Policy

The purpose of this policy is to delineate Steward Health Care’s Plan for ensuring the safety and protection of our patients and workforce from a COVID-19 infection. This plan complies with the Centers for Medicare & Medicaid Services (CMS) requirements to protect the health and safety of residents, clients, patients, and staff by implementing a COVID-19 vaccination requirement for institutions regulated by CMS.

Scope

This vaccination requirement applies to all current and new covered personnel/workforce, as defined below, working at Steward Health Care institutions regulated by CMS (acute care hospitals, long term care hospitals, LTC facilities & TCU) regardless of clinical responsibility or patient contact. The vaccination requirement also applies to certain individuals who enter a CMS regulated facility.

Definitions

Acceptable Exemptions: Recognized medical conditions where the vaccine is contraindicated, or where religious beliefs, observances, or practices prohibit the vaccination.

Centers for Medicare and Medicaid Services (CMS): is a Federal agency responsible for establishing health and safety regulations for Medicare and Medicaid-certified providers and suppliers

Covered Entity: for the purpose of this policy, a covered entity is defined as a CMS regulated facility (acute care hospitals, long term care hospitals, rehabilitation and long-term care facilities, and transitional care units). This policy does NOT apply to assisted living facilities, group homes, community-based services, or physician offices.

Covered Personnel: current and new staff working at a covered entity regardless of clinical responsibility or patient contact. This includes:

- Employees
- Licensed Practitioners
- Students and Trainees
- Volunteers
- Contracted Staff
- Steward employees and contractors who regularly work at a non-covered entity location (such as an office building not on a covered entity’s grounds), but who have cause to enter a covered entity for work-related reasons
- All individuals who enter a CMS regulated facility (exclusive of patients and visitors)
Excluded Personnel: This policy does not apply to staff who exclusively provide telework or telemedicine services outside of the facility setting and who do not have any direct contact with patients or other staff members, and staff who provide support services for the facility that are performed exclusively outside of the facility setting. In addition, “one-off vendors” who do not have any direct contact with patients or other staff members (see definition below) are also excluded from this policy.

Fully Vaccinated: defined as being 2 weeks or more since completion of a primary vaccination series, single dose vaccine, OR for the purpose of this regulation, have completed the primary series for the vaccine by the Phase 2 implementation date, even if they have not completed the 14-day waiting period.

One-Off Vendor: Individuals who infrequently provide an ad-hoc non health care service, provided they follow all precautionary source control directives.

Occupational Safety and Health Administration (OSHA): is a Federal agency responsible for setting and enforcing standards to ensure safe and healthy working conditions for workers.

Undue Hardship: defined as an “action requiring significant difficulty or expense” when considered in light of a number of factors. The factors include the nature and cost of the accommodation in relation to the size, resources, nature, and structure of the employer’s operation.

Vaccinator Providers: for purposes of this policy, the Vaccinator Providers are listed as Steward Health Care licensed hospitals designated to distribute vaccine for this program

Workforce Member: persons whose conduct, in the performance or work for a Steward Covered Entity, is under the control of such entity, including employees, students, residents, volunteers, trainees, Licensed Independent Practitioners, (LIPs), vendors, and contractors whether or not they are paid by the System.

Procedure

I. PLAN TO VACCINATE COVERED WORKFORCE

A. CORPORATE REQUIREMENTS/RESPONSIBILITIES

1. This Policy is divided into three sections:
   
   I. Plan to Vaccinate Covered Workforce

   II. Plan for Workforce Requested Exemptions and Accommodations for Those Exempt

   III. Plan for Tracking Workforce Compliance with Vaccinations and Exemptions

2. Steward Corporate Team will oversee the implementation of this policy to assure all covered Steward entities are in compliance, and to address issues related to non-compliance, exemptions, and tracking. The Steward Corporate Team will be led by the System Chief Medical Officer (CMO) and Executive Vice President of Human Resources and will include senior members of Employee Health, Pharmacy, Risk Management, Infection Control,
Regulatory Preparedness, Information Systems (IS), and Legal Counsel. The team will meet as needed to assure the following:

a. All covered Steward entities have received and adopted this policy.
b. Review regulatory updates from CMS or other agencies which may require policy revisions.
c. All Workforce members have been informed of the CMS COVID-19 vaccination mandate and have access to, or received a copy of, this policy.
d. Assemble a corporate team to review any requested clinical or religious exemptions that cannot be resolved at the covered entity level.

3. Steward Corporate Team will assure notification of all system contractors regarding the CMS COVID-19 vaccination mandate

4. Steward Corporate Human Resources, in conjunction with Information Systems, will develop and implement an electronic portal for the purpose of tracking compliance with the vaccination requirements delineated in this policy.

5. Corporate Infection Control directors in cooperation with facility Infection Control and Clinical Quality leaders will oversee the organization’s accommodations for exempt staff

6. Steward Corporate Regulatory personnel will oversee random audits to assure workforce members entering the covered entity are fully compliant with this policy.

7. Steward Corporate Pharmacy directors will be responsible for the procurement, storage, and distribution of vaccine to designated vaccination sites prior to the start date of vaccine clinics.

8. Corporate team’s role in reviewing exception requests:
   a. The System CMO, Chief of Infectious Diseases, System VP of Human Resources and legal counsel will review the following exemptions:
      i. Any requested exemptions referred from covered entities (e.g., appeals)
      ii. All exemptions denied at the local level

9. A HIPAA and ADA compliant portal is in place for covered workforce members to be tracked for compliance with the vaccine requirements. Corporate HR leadership will oversee the covered entities HR/Employee Health tracking and reporting process. Medical Staff members’ vaccination status will be tracked by the medical staff office director at each covered entity.
B. COVERED ENTITY ORGANIZATIONAL REQUIREMENTS/RESPONSIBILITIES

1. The Senior Leadership Team (SLT) at the covered entity will identify a team to oversee the implementation of this policy. Meeting frequency will be determined by the SLT to ensure all covered workforce members meet the vaccination requirements.

2. The covered entities Human Resource (HR) Department will maintain a weekly compliance report with a list of covered workforce members and vaccination status.

3. Covered entities will ensure that all contractors, volunteers, employees, students, trainees, Licensed Independent Practitioners, (LIPs), vendors, whether or not they are paid by the System, have received notice of vaccination mandate.

4. Each covered entity will be responsible for establishing local vaccination clinics, and/or providing workforce members with information regarding nearby locations where they can receive a COVID-19 vaccine.
   a. Vaccine clinic schedules will be available from Employee Health and will be communicated throughout the covered entity

5. Covered workforce members will be provided reasonable time to receive each vaccination dose, and paid sick leave to recover from any possible side effects experienced following vaccination, in accordance with federal mandates.

6. Any workforce member refusing vaccination and/or not receiving a clinical or religious exemption by December 5, 2021 may be subject to disciplinary action up to and including termination.

7. COVID-19 vaccination may be delayed if the workforce member has symptoms consistent with a COVID-19 infection or meets any of the criteria as defined in Appendix B Temporary Deferral Guidelines.
   a. Deferred workforce members will be notified by Employee Health when they are eligible to receive the vaccine.
   b. Workforce members who meet the deferral definition must receive the COVID-19 vaccine series after meeting the delayed timeframe as specified in Appendix B.
   c. During the deferral time, workforce members must adhere to all source-control guidelines listed in the accommodation section of the policy.

C. WORKFORCE MEMBERS REQUIREMENTS/RESPONSIBILITIES

1. All Steward workforce members will receive a copy of this policy outlining the individual’s obligation to comply with the following:
   a. As a condition of employment, appointment to the medical staff, participation in a residency program, student affiliate, contracted employee or volunteer, all covered workforce members (including the Active, Locum Tenens/Moonlighter, Active
Community and Allied Health Professionals) must be fully vaccinated with a FDA approved, or Emergency Use Authorization (EUA) approved dose(s) of a COVID-19 vaccine or must apply and be approved for a medical or religious exemption and if granted, follow mandatory accommodations.

b. A Booster vaccine is not currently required by this policy.

c. Additional COVID-19 Vaccine Information is available– Refer to Appendix A.

D. COVERED WORKFORCE UNVACCINATED PRIOR TO 12/05/2021

1. To be compliant with this policy, unvaccinated workforce members must receive the COVID-19 vaccine by December 5, 2021 based on the following schedule:
   - **Phase 1**: all covered workforce members must have received the first dose of a vaccine series or single-dose of an approved COVID-19 vaccine or have requested and received an exemption by December 5, 2021.
   - **Phase 2**: all covered workforce members must complete the primary vaccination series by January 4th, 2022 (except for those who have been granted exemptions from the COVID-19 vaccine or those for whom COVID-19 vaccination must be temporarily delayed).

2. For the purposes of this policy, covered workforce members who receive the second dose of a two-dose regimen by January 4th are considered to have met the vaccination requirement, even if they have not yet completed the 14-day waiting period. Workforce members must follow the additional precautions until the completion of the 14-day period.

3. The presence of antibodies after a COVID-19 infection does not meet this vaccination requirement, workforce members must still receive the vaccine even if they have had a COVID-19 infection in the past.

4. Workforce members hired on or after January 4th, 2022 must be compliant with the policy and the dates outlined above; or apply for a medical or religious exemption.

II. PLAN FOR WORKFORCE REQUESTED EXEMPTIONS

A. GENERAL

1. The CMS COVID-19 vaccine mandate requires covered entities to allow for exemptions for workforce members with recognized medical conditions and/or religious beliefs for which vaccines are contraindicated
2. Exemptions may be appropriate in certain limited circumstances, but no exemption should be provided to any workforce member for whom it is not legally required or who requests an exemption solely to evade vaccination

3. All requests for vaccination exemptions by employees must be submitted to the local HR Department no later than November 30, 2021 to allow the entity time to review, consider, and respond to the request.

4. All requests for vaccination exemptions by medical staff members/providers must be submitted to the local Medical Staff Office no later than November 30, 2021 to allow the covered entity to review, consider, and respond to the request.

5. Workforce members granted exemptions are responsible for complying with accommodation guidelines for minimizing the risk of transmission of COVID-19 to at risk individuals (see Accommodations).

B. MEDICAL EXEMPTIONS

1. Employee’s requests for a medical exemption must be made in writing, utilizing the attached form, and submitted to the covered entity’s local Human Resource Department by the date noted above on II.A.3.

2. Medical staff request for a medical exemption must be made in writing, utilizing the attached form and submitted to the covered entity’s local Medical Staff Office by the date noted above on II.A.4.

3. The medical exemption request documentation must contain information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the workforce member; the recognized clinical reasons for the contraindication; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility’s COVID-19 vaccination requirements.

4. The medical exemption must be accompanied by documentation signed and dated by a licensed practitioner who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. (See Attachment A: COVID-19 Medical Exemption Request Form).

5. Medical exemptions will be reviewed and decided at the facility level by the Chief Medical Officer (CMO) or designated physician leader. Decisions requiring additional review or denials of exemptions will be elevated to a corporate clinical team led by the system CMO.

6. Appeals process- all appeals and denied medical exemptions will be reviewed by a corporate team led by the system CMO and Executive VP for Human Resources whose decision will be final.

---

1 ADA or Title VII or the Civil Rights Act of 1964

Disclaimer: The electronic version of this policy is considered to be the controlled version. Printed copies are considered uncontrolled documents. Before using a printed copy, verify that it is the current version.
7. All approved and/or denied medical exemptions will be communicated in writing to the covered workforce member and a copy of the request form and decision will be placed in the employee health file or Medical Staff personnel file.

C. RELIGIOUS EXEMPTIONS

1. Requests for Religious Exemptions must be made in writing, utilizing the approved form, and submitted to the Human Resource Department or for medical staff members/providers, to the Medical Staff Office by the established date above to allow for review, consideration, and response. (See Attachment B: COVID-19 Vaccine Religious Accommodation Request Form)

2. All approved or denied religious exemptions will be communicated in writing to the covered workforce member and a copy placed in the employee health file or the Medical Staff personnel file.

3. Appeals process- all appeals and denied religious exemptions will be reviewed by a corporate team led by the Executive VP for Human Resources and system CMO whose decision will be final.

4. Additional information regarding the religious exemption process can be found on Appendix C.

D. ACCOMMODATIONS FOR MEDICAL AND RELIGIOUS EXEMPT WORKFORCE MEMBERS

1. Any workforce member who is unable to receive the COVID-19 vaccine due to an approved religious or medical exemption will be subjected accommodations as determined by the local entity’s Employee Health policy. Potential accommodations could include but are not limited to frequent COVID-19 testing, additional PPE requirements, physical distancing protocols, and other source control mandates. Accommodations for any workforce member may be amended or terminated, at Steward’s sole discretion, at any point, based upon government guidance and regulation, best practices, and/or Steward’s ongoing response to the pandemic.

2. Accommodations will not include access to remote work for workforce members whose duties require onsite presence to perform job related responsibilities. 3. Individual entities reserve the right to terminate the employment of a workforce member who is unable to receive the COVID-19 vaccine, where such workforce member may pose an undue risk of transmission of COVID-19 to a facility’s patients, staff, visitors, or employees or where accommodations pose an undue hardship.
III. PLAN FOR TRACKING WORKFORCE COMPLIANCE WITH VACCINATION AND EXEMPTIONS

A. LEADERSHIP TEAM

1. For the purpose of this policy, each covered entity’s ELT is required to keep a record of the following:
   a. Vaccination status of each workforce member
   b. Workforce members for whom there is a temporary delay in vaccination, such as recent COVID-19 symptoms, receipt of monoclonal antibodies or convalescent plasma
   c. Medical exemption requests and documented approvals and denials outcomes
   d. Religious exemption requests and documented approvals and denials
   e. Assuring medical and religious exemption forms are uploaded to the portal
   f. For contracted services, students, and other agency covered workforce members: the agency will be required to provide a guarantee of compliance with the CMS mandated COVID-19 vaccination requirement
   g. Maintaining and submitting weekly staff vaccination rates and exemptions granted/denied
   h. Maintaining vaccination information available for regulatory agencies upon request
   i. Maintaining all information in a confidential fashion and stored separately from an employer’s personnel files, pursuant to ADA and Rehabilitation Act.

B. VACCINATED WORKFORCE MEMBER RESPONSIBILITIES

1. Covered workforce members who are fully vaccinated with an approved COVID-19 vaccine must provide acceptable forms of documentation no later than December 5, 2021. Acceptable forms of vaccination documentation include:
   a. CDC COVID-19 vaccination record card (or legible photo of the card)
   b. Documentation of vaccination from a health care provider or electronic health record including provider’s signature
   c. State immunization information system record
   d. A copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s).
e. If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples

f. In instances where an employee is unable to produce acceptable proof of vaccination, per above, a signed and dated statement by the employee, subject to criminal penalties for knowingly providing false information, attesting to their vaccination status (fully vaccinated or partially vaccinated), and attesting that they have lost and are otherwise unable to produce proof required by this policy, will be acceptable.

g. For personnel receiving the optional COVID-19 booster, documentation should be submitted following the same process outlined below.

h. Submission of proof of vaccination (due December 5th, 2021) can be accomplished by the following methods:

   • Emailing a copy of the vaccine card to Covid.vax@steward.org with the following information:
     o Full name
     o Date of Birth (day/month/year)
     o Name of Steward entity where employed
     o If you do not work at a hospital, please list where your work (i.e., SHCN, SMG, Corporate Offices)

   • Bringing a copy of the vaccine card to the Employee Health Office or Medical Staff Office at the local entity

i. Verbal, text and/or telephonic communication of compliance with vaccination requirement is not acceptable.

C. Data Submission

   1. Vaccination data will be entered and stored in the Steward COVID portal

   2. Data Submission to state, federal or other regulatory agencies will be completed in accordance with the individual regulatory agency requirements

D. Recordkeeping

   1. Records are maintained in accordance with Hospital or Steward entity’s policy and procedures for the duration of employment plus 30 years.

   2. Employee COVID-19 Vaccine Education/Consent Forms will be collected by Employee Health and filed in the Employee’s Health record.
3. Medical Staff COVID-19 Vaccine Education/Consent Forms if collected by Employee Health will be forwarded to the MSO/CVO, as appropriate, and will be filed in the provider’s health record.

E. Enforcement

1. Workforce members who fail to comply with the vaccination requirements outlined in this policy will be subject to disciplinary procedures established by their respective Steward entity, as it relates to conditions of employment, appointment to the medical staff, or access to the Steward entity, up to and including termination.

2. Covered workforce members will be removed from the schedule without pay until proof of completion has been received by the local entity’s Employee Health office.

3. Providers / medical staff members must comply with applicable laws and policies. Providers who have not complied with the vaccine requirements of this policy will be subject to disciplinary actions consistent with existing Medical Staff Bylaws which may include revocation of medical staff privileges.

4. Any workforce members who provide knowingly false or incorrect information concerning COVID-19 vaccination status or exclusions will be subject to disciplinary action up to and including termination; or for medical staff members, disciplinary action as delineated by Medical Staff policy.

Attachments

Attachment A: Steward Health Care Medical Exemption Request Form
Attachment B: Steward Health Care Religious Exemption Request Form
Attachment C: MODERNA COVID-19 Fact Sheet for Recipients and Caregivers (10/20/2021)
Attachment D: PFIZER-BIONTECH COVID-19 Fact Sheet for Recipients and Caregivers (8/23/2021)
Attachment E: JANSSEN COVID-19 Fact Sheet for Recipients and Caregivers (10/20/2021)
Attachment F: COVID 19 Vaccine/Booster Consent Form
Attachment G: COVID-19 Post Immunization Information
Attachment H: COVID-19 Vaccination Status for Healthcare Personnel
Appendix A: COVID-19 Vaccine Information
Appendix B: COVID-19 Vaccine Temporary Deferral Guidelines
Appendix C: Religious Exemption Process

Disclaimer: The electronic version of this policy is considered to be the controlled version. Printed copies are considered uncontrolled documents. Before using a printed copy, verify that it is the current version.
References


Centers for Disease Control and Prevention (CDC). Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, retrieved at Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States - FactSheet (cdc.gov)


Review and Approval

The following Steward Health Care System personnel originated and approved this policy:

<table>
<thead>
<tr>
<th>Date</th>
<th>Contact</th>
<th>Approved By</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/12/2021</td>
<td>Human Resources</td>
<td>Steward Clinical Excellence Committee</td>
<td>New Update 11/17/2021- Updated Attachment B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Steward Health Care Religious Exemption Request Form.</td>
</tr>
</tbody>
</table>

Disclaimer: The electronic version of this policy is considered to be the controlled version. Printed copies are considered uncontrolled documents. Before using a printed copy, verify that it is the current version.
COVID 19 VACCINE MEDICAL EXEMPTION REQUEST FORM

To request a medical exemption from the COVID-19 required vaccination, please complete Section 1 below and have your medical provider complete Section 2 before returning this form to your local Human Resources department.

Section 1

<table>
<thead>
<tr>
<th>Name (print):</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.O.B.</td>
<td>Position:</td>
</tr>
<tr>
<td>Manager:</td>
<td>Dept.:</td>
</tr>
<tr>
<td>Facility:</td>
<td>Work/Cell Phone:</td>
</tr>
</tbody>
</table>

I am requesting a medical exemption from Steward Health Care’s mandatory vaccination policy for the COVID-19 vaccination due to:

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

I verify that the information I am submitting to substantiate my request for exemption from Steward Health Care’s COVID-19 vaccination policy is true and accurate to the best of my knowledge. I understand that any falsified information can lead to disciplinary action, up to and including termination.

I further understand that Steward Health Care is not required to provide this accommodation if doing so would pose a direct threat to patients or others in the workplace or would create an undue hardship for Steward Health Care (as defined by state and federal law).

I authorize my health care provider(s) to release the following information from my patient file for the purpose of determining an accommodation related to the required COVID-19 vaccine.

<table>
<thead>
<tr>
<th>Employee Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>
Section 2

Medical Certification for Vaccination Exemption

Employee Name: ___________________________________________

Dear Medical Provider,

Steward Health Care requires vaccination against COVID-19 as a condition of employment. The individual named above is seeking an exemption to this policy due to medical contraindications.

Please complete this form to assist Steward Health Care in the exemption review process.

1.) Identify which of the authorized COVID-19 vaccines are clinically contraindicated for the employee:

2.) Identify the recognized clinical reasons for the contraindication:

This exemption should be:

- Temporary, expiring on: __/__/____, or when ______________________________.
- Permanent.

I certify the above information to be true and accurate and that I am acting within the scope of my practice based on applicable state and local laws, and I hereby request exemption from the COVID-19 vaccination for the above-named individual.

Medical Provider Name (print):

Medical Provider Signature: Date:

Practice Name & Address: Provider Phone:
Date of initial request: __/__/____  Date certification received: __/__/____

Interactive Process discussion date and details (if applicable): ______________________________________

Accommodation request:

• Approved __/__/____

Describe specific accommodation details: _______________________________________________________

• Denied __/__/____

Describe why accommodation is denied: _______________________________________________________

Name of HR Representative: ________________________________________

Signature of HR Representative: ________________________________________

Date: _______________
COVID-19 Vaccine Religious Exemption Request Form

To request a religious exemption from the COVID-19 required vaccination, please complete Section 1 below and return this form to your local Human Resources department.

**Part 1: To be completed by employee**

Name: ___________________________ Department: ___________________ Position: _________________

Date of request: ______________________________________

Immediate supervisor: ________________________________

Requested exemption details (COVID-19 vaccination exemption):

_____________________________________________________________________________________

_____________________________________________________________________________________

Length of time the exemption is needed: _________________________________

Describe the religious belief or practice that necessitates this request for exemption:

_____________________________________________________________________________________

_____________________________________________________________________________________

Describe any alternate accommodations that might address your needs:

_____________________________________________________________________________________

_____________________________________________________________________________________

I have read and understand Steward Health Care’s COVID-19 policy. My religious beliefs and practices, which result in this request for a religious exemption, are sincerely held. I verify that the information I am submitting in support of my request for an exemption is complete and accurate to the best of my knowledge.

I further understand that the exemption requested above may not be granted but that the company will attempt to provide a reasonable accommodation that does not create an undue hardship and/or does not pose a direct threat to the health and/or safety of patients and/or others in the workplace. I understand that Steward Health Care may request supporting documentation to further evaluate this religious exemption.

Employee signature: _________________________________ Date: _________________
Part 2: To be completed by Human Resources

Describe the requested accommodation:

_____________________________________________________________________________________
_____________________________________________________________________________________

Evaluation of impact (if any): _____________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

Approved: _____________ Denied: _______________

If the requested exemption is denied, what are some alternative accommodations (list in order of preference):

1. ____________________________________________________________________________
2. ____________________________________________________________________________
3. ____________________________________________________________________________

Date discussed with employee:  ____________________________________________

Final accommodation agreed upon: _________________________________________

If no agreement on an accommodation, provide an explanation:

_____________________________________________________________________________________
_____________________________________________________________________________________

Human resources director or designee name: _____________________________

Human resources director or designee signature: __________________________

Date: _____________
FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF
THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine has received EUA from FDA to provide:

- a two-dose primary series to individuals 18 years of age and older;
- a third primary series dose to individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose to the following individuals who have completed a primary series with the Moderna COVID-19 Vaccine:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose to certain individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.
WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?
Tell your vaccination provider about all of your medical conditions, including if you:

• have any allergies
• have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
• have a fever
• have a bleeding disorder or are on a blood thinner
• are immunocompromised or are on a medicine that affects your immune system
• are pregnant or plan to become pregnant
• are breastfeeding
• have received another COVID-19 vaccine
• have ever fainted in association with an injection

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?
FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?
You should not get the Moderna COVID-19 Vaccine if you:

• had a severe allergic reaction after a previous dose of this vaccine
• had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?
The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

Primary Series: The Moderna COVID-19 Vaccine is administered as a 2-dose series, one month apart. A third primary series dose may be administered at least one month after the second dose to individuals who are determined to have certain kinds of immunocompromise.
Booster Dose:

- A single booster dose of the Moderna COVID-19 Vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

- A single booster dose of the Moderna COVID-19 Vaccine may be administered to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?
The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine. Millions of individuals have received the vaccine under EUA since December 18, 2020.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?
In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart
Side effects that have been reported in clinical trials with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, and rash

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

**WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html). Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.
ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving Moderna COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third primary series dose of the Moderna COVID-19 Vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine website</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
<td>1-866-MODERNA</td>
</tr>
<tr>
<td></td>
<td>(1-866-663-3762)</td>
</tr>
</tbody>
</table>
HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of
these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Moderna US, Inc.
Cambridge, MA 02139

©2021 ModernaTX, Inc. All rights reserved.
Patent(s): www.modernatx.com/patents
Revised: Oct/20/2021
You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.
- It is also authorized under EUA to be administered to:
  - prevent COVID-19 in individuals 12 through 15 years, and
  - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to:

- prevent COVID-19 in individuals 12 years of age and older, and
- provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine are administered as a 2-dose series, 3 weeks apart, into the muscle.

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.
Under EUA for individuals who are determined to have certain kinds of immunocompromise, a third dose may be administered at least 4 weeks after the second dose.

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?
COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.¹

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

¹ The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.
WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD GET THE VACCINE?
FDA has approved COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 16 years of age and older and has authorized it for emergency use in individuals 12 through 15 years.

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

WHO SHOULD NOT GET THE VACCINE?
You should not get the COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?
COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine include the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediy)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE VACCINE GIVEN?
COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the vaccine, you should receive a second dose of the vaccine 3 weeks later to complete the vaccination series.
HAVE COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020.

WHAT ARE THE BENEFITS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?
The vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
• muscle pain
• chills
• joint pain
• fever
• injection site swelling
• injection site redness
• nausea
• feeling unwell
• swollen lymph nodes (lymphadenopathy)
• diarrhea
• vomiting
• arm pain

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either “COMIRNATY (COVID-19 Vaccine, mRNA)” or “Pfizer-BioNTech COVID-19 Vaccine EUA”, as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

<table>
<thead>
<tr>
<th>Website</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
</table>

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.
WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose or if you have certain kinds of immunocompromise, your third dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.
ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<table>
<thead>
<tr>
<th>Global website</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></td>
<td>1-877-829-2619</td>
</tr>
<tr>
<td></td>
<td>(1-877-VAX-CO19)</td>
</tr>
</tbody>
</table>

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the
date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Manufactured by
Pfizer Inc., New York, NY 10017

BioNTech
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-7.2

Revised: 23 August 2021
FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine has received EUA from FDA to provide:

• A single dose primary vaccination to individuals 18 years of age and older.

• A single booster dose to individuals 18 years of age and older who have completed a primary vaccination with Janssen COVID-19 Vaccine.

• A single booster dose to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.
The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,
- have ever fainted in association with an injection.

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.
HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

**Primary Vaccination:** The Janssen COVID-19 Vaccine is administered as a **single dose**.

**Booster Dose:**

- A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose of the Janssen COVID-19 Vaccine may be administered to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding eligibility for and timing of the booster dose.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In clinical trials, more than 61,000 individuals 18 years of age and older have received at least 1 dose of the Janssen COVID-19 Vaccine. Millions of individuals have received the vaccine under EUA since February 27, 2021.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine has been shown to prevent COVID-19. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.
- Swollen lymph nodes.
- Blood clots.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

**Severe Allergic Reactions**

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after
getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

**Blood Clots with Low Levels of Platelets**

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote.

You should seek medical attention right away if you have any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

**Guillain Barré Syndrome**

Guillain Barré syndrome (a neurological disorder in which the body’s immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur
very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that’s worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

**WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to [FDA/CDC Vaccine Adverse Event Reporting System (VAERS)](https://vaers.hhs.gov/reportevent.html). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

<table>
<thead>
<tr>
<th>e-mail</th>
<th>Fax number</th>
<th>Telephone numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:JNJvaccineAE@its.jnj.com">JNJvaccineAE@its.jnj.com</a></td>
<td>215-293-9955</td>
<td>US Toll Free: 1-800-565-4008</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US Toll: (908) 455-9922</td>
</tr>
</tbody>
</table>

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?**

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.
ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

<table>
<thead>
<tr>
<th>QR Code</th>
<th>Fact Sheets Website</th>
<th>Telephone numbers</th>
</tr>
</thead>
</table>

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
Contact your local or state public health department.

**WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

**CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

**WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

**WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

**WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.
The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

© 2021 Janssen Pharmaceutical Companies

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: 10/20/2021
EMPLOYEE HEALTH CONSENT FOR COVID-19 VACCINE

<table>
<thead>
<tr>
<th>Name: (PLEASE PRINT CLEARLY)</th>
<th>(PLEASE CHECK WHICH APPLIES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Employee □ Medical Staff □ Student □ Other:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth (REQUIRED):</th>
<th>Hospital Name/Affiliated/Practice/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Department:</td>
</tr>
</tbody>
</table>

1. **SELECT EITHER “A” OR “B” BELOW**
   
   **A. Initial COVID vaccine regimen** – CHECK ONE, this is your: □ First □ Second dose
   
   If this is your second dose, please provide the vaccine name and the date of the first dose
   
   □ Pfizer-BioN Tech □ Moderna □ Janssen □ Don’t Know
   
   Date: ________ Date: ________ Date: ________

   **B. BOOSTER Dose** – PLEASE CHECK if receiving a COVID Booster □
   
   Please provide the vaccine name and the date of the second dose of Pfizer/Moderna or single dose of Janssen
   
   □ Pfizer-BioN Tech □ Moderna □ Janssen
   
   Date: ________ Date: ________ Date: ________

2. I understand that I have to wait at least six (6) months after receiving my second dose of Moderna/Pfizer and two (2) months after receiving a single dose of Janssen to be eligible for a booster vaccine.

3. I understand that this vaccine has been granted an Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) and the Advisory Committee on Immunization Practices (ACIP) has recommended the use of the vaccine.

4. I have been provided the FACT SHEET FOR RECIPIENTS AND CAREGIVERS – EMERGENCY USE AUTHORIZATION (EUA) OF THE FOLLOWING VACCINE:
   
   □ Pfizer-BioN Tech □ Moderna □ Janssen

**TO PREVENT CORONAVIRUS DISEASE 2019 (“FACT SHEET”)** provides important information about the vaccine I receive.

5. I understand that I must wait to receive the vaccine if any of the following apply to me:
   
   • I have a fever
   • I have received monoclonal antibody treatment for COVID-19 infection
   • The brand of the COVID-19 vaccine you need is not available; or
   • I have any sickness or illness for which my primary care physician recommends that I do not receive the vaccine.

6. I understand that if I have any questions about the vaccine, or the information in the FACT SHEET, I have had the opportunity to speak with my personal physician before receiving the vaccine. I agree to being immunized if any of these conditions apply to me:
   
   • I have any allergies
   • I have a bleeding disorder or am on a blood thinner
   • I am immunocompromised or am on a medicine that affects my immune system
   • I am pregnant or plan to become pregnant; or
   • I am breast-feeding.
ACKNOWLEDGEMENT AND CONSENT

I have been provided the **FACT SHEET** corresponding to this vaccine that I am receiving, and I have read the information provided about the vaccine that I will receive. I have had the opportunity to discuss with my personal physician all the information provided to me in the **FACT SHEET**, including the medical conditions identified above, and I have had the chance to ask questions that were answered to my satisfaction. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccines. I further understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand I should remain in the vaccine administration clinic for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand that if I experience serious side effects, I should call my physician or 911. I understand that I must report any side effects to the Hospital where I received this vaccine (see Post Vaccination Information Sheet for details).

At this time, I request the COVID-19 Vaccine or Booster be given to me

<table>
<thead>
<tr>
<th>NAME OF HEALTHCARE WORKER</th>
<th>SIGNATURE</th>
<th>DATE/TIME</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NAME OF WITNESS</th>
<th>SIGNATURE</th>
<th>DATE/TIME</th>
</tr>
</thead>
</table>

Interpreter and/or Translation Services was offered and provided to me:  □ YES  □ NO  □ NA

<table>
<thead>
<tr>
<th>INTERPRETER NAME</th>
<th>SIGNATURE</th>
<th>DATE/TIME</th>
</tr>
</thead>
</table>
COVID-19 Post Vaccination Guidance

Please review the FACT SHEET FOR RECIPIENTS AND CAREGIVERS (‘FACT SHEET’) provided for all necessary information you will need in the following weeks.

ADVERSE REACTION RECOGNITION AND REPORTING

1. Although unlikely, if you have any of the following:
   - Difficulty breathing
   - Swelling of your face and throat
   - A fast heartbeat
   - A bad rash all over your body
   - Dizziness and weakness

   **CALL 9-1-1, or go the nearest hospital**
   Please call Employee Health at your Hospital to let them know as soon as possible

2. A list of common side effects that may occur is also noted in the FACT SHEET. It is important that you contact Employee Health for the following situations:

   - **SITUATION #1**: If you develop persistent systemic symptoms consistent with COVID-19 illness after immunization (cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) please call Employee Health at your Hospital before coming into your next scheduled shift.

   - **SITUATION #2**: If you develop any systemic signs and symptoms that last more than 48 hours post vaccination (fever, fatigue, headache, chills, myalgia, arthralgia), please call Employee Health at your Hospital before coming into your next scheduled shift.

2. The CDC is offering a smartphone-based tool called v-safe that uses text messaging and web surveys to provide personalized health check-ins after you receive your first COVID 19 Vaccine. Once you receive your first vaccine, you can enroll in v-safe using your smartphone - see attached V-Safe Instruction sheet.

3. Alternatively, you may report your side effects directly to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include “PFIZER BioNTech COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

NEXT SCHEDULED DOSE

1. **If Your Second DOSE appointment has been scheduled**- be sure to attend this appointment. If you have had a reaction to the first and decide not to attend your second appointment, PLEASE CALL YOUR HOSPITAL VACCINE CLINIC to let them know. The Phone number will be listed on your confirmation email for your second appointment.

2. Be sure to bring your COVID-19 Vaccination Card to your next scheduled appointment.

3. Questions may be referred to your local Employee Health office who may be able to assist you or you may send in a question to: COVIDquestions@steward.org
<table>
<thead>
<tr>
<th>Post-vaccination Reaction/Symptoms</th>
<th>Notification of EMPH</th>
<th>SARS-CoV-2 PCR Test Required</th>
<th>Work restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local injection site reaction only (i.e., redness or swelling at the injection site)</td>
<td>Not required.</td>
<td>No</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Mild allergic symptoms (i.e., pruritis/itching, rash but NOT hives) that occur after observation period</td>
<td>Not required; HCP can contact EMPH with questions or concerns.</td>
<td>No</td>
<td>No restrictions</td>
</tr>
<tr>
<td>More severe allergic reactions including hives; swollen lips, tongue, eyes, or face; wheezing, chest tightness, or shortness of breath, that occur after observation period and ≤ 3 days after vaccination</td>
<td>Yes</td>
<td>No</td>
<td>Contact Employee Health for return to work clearance if symptoms resulted in work absence.</td>
</tr>
</tbody>
</table>
| Mild to moderate post-vaccination symptoms ≤ 3 days post-vaccination, including the following:  
  • mild symptoms < 101F  
  • mild headache  
  • mild fatigue characterized by sense of tiredness  
  • mild myalgias (muscle aches)  
  • mild arthralgias (joint pains) | Yes | Yes | Able to work wearing appropriate PPE while PCR test is pending |
| Severe symptoms ≤ 3 days post-vaccination, including the following:  
  • fever ≥ 101°F or  
  • severe headache or  
  • severe fatigue characterized by sense of exhaustion leading to curtailment of daily activities or  
  • severe myalgias (muscle aches) or  
  • severe arthralgias (joint pains) or any other symptoms consistent with COVID-19 | Yes | Yes | Restricted from on-site work pending COVID-19 test results and suggest follow up with health care provider |
| ≥ 3 days post-vaccination, any symptoms consistent with COVID-19 | Yes | Yes | Restricted from onsite work pending COVID-19 test results and 24 hours post symptom resolution |
Appendix A
COVID-19 Vaccine Information

I. Definitions

Advisory Committee on Immunization Practices (ACIP): The Advisory Committee on Immunization Practices, is a committee within the United States Centers for Disease Control and Prevention that provides advice and guidance on effective control of vaccine-preventable diseases in the U.S. civilian population.

Janssen COVID-19 Vaccine is for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a recombinant, replication-incompetent human adenovirus serotype 26 (Ad26) vector, encoding the SARS-CoV-2 viral spike (S) glycoprotein, stabilized in its pre-fusion form.

Messenger RNA (mRNA) Vaccine: vaccines that take advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to COVID-19. mRNA vaccines DO NOT contain a live virus, carry a risk of causing infection in the vaccinated person, or enter the nucleus of the cell or affect or interact with a person’s DNA.

Moderna COVID-19 Vaccine is for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles.

Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles.

II. Acceptable Vaccines and Vaccine Schedules

a. Any vaccine that is currently licensed or authorized for emergency use by the US Food and Drug Administration (FDA) and/or the World Health Organization is considered acceptable. This currently includes the Pfizer-BioNTech COVID-19 vaccine (interchangeable with the licensed Comirnaty vaccine), Moderna COVID-19 Vaccine, and the Janssen (Johnson & Johnson) COVID-19 Vaccine.

b. This requirement will be met for workforce member who received a vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or who received a vaccine during their participation in a clinical trial vaccinated outside US for recommendation

c. Recommended vaccines, vaccine schedules, and vaccine administration requirements are per the CDC’s Advisory Committee on Immunization Practices (ACIP) including the definitions of full vaccination.
III. Contraindications for receiving the COVID-19 vaccine may include the following

a. MODERNA COVID-19 Vaccine Contraindications
   - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of this COVID-19 vaccine
   - Known (diagnosed) severe allergic reaction of any severity to any component of this vaccine

b. The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimeristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

c. PFIZER COVID-19 Vaccine Contraindications
   - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of this vaccine
   - Known (diagnosed) severe allergic reaction of any severity to any ingredient of this vaccine

d. The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ([(4-hydroxybutyl)azanediyl]bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

e. JANSSEN COVID-19 Vaccine Contraindications
   - Severe allergic reaction (of any severity) to any ingredient of this vaccine

f. The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

g. For questions regarding Clinical Contraindications refer to the CDC Summary Document for Interim Clinical Consideration for the use of COVID-19 vaccines currently available in the US. [https://www.cdc.gov/vaccine/covid-19/downloads/summary-interim-clinical-considerations.pdf](https://www.cdc.gov/vaccine/covid-19/downloads/summary-interim-clinical-considerations.pdf)

IV. Workforce members with the following allergy history should be provided counseling prior to vaccine administration

a. History of severe allergic reaction (anaphylaxis) to a vaccine; 30-minute post-vaccination observation required

b. History of a severe allergic reaction (anaphylaxis) to polyethylene glycol (PEG) or PEG-containing products such as Miralax or an injectable steroid: pre-vaccination virtual and/or in-person allergy evaluation required

c. History of a severe allergic reaction (anaphylaxis) to polysorbate or polyoxyl 35 castor oil (e.g., paclitaxel) containing injectable or vaccine: consider pre-vaccination e-consult or virtual allergy visit at HCP’s discretion

d. History of a severe allergic reaction (anaphylaxis) to another antigen (e.g., food, medication, venom, latex): 30-minute post-vaccination observation required
e. History of severe allergic reaction to specific formulation of COVID-19 vaccine after receipt of the vaccine; pre-vaccination virtual and/or in-person allergy evaluation required

V. Immunization Schedule

a. The COVID-19 vaccine will be administered intramuscularly in the deltoid
   1. Janssen is given as a one-dose vaccine
   2. As a 2-dose series following the schedule below:
      o Moderna – 2 doses, 1 month apart
      o Pfizer – 2 doses, 3 weeks apart
          • If the second dose is not given within the timeframes listed above, it should be given as soon as possible

VI. Side effects of the COVID-19 Immunization

a. Vaccine side effects may occur. But for most people, these side effects are mild to moderate, and should dissipate on their own in a few days.

b. The most common side effects are:
   • Injection site pain
   • Fatigue
   • Headache
   • Muscle pain
   • Chills
   • Joint pain
   • Fever
   • Injection site swelling
   • Injection site redness
   • Nausea/ Vomiting
   • Malaise
   • Lymphadenopathy (particularly axillary, in vaccination arm)

c. Throughout the safety follow-up period, there were 3 reports of Bell’s palsy (facial nerve paralysis) in the vaccine group and 1 in the placebo group; there is insufficient data to determine a potential contribution of the vaccine.

d. Side effects may be more noticeable than side effects from other adult vaccines (e.g., Pneumovax, Influenza)

e. Side effects may be more likely after the second dose of the vaccine.

f. Additional side effects may be noted after wide distribution of the vaccine.

g. HCP should report adverse events to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967 or www.vaers.hhs.gov
VII. Pre-Vaccination Information

a. Pre-vaccination will be provided via the vaccination-specific Fact Sheet.
   • Additionally, personnel will be advised that the COVID-19 vaccination is required, and that
     immunity may not be effective for approximately two weeks following vaccination.
   • Personnel may be provided with any additional educational information provided by regulating
     agencies as deemed appropriate

VIII. Vaccine Administration

1. COVID-19 vaccine(s) will be administered according to the recommended schedule and
   vaccine administration guidelines.
   a. A copy of the MODERNA COVID -19 Fact Sheet for Recipients and Caregivers –
      ATTACHMENT C will be provided to all candidates prior to receiving the MODERNA
      COVID-19 Vaccine.
   b. A copy of the PFIZER-BIONTECH COVID-19 Fact Sheet for Recipients and Caregivers –
      ATTACHMENT D will be provided to all candidates prior to receiving the PFIZER
      BIONTECH COVID-19 Vaccine
   c. A copy of the JANSSEN COVID-19 Fact Sheet for Recipients and Caregivers
      ATTACHMENT E will be provided to all candidates prior to receiving the JANSSEN COVID-
      19 Vaccine
   d. A copy of the COVID 19 Vaccine/Booster Consent Form will be provided and must be read and
      signed prior to receiving the vaccine, after showing proof of receiving a previous COVID-19
      vaccine, or if providing proof on an acceptable contraindication - ATTACHMENT F.
   e. A copy of the COVID-19 Post Immunization Information will be provided to all recipients of
      vaccine- this will include V-Safe information sheet – ATTACHMENT G.
   f. HCP will be required to wear mask and eye protection and maintain social distancing at all
      times.
   g. HCP will be monitored for 15 minutes after vaccine administration for signs/symptoms.
   h. Once the monitoring period has elapsed, the HCP will be given a follow up appointment date
      and time for their second dose along with instructions to report any adverse reaction that may
      occur after leaving the vaccination clinic.
   i. The second dose must be given within the specified timeframe according to the vaccine
      manufacturer’s instructions.

2. Health Care Personnel (under the age of 18) will be referred to their Primary care Provider (PCP)
   for COVID-19 Vaccination. Steward Health Care will reimburse the employee for cost of the office
   visit fee if applicable.

3. Employees should report possible reactions and symptoms to EMPH. Restrictions from work
   depend on both the type of possible post-vaccination reactions and symptoms of timing of onset
   relative to vaccination (Refer to ATTACHMENT H, COVID-19 Vaccination Status
   for Healthcare Personnel)
Appendix B
COVID-19 Vaccine Temporary Deferral Guidelines

I. Indications for temporary deferral of COVID-19 vaccination may be made under the following conditions.
   
a. Prior infection with SARS-CoV-2. Prior infection with SARS-CoV-2 is not a contraindication, however, HCP must have recovered from illness and be cleared for return to work prior to vaccine administration and have associated infection statuses resolved by EMPH prior to vaccination.

b. Receipt of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment in the prior 90 days. Vaccination should be deferred for at least 90 days after receiving monoclonal antibodies or convalescent plasma. There is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

c. History of Multi-System Inflammatory Syndrome in Adults (MIS-A). A history of MIS-A is not a contraindication, however, workforce members with a history of MIS-A should discuss with their provider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

d. Vaccination for COVID-19 during the quarantine period. Workforce members who are within the quarantine period after a confirmed exposure must defer vaccination until the exposure window has concluded and COVID-Exposed is auto-resolved based on time criteria. Note that EMPH will only manually resolve this infection status when appropriate if it will impact timing of the COVID-19 vaccine dose.

e. Symptoms consistent with COVID-19 on the day of scheduled vaccination. On the day of scheduled vaccination, workforce members must attest to lack of symptoms consistent with COVID-19. If HCP have symptoms consistent with COVID-19, vaccination must be deferred pending evaluation by EMPH.

f. Workforce members with evaluation for symptoms consistent with COVID-19 in prior 10 days. Workforce members who are undergoing or who have undergone an evaluation for symptoms consistent with COVID-19 in the prior 10 days must defer vaccination until the risk is auto-resolved. Note that EMPH will only manually resolve this infection status if appropriate if it will impact timing of the COVID-19 vaccine dose.
Appendix C

Religious Exemption Process

a. Under Title VII of the Civil Rights Act, Steward Health Care will assume that a request for religious accommodation is based on sincerely held religious beliefs. However, if an employer has an objective bases for questioning either the religious nature or the sincerity of a particular belief, Steward will be justified in making a limited factual inquiry and seek additional supporting information.

b. If Steward Health Care demonstrates that it is unable to reasonable accommodate an employee’s religious belief without an “undue hardship” on its operations, then Title VII does not require the employer to provide the accommodation.

c. Steward will thoroughly consider all possible reasonable accommodations, including telework and reassignment (when applicable).