordering Guidance One-Pager](#) for vaccine ordering details.

Providers can choose to use CVMS or NCIR to manage their COVID-19 vaccine inventory. Please see the [NCIR Process Guide](#) if you wish to make this change.

Whether a provider uses CVMS or NCIR, the COVID-19 Vaccination Program Provider Enrollment Process takes place in the CVMS Provider Enrollment Portal.

- CVMS
 - [CVMS User Guide](#)
 - [CVMS Upcoming Trainings](#)
 - [CVMS Provider Portal](#)
 - [CVMS Organization Portal for Healthcare Location Managers User Guide](#)
 - [CVMS Managing Inventory Best Practices document.](#)
- NCIR
 - [NCIR User Guide](#)
 - [NCIR interoperability with electronic health records](#)

Important Notes:

- All lots of Moderna 14 dose vials expired April 8th, and no more is available for ordering.
- We encourage all providers to post and manage their available excess inventory that is below the Minimum Order Quantity (MOQ) they are willing to transfer on Vaccine Marketplace.

Additional Resources:

- [Inventory Manager User Manual](#)
- [NC Vaccines HelpDesk Portal](#)
- Tips for Preparing for First Vaccine Allocation

15b. Transporting Vaccine

Please see the [COVID-19 Vaccine Transport Guidance](#).

15c. Wastage

Guidance for physical wastage of unused vaccine

- Empty vaccine vials are usually not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, to reduce the risk of fake or counterfeit COVID-19 vaccines, the CDC recommends providers “dispose of vials and packaging as medical waste by placing vials in a sharps container and packaging in a red medical waste bag.
- If medical waste containers are in short supply, deface or safely crush packaging materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced or destroyed, dispose with regular waste". There is currently no vaccine return program. Do NOT return vaccine in the thermal shipping container.
- Do not dispose of the ancillary kit supplies received to administer the vaccine(s) that has since expired.

Additional Resources:

- [Updated CDC's Storage and Handling Toolkit](#)
- [CDC Webpage: Identifying, Disposing, and Reporting COVID-19 Vaccine Wastage](#)

16. COVID-19 Vaccine Coding and Billing

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- [SPECIAL BULLETIN COVID-19 #249: Pfizer-BioNTech Vaccine Booster Dose for Children Age 5 through 11 | NC Medicaid \(ncdhhs.gov\)](#)
 - [AMA COVID-19 Vaccine CPT® Codes](#) to find the appropriate CPT code combination for the type of vaccine and services being offered
 - [NC Medicaid billing guide](#)
 - Note: [HRSA has stopped accepting](#) COVID-19 administration claims as of April 6, 2022.

COVID-19 Vaccination

A Quick Guide to Coding and Billing



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

Did you know?

NC Medicaid has **increased** the reimbursement for COVID vaccine administration from **\$40** to **\$65**.



The 3rd dose of a primary series vaccine (Pfizer and Moderna) given to immunocompromised kids **can be billed**.

NC Medicaid-enrolled providers can bill code **99401** for telephone outreach to unvaccinated Medicaid beneficiaries.



Find your COVID-19 Vaccine CPT® Codes

The American Medical Association (AMA) has created a **CPT Combination Tool**. Just type in the vaccine type and dose of vaccine that you are using, and pull up your CPT codes immediately!

Additional Resources:

- [NC Medicaid COVID-19 Guidance & Resources for Medicaid Providers](#)
- [NC Medicaid Policy Modifications](#)

- [NC Medicaid Special Bulletins](#)

17. Research of Interest

- CDC Long COVID study information [Innovative Support for Patients with SARS-CoV-2 Infections \(INSPIRE\): Prospective cohort study](#)
- [Long-term Immune Response to SARS-CoV-2 Infection Among Children and Adults After Mild Infection | Allergy and Clinical Immunology | JAMA Network Open | JAMA Network](#)
- [Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US](#)
- [Effectiveness of 2, 3, and 4 COVID-19 mRNA Vaccine Doses Among Immunocompetent Adults During Periods when SARS-CoV-2 Omicron BA.1 and BA.2/BA.2.12.1 Sublineages Predominated — VISION Network, 10 States, December 2021–June 2022](#) - a third and fourth COVID-19 vaccine dose offered substantial protection among adults with healthy immune systems who were eligible to receive them during Omicron variant evolution in early 2022. The findings of this study, in conjunction with [recently published data](#) showing people infected with BA.2 may also have antibodies that can protect against illness with BA.5, suggest that currently available vaccines may provide protection against serious illness caused by the currently circulating BA.5 variant.
- [Safety Monitoring of COVID-19 mRNA Vaccine First Booster Doses Among Persons Aged ≥12 Years with Presumed Immunocompromise Status — United States, January 12, 2022–March 28, 2022](#)
- [Factors Associated with Severe Outcomes Among Immunocompromised Adults Hospitalized for COVID-19 — COVID-NET, 10 States, March 2020–February 2022](#)
- [One coronavirus infection wards off another — but only if it's a similar variant \(nature.com\)](#)

Videos:

[Comfort and Restraint Techniques](#): This training demonstrates comfort and restraint techniques. Determine the best position for the patient based on comfort, age, activity level, administration site, and safety. Instruct the parent on how to help the infant or child stay still so you can administer the vaccine(s) safely.

[Intramuscular \(IM\) Injection: Supplies \(Children Birth through 18 Years of Age\)](#): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for children from birth through 18 years of age. A supply of needles of the appropriate lengths should be available. Aseptic technique must be used to protect supplies from microbial contamination. Safe injection practices minimize risk of injuries, infections, and non-infectious adverse events for both patients and providers. Health care providers are always advised to observe patients for 15 minutes after vaccination.

[Intramuscular \(IM\) Injection: Sites](#): This training helps providers identify intramuscular (IM) injection sites. A needle is used to inject the vaccine into the muscle. The appropriate site for an intramuscular injection for those under 2 years of age is the vastus lateralis muscle. The deltoid muscle over the triceps area of the upper arm is preferred for persons 3 years of age and older. Safe injection practices minimize

risk of injuries, infections, and non-infectious adverse events for both patients and providers. Health care providers are always advised to observe patients for 15 minutes after vaccination.

18. Additional Help

The NC Vaccines Help Center is available for providers and organizations to call and receive live support for COVID-19 vaccine and CVMS-related questions, issues, or requests. To reach the Help Center, call **(877) 873-6247 and select option 1 for COVID-19 questions.**

- The NC Vaccines Help Center is available: Monday – Friday 7:00 AM – 7:00 PM ET and Saturday 8:00 AM – 4:00 PM ET.

Please submit any COVID-19 Therapeutics-related inquiries, issues, and feedback to the Therapeutics Mailbox (therapeutics.covid19@dhhs.nc.gov).

[Request a COVID-19 CISA Clinical Consultation](#)

Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

Calling 800-CDC-INFO (800-232-4636), or

Submit a request via [CDC-INFO webform](#)

Additional Resources:

- See the COVID-19 vaccine for children [page on AAP.org](#) for guidance on vaccine implementation, coding information, educational resources for clinicians and families, an FAQ, and more.
- [How to Submit a HelpDesk Case One-Pager](#)
- [CDC Learning Connection](#)
- [FAQs for Private and Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices](#)
- **NEW** The U.S. Department of Health and Human Services' (HHS) public education campaign, [We Can Do This](#), recently launched the [Pediatricians and Family Physicians Toolkit](#) to help physicians increase confidence in and uptake of COVID-19 vaccines among their patients and in the communities they serve.

- **NEW** 2022 Pink Book Web-on-Demand Series visit the [Pink Book Series webpage](#) for updates on the 2022 release schedule and additional information. Continuing Education will be available for this event.

Vaccines.gov/VaccineFinder Support	Available M-F, 8am – 8pm ET Email: CARS_HelpDesk@cdc.gov Phone: 1-833-748-1979
Reporting Administration Data via CVRS Data Extract	CVRS Support: IZGateway@cdc.gov Data Clearinghouse: DCHInfo@cdc.gov Pharmacy Liaison: eocevent481@cdc.gov
VAMS	These help options are only for jurisdictions and providers using VAMS: VAMS Help Desk: 1-833-957-1100 **preferred contact method** VAMS Help: VAMSHelp@cdc.gov
V-safe	eocevent523@cdc.gov
HHS Protect/Tiberius	Log-in: Protect-ServiceDesk@hhs.gov Platform: ows-support@palantir.com ows-support-microplanning@palantir.com Tiberius: Tiberius-Help@cdc.gov