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1. What’s New

- **Vaccines and Long COVID**
  Data from people infected with SARS-CoV-2 early in the pandemic suggest that vaccination may help reduce the risk of long COVID. Further study is underway, but in the meantime, this offers yet another reason to make sure patients are up to date on their COVID-vaccines. Helpful resources for patients and parents can be found at Long Covid Support and Long Covid Kids.

- **CDC COVID-19 Vaccine Lot Number and Expiration Dates** reflects the most up-to-date expiry information for all vaccine products.

- **HRSA COVID-19 Uninsured Program (UIP)** will stop accepting claims for vaccine administration at 11:59 PM on **April 5, 2022**. Any vaccine administration claims submitted in the Portal after April 5, 2022, will not be adjudicated for payment. FAQs about the claims submission deadlines are online at:
  - [https://www.hrsa.gov/coviduninsuredclaim](https://www.hrsa.gov/coviduninsuredclaim)
  - [https://www.hrsa.gov/covid19-coverage-assistance](https://www.hrsa.gov/covid19-coverage-assistance)

- **Pediatric Needle Guidance**
  COVID-19 ancillary kits contain only 1-inch needles. The Advisory Committee on Immunization Practices recommends using this length for children 1 year of age and older when administering vaccines to ensure the vaccine is deposited well into the muscle tissue. A 5/8-inch needle may be used in some circumstances if the child’s skin is stretched tightly, and subcutaneous tissues are not bunched - HCPs should use professional judgement. For additional guidance see:
  - General Best Practice Guidelines on Immunizations [ACIP Vaccine Administration Guidelines for Immunization | CDC](https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf)
  - Needle gauge and length for all ages: [https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf](https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf)
  - IM injection, 3-6 years: [https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf](https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf)

- **Surplus Vaccination Cards**
  Shred or destroy unused surplus cards. If you are unable to do so, you must keep extra vaccination cards under lock and key. COVID-19 vaccine must also be kept secure. Stolen, fraudulently reproduced, and illegally sold vaccination cards have been used to reflect full
vaccination status for someone who has not received a COVID-19 vaccine. There have also been reported incidents of stolen and lost vaccine vials.

- Monitor both the inventory of COVID-19 vaccine and blank vaccination cards and keep them secure. If you are unable to store the excess cards, offer them to jurisdictional health department(s), or, as a last resort, destroy them.
- Report suspected fraud and theft incidences to your local law enforcement agencies and to the HHS Office of Inspector General and/or the FBI.

- **New CDC COVID-19 Community Levels** can help providers and communities make localized decisions about how to respond to COVID-19 in their area.
  - COVID-19 Community Levels do not apply in healthcare settings, such as hospitals and nursing homes. These settings should continue to use community transmission rates and follow CDC’s infection prevention and control recommendations for healthcare workers.

- Updated end dates for member vaccine incentives: [Update on Vaccination Counseling Code Reimbursement SPECIAL BULLETIN COVID-19 #240](#)

- **EUI and EUA Fact Sheet Considerations**
  - Should BOTH the COVID-19 Emergency Use Authorization (EUA) and Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers be provided before administering a dose of mRNA COVID-19 vaccine?
    - It is NOT necessary to provide both EUA and EUI Recipient Fact Sheets. Before administering an mRNA COVID-19 vaccine, provide either the appropriate EUA or EUI Recipient Fact Sheet depending on the authorized or allowed use of the vaccine being exercised at the time (i.e., based on which COVID-19 vaccine and dose being given).

  - **When should the Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers be provided?**
    - The EUI Recipient Fact Sheet should be provided if a provider administers COVID-19 vaccine:
      - For moderately or severely immunocompromised persons:
      - An additional COVID-19 mRNA dose to a person who received primary vaccination with Janssen COVID-19 Vaccine
      - A COVID-19 mRNA booster dose at least 3 months after an mRNA vaccine primary series (instead of 5 months)
      - A COVID-19 mRNA dose or doses as part of revaccination of a person who received HCT or CAR-T-cell therapy prior to or during treatment
      - A COVID-19 mRNA dose outside of the FDA-authorized or FDA-approved labeling and CDC dosing intervals based on clinical judgement
      - A COVID-19 mRNA primary, additional, or booster dose to a person vaccinated with a COVID-19 vaccine outside the United States or as part of a clinical trial
• A second COVID-19 mRNA dose 8 weeks after the first dose (instead of 3 weeks [Pfizer-BioNTech] or 4 weeks [Moderna])

▪ In all other situations in which mRNA COVID-19 vaccine is administered following the recommended schedule under Emergency Use Authorization (EUA), the EUA Recipient Fact Sheet should be provided.

  o Is it required that the Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers be provided?
    ▪ If the COVID-19 vaccine is given based on criteria in the EUI, the EUI Recipient Fact Sheet should be provided. While it is not a violation of the COVID-19 vaccination provider agreement it is not given, providers are still encouraged to provide the EUI Recipient Fact Sheet because the Emergency Use Authorization (EUA) Recipient Fact Sheet does not cover the same situations.

  o How should the Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers be provided?
    ▪ Vaccinators should provide COVID-19 vaccine recipients with the EUI Recipient Fact Sheet through appropriate means (e.g., hard copy, electronic dissemination like QR code, URL), similar to what they have in place for providing the Emergency Use Authorization (EUA) Recipient Fact Sheet.

• UPDATED - Pfizer Webinars for Healthcare Providers: COVID-19 Vaccine Medical Updates and Immunization Site Training: Maroon Cap training has been paused, but provider education on Purple, Gray, and Orange Caps will continue. Training is offered 3 days per week; click here for a complete schedule.

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.

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

Please see the NC Vaccine Strategy page for full details 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. Important notes include:

- The vaccine is free everywhere in North Carolina.
  - See the Medicaid billing guide
- No photo or government ID or insurance is required.
See the Health Resources and Services Administration HRSA Fact Sheets:
- Patient Fact Sheet (English | Spanish)
- Provider Fact Sheet (English | Spanish)

- Everyone can be vaccinated, regardless of their immigration status. Getting vaccinated will not affect an individual’s immigration status.
- The CDC now recommends the Moderna or Pfizer COVID-19 vaccines as the preferred vaccine for both the initial series and booster dose.
- 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 ages 5 years and older in the United States for the prevention of COVID-19.

- 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 12 years and older.

Additional Resources
- 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 Vaccine Recipient Education Information
- Bilingual Community Protection Poster
- CDC Resources for Health Departments
- CDC Learning Connection

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
- NEW Interactive COVID-19 Vaccine Conversations Module for Healthcare Professionals
5d. Booster Information

For the general population, a booster dose of COVID-19 vaccine is recommended for everyone ages 12 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.

Individuals 12 to 17 years of age can only receive the Pfizer booster, and adults 18 years of age and older can get any brand.

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.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0 month</th>
<th>1 month</th>
<th>2 month</th>
<th>3 month</th>
<th>4 month</th>
<th>5 month</th>
<th>6 month</th>
<th>7 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>1st dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ages 5–11 years)</td>
<td></td>
<td></td>
<td>2nd dose(3 weeks after 1st dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>1st dose</td>
<td>2nd dose(3–8 weeks after 1st dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Booster dose# (at least 5 months after 2nd dose)</td>
</tr>
<tr>
<td>(ages 12 years and older)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderna</td>
<td>1st dose</td>
<td>2nd dose(4–8 weeks after 1st dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Booster dose# (at least 5 months after 2nd dose)</td>
</tr>
<tr>
<td>(ages 18 years and older)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Janssen</td>
<td>1st dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Booster dose# (at least 2 months after 1st dose)</td>
</tr>
<tr>
<td>(ages 18 years and older)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Resources:
- NCDHHS COVID-19 Vaccine Boosters
- NCDHHS “Double Your Protection” flyer

5e. 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 are currently no vaccine return programs. 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 Webpage: Identifying, Disposing, and Reporting COVID-19 Vaccine Wastage](#)

## 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](#)

### 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:**
- 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 Homebound Vaccine Providers
- 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 Pfizer-BioNTech 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
• NCDHHS Pregnant and Nursing Flyer for patients
• CDC COVID-19 Vaccines While Pregnant or Breastfeeding
• CDC Guidance for Breastfeeding in the Context of COVID-19
• CDC Statement on Pregnancy Health Advisory
• CDC Statement on Pregnancy Health Advisory
• ACOG patient videos on recommended vaccines during pregnancy

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 5 years and older who are moderately or severely immunocompromised, followed by a booster dose in those ages 12 years and older.

See the CDC's guidance for COVID-19 vaccinations for people who are moderately or severely immunocompromised.

<table>
<thead>
<tr>
<th>Primary Vaccination</th>
<th>Age Group</th>
<th>Number of Primary Vaccine Doses</th>
<th>Number of Booster Doses</th>
<th>Interval Between 1st and 2nd Dose</th>
<th>Interval Between 2nd and 3rd Dose</th>
<th>Interval Between 4th and 5th dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>5–11 years</td>
<td>3</td>
<td>NA</td>
<td>3 weeks</td>
<td>≥4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥12 years</td>
<td>3</td>
<td>1</td>
<td>3 weeks</td>
<td>≥4 weeks</td>
<td>≥3 months</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18 years</td>
<td>3</td>
<td>1</td>
<td>4 weeks</td>
<td>≥4 weeks</td>
<td>≥3 months</td>
</tr>
<tr>
<td>Janssen</td>
<td>≥18 years</td>
<td>1 Janssen, followed by 1 mRNA</td>
<td>1</td>
<td>4 weeks</td>
<td>≥2 months</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Additional Resources

- CDC “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

- 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

7. Pediatric Vaccines

7a. Children 6 months – 4 years old

The FDA is delaying next steps of the authorization process for the Pfizer’s COVID-19 vaccine for children ages 6 months – 4 years old. This means that the Wave 1 orders for this product placed in February have been canceled by the CDC. Should this product become available again in the Spring, we will communicate its ordering process and next steps.

Additional Resources:

- Pediatric vaccine social media assets
- How to Talk with Parents and Caregivers about COVID-19 Vaccination
- Barriers to Equity in Childhood Vaccination
- Ingredients included in the COVID-19 Vaccines

7b. Children 5 and Older

All children over the age of 5 are eligible to receive the age-appropriate Pfizer BioNTech COVID-19 vaccine.

See the CDC’s Clinical Considerations for offering pediatric vaccines
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 5 – 15 years of age as primary series
- Children and teens (5 years and older) eligible for an additional dose of a Pfizer-BioNTech COVID-19 vaccine due to being moderately or severely immunocompromised; and
- Teens (12 -17 years of age) who are eligible for a booster dose of a Pfizer-BioNTech COVID-19 vaccine.

9. Moderna COVID-19 Vaccines

*Moderna COVID-19 Vaccine* is FDA-approved or FDA-authorized in people ages 18 years and older as a 2-dose primary series, with an interval of 4 weeks between doses.
• 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 Fact Sheet for Healthcare Providers and the Moderna Storage and Handling Overview for the most recent product info.

Additional Resources:
• Communication Resources for COVID-19 Vaccines
• Moderna Online Training Module
• CDC COVID-19 Vaccine Product Information Guide
• Ingredients included in the COVID-19 Vaccines
• Interchangeability of COVID-19 Vaccine Products
• NEW Lookup Vaccine Expiration for Moderna COVID-19 vaccine

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


Pfizer-BioNTech COVID-19 Vaccine is FDA-approved or FDA-authorized in people ages 5 years and older as a 2-dose primary series, with an interval of 3 weeks between doses.
• 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.
• 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.
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.

### Pfizer BioNTech COVID-19 Vaccine: Product Characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Group</td>
<td>12 years and older</td>
<td>12 years and older</td>
<td>5 through 11 years</td>
<td>6 mos through 4 years¹</td>
</tr>
<tr>
<td>Vial Cap Color and Label with Color Border</td>
<td>PURPLE</td>
<td>GRAY</td>
<td>ORANGE</td>
<td>MAROON</td>
</tr>
<tr>
<td>Dose</td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>10 mcg</td>
<td>3 mcg</td>
</tr>
<tr>
<td>Dose Volume</td>
<td>0.3 mL</td>
<td>0.3 mL</td>
<td>0.2 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>Amount of Diluent* Needed per Vial</td>
<td>1.8 mL</td>
<td>NO DILUTION</td>
<td>1.3 mL</td>
<td>2.2 mL</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>6 doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
<td>10 doses per vial (after dilution)</td>
</tr>
</tbody>
</table>

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 any other diluent.*

### Additional Resources:

- NEW [Expiry Information for Pfizer COVID-19 vaccines](#)
- FAQ for Comirnaty
- Pfizer Online Training Module
- Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 12 years of age and older
- Package Insert (gray cap)
- Package Insert (purple cap)
- Communication Resources for COVID-19 Vaccines
- [CDC COVID-19 Vaccine Product Information Guide](#)
- Ingredients included in the COVID-19 Vaccines
- Interchangeability of COVID-19 Vaccine Products

### 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

**Janssen COVID-19 Vaccine** is FDA-authorized for use in people ages 18 years and older. The primary series is a single primary dose.

- See the [CDC Guidance for contraindications and precautions](https://www.cdc.gov/vaccines/available/covid-19/contraindication.html) and [Triage of People with a History of Allergies or Allergic Reactions](https://www.cdc.gov/vaccines/available/covid-19/treatment.html) before administering 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.
- 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 [Considerations for Janssen COVID-19 Vaccine](https://www.cdc.gov/vaccines/available/covid-19/considerations.html), [Janssen COVID-19 Vaccine Fact Sheet](https://www.cdc.gov/vaccines/available/covid-19/vaccine-fact-sheet.html), and the [Janssen Storage and Handling Overview](https://www.cdc.gov/vaccines/available/covid-19/storage-handling.html).

**Additional Resources:**

- Communication Resources for COVID-19 Vaccines
- [Janssen Online Training](https://www.janssen.com/our-corporate-site/covid-19-training)
- [Ingredients included in the COVID-19 Vaccines](https://www.cdc.gov/vaccines/available/covid-19/vaccine-ingredients.html)
- [Interchangeability of COVID-19 Vaccine Products](https://www.cdc.gov/vaccines/available/covid-19/vaccine-interchangeability.html)

**Jansen Customer Service**

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

12. Safety Monitoring and Resources

The CDC and FDA are actively engaged in safety monitoring of COVID-19 vaccines with numerous [vaccine safety monitoring systems](https://www.cdc.gov/vaccines/dis/monitor.html), 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.*

- **Emergency Preparedness for Vaccine Safety**  
  *In the event of a disease outbreak in which a mass vaccination campaign is needed, CDC activates emergency preparedness activities to ensure that vaccines remain safe.*

- **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. The major partners for BEST currently are Acumen, IBM Federal HealthCare, IQVIA, and Columbia University and many affiliated partners such as MedStar Health, BlueCross BlueShield of America, the Observational Health Data Sciences and Informatics (OHDSI), OneFlorida, University of California and several others.
Using BEST, CBER plans to monitor about 15 adverse events that have been seen with the deployment of previous vaccines but have yet to be associated with a safety concern for an authorized COVID-19 vaccine at this time. CBER further plans to use the BEST system to conduct more in-depth analyses should a safety concern be identified from sources such as VAERS.

- **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
- Vaccine Safety Information for Healthcare Providers
- How Vaccines are Tested, Licensed, and Monitored for Safety
- Reporting Adverse Events
- Understanding Side Effects and Adverse Events
- Vaccine Safety Research
- Birth Defects Study to Evaluate Pregnancy Exposures (BD-STEPS)

### 13. Statewide Standing Orders

Please see the latest Statewide Standing Orders:
- Statewide Standing Order for FDA Approved Pfizer/COMIRNATY COVID-19 Vaccine Administration in Patients Ages 5-11 Years (Feb. 15, 2022)
- Statewide Standing Order for FDA Approved Pfizer/COMIRNATY COVID-19 Vaccine Administration in Patients Ages 12 Years and Older (Feb. 15, 2022)
- Statewide Standing Order for FDA Authorized Moderna COVID-19 Vaccine Administration (Feb. 15, 2022)
- Statewide Standing Order for FDA Authorized Johnson and Johnson (Janssen) COVID-19 Vaccine Administration (Feb. 15, 2022)

### 14. Documentation, Reporting, and Transfer
14a. 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
  - [CVMS Managing Inventory Best Practices document](#)

- **NCIR**
  - [NCIR User Guide](#)
  - [NCIR interoperability with electronic health records](#)
  - [NCIR Managing Inventory Best Practices](#)

**Important Notes:**
- If you plan to administer vaccines during scheduled maintenance outages, you must collect the CVMS required information offline and add it to the system when it is available again, within 72 hours from vaccine administration.
- 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:**
- [NC Vaccines HelpDesk Portal](#)
- [Tips for Preparing for First Vaccine Allocation](#)

14b. Transporting Vaccine

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

15. COVID-19 Vaccine Coding and Billing
• 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

Additional Resources:
16. Research of Interest

- Efficacy of a Fourth Dose of Covid-19 mRNA Vaccine against Omicron | NEJM
- Population Attributable Fraction of Non-Vaccination of Child and Adolescent Vaccines Attributed to Parental Vaccine Hesitancy, 2018–2019
- Durability of omicron-neutralising serum activity after mRNA booster immunisation in older adults - The Lancet Infectious Diseases
- Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant
- Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5–17 Years
- Hospitalization of Infants and Children Aged 0–4 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 2020–February 2022
- Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5–11 Years and Adolescents Aged 12–15 Years — PROTECT Cohort, July 2021–February 2022
- SARS-CoV-2 Incidence in K–12 School Districts with Mask-Required Versus Mask-Optional Policies — Arkansas, August–October 2021
- SARS-CoV-2 B.1.1.529 (Omicron) Variant Transmission Within Households — Four U.S. Jurisdictions, November 2021–February 2022
- Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5–17 Years — VISION Network, 10 States, April 2021–January 2022
- Diabetes & COVID-19: Scientists explore potential connection | AP News
17. 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.

Additional Resources:
• How to Submit a HelpDesk Case One-Pager
• CDC Learning Connection

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