COVID-19 Vaccine Guidance

Federal Bureau of Prisons Clinical Guidance

February 25, 2022

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What's New

- ***Updates for moderately or severely immunocompromised persons:*** These individuals should receive an additional primary series vaccination dose (i.e., a total of three COVID-19 mRNA primary vaccine doses *OR* a Janssen COVID-19 vaccine followed by a COVID-19 mRNA vaccine dose) in addition to a booster dose. The length of time between the final dose of the COVID-19 primary vaccination series and booster dose is shortened to 3 months.
- Addition of references to the FDA-approved Moderna COVID-19 vaccine, Spikevax®
- Clarification of the following terms:
  - An individual is considered **FULLY VACCINATED**, if they have completed a primary COVID-19 vaccination series
  - An individual is considered **UP TO DATE** on COVID-19 vaccinations, if they have completed a primary vaccination series along with any recommended booster doses for which they are eligible.
- Clarification that institutions will provide inmates their ***CDC COVID-19 vaccination card*** as proof of vaccination upon release.
- Removal of the requirement to delay COVID-19 vaccination following administration of monoclonal antibodies.
- Administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after vaccination
- Update regarding multisystem inflammatory syndrome in adults (MIS-A) and the use and timing of COVID-19 vaccination in those who develop MIS-A.
- ***Medical holds are no longer required*** for patients undergoing their primary series or waiting for their booster dose. All vaccines are available at all institutions and there is no need to delay inmate movement due to vaccination administration schedules.
- ***The mRNA COVID-19 vaccine primary series is given in two or three doses (30 mcg/0.3 mL each for Pfizer-BioNTech, 100 mcg/0.5 mL each for Moderna) scheduled 3-8 weeks apart (Pfizer-BioNTech) or 4-8 weeks apart (Moderna).***
  - ***Use the shorter interval*** for those who are immunocompromised, 65 years of age and older, or in need of rapid protection due to concerns about the risk of severe disease or when SARS-CoV-2 transmission levels in the community and/or facility are high (i.e., Level 2 or 3 Operations as per the Modified Operation Matrix).
  - ***Use the longer interval*** for those who are less than 65 years of age, particularly males under the age of 40 years. Data have shown that a longer interval may increase vaccine effectiveness and immunogenicity while decreasing the risk of myocarditis and pericarditis.
- Removal of requirement for written documentation in order to verify vaccinations given outside of the BOP. A reliable verbal report from an inmate may be accepted for documentation of history of vaccination in the immunization flow sheet. Refer to Documentation section for additional information.

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PURPOSE

The purpose of this guidance is to provide direction on use of COVID-19 vaccines for all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). The goal of this guidance is to promote vaccine use as a means of controlling pandemic transmission of SARS-CoV-2 (the virus that causes COVID-19) and reducing morbidity and mortality from this infection.

THE COVID-19 VACCINATION IS AN IMPORTANT TOOL TO HELP STOP THE PANDEMIC.

- The combination of getting vaccinated and following other CDC recommendations offers the best protection from COVID-19 at the present time.
  - *All current recommendations for preventing and managing SARS-CoV-2 infection should continue to be followed.*
- Wearing face coverings, social distancing, avoiding larger group or public gatherings, limiting travel, and washing hands frequently help reduce the chances of being exposed to the virus or spreading it to others, but these measures are not enough. Vaccines work with the immune system so it will be ready to fight the virus if a person is exposed.
- Stopping a pandemic requires using all available tools. Recommendations will continue to be updated using the latest science.
- For general guidance related to vaccines including Immunization Key Principles and Storage and Handling of Immunizations, refer to the *BOP Immunization Clinical Guidance Document.*
- It is recommended that each BOP facility: (1) create and implement a COVID-19 immunization plan to offer vaccine as recommended for staff and inmates, (2) develop a plan for when and by whom staff and inmates will be scheduled for the vaccine, and (3) ensure that responsibility be assigned to health care personnel for patient assessment and vaccine administration.
  - *This document will be updated as new information becomes available (e.g., when new vaccine products become available and are used by the BOP and when vaccination indications change).*

OVERVIEW OF AVAILABLE VACCINES

The following COVID-19 vaccines are either approved (via a Biologic License Application) or authorized (via an Emergency Use Authorization [EUA]) for use in the United States by the U.S. Food and Drug Administration:

PFIZER-BIONTECH COVID-19 VACCINE (AN MRNA VACCINE)

- For persons 5 years of age and older: Two-dose or, if immunocompromised, three-dose primary vaccine series followed by a booster dose for those 12 years of age and older.
- Fact sheets for the approved and authorized Pfizer-BioNTech COVID-19 vaccine are available for the following groups:
  - Recipients and caregivers: *https://www.fda.gov/media/153716/download*
  - Healthcare providers: *https://www.fda.gov/media/153715/download* (grey cap, no dilution)
  - Healthcare providers: *https://www.fda.gov/media/153713/download* (purple cap, must dilute)

MODERNA COVID-19 VACCINE (AN MRNA VACCINE)

- For persons 18 years of age and older: Two-dose or, if immunocompromised, three-dose primary vaccine series followed by a booster dose.
- The EUA fact sheets for the Moderna COVID-19 vaccine are available for the following groups:
  - Recipients and caregivers: *https://www.fda.gov/media/144638/download*
  - Healthcare providers administering vaccine: *https://www.fda.gov/media/144637/download*

For both the Pfizer-BioNTech and Moderna vaccines, certain immunocompromised persons should receive an additional primary (i.e., third) dose of vaccine four weeks after their second primary series vaccine dose followed by a vaccine booster dose at least three months later.

The FDA-approved Pfizer-BioNTech COVID-19 vaccine, Comirnaty®, and the Moderna COVID-19 vaccine, Spikevax®, may be used interchangeably with their respective EUA-authorized COVID-19 vaccine for individuals ages 12 years and older (Pfizer-BioNTech) and individuals ages 18 years and older (Moderna). The FDA-approved products are legally distinct from the EUA-authorized product with certain differences that do not impact safety or effectiveness.

JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE (A RECOMBINANT, REPLICATION-INCOMPETENT VIRAL VECTOR VACCINE)

- For persons 18 years of age and older: One dose as primary vaccine dose followed by a booster dose for most persons. For those who are immunocompromised, refer to *Section 1. Vaccination Considerations* for additional information.
- The EUA fact sheets for the Janssen COVID-19 vaccine are available for the following groups:
  - Recipients and caregivers: *https://www.fda.gov/media/146305/download*
  - Healthcare providers administering vaccine: *https://www.fda.gov/media/146304/download*

CDC guidance for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States is available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

PROCEDURE

Using this document, eligible healthcare professionals (as defined by scope of duty) may vaccinate adults who meet the indications below, upon successful completion of the manufacturer-specific COVID-19 vaccine skills checklist and completion of the COVID-19 Vaccine Administration Signature Sheet. The signature sheet should be signed by the appropriate administrative staff and the healthcare provider who will be administering vaccine.

Appendix 1. Skills Checklist for COVID-19 Vaccine Administration
Appendix 2. COVID-19 Vaccine Administration Signature Sheet

1. VACCINATION CONSIDERATIONS

- Distribution of vaccine is directed by the Health Services Division of the BOP Central Office and through the Vaccine Point of Contact (VPOC) or their designee.
- ***Testing for SARS-CoV-2 infection is NOT required prior to administering the COVID-19 vaccine*** unless otherwise clinically indicated. If SARS-CoV-2 testing is performed on a COVID-19 vaccine recipient, test results will not be affected if a viral test is used (i.e., either molecular/PCR or antigen

tests). Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination.

- Vaccination should be offered regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, including to those with prolonged post-COVID-19 symptoms. This applies to primary vaccination series and booster doses.
- Primary COVID-19 vaccination series by vaccine type consist of the following:
  - mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech or Moderna): 2-dose series *OR* if moderately to severely immunocompromised, a 3-dose series.
  - Janssen COVID-19 vaccine: single dose *OR* if moderately to severely immunocompromised, single dose followed by a second dose of an mRNA vaccine.

  If the Moderna COVID-19 vaccine is used to complete the primary vaccination series, the 100 mcg dose should be used.
- An individual is considered **FULLY VACCINATED**, if they have completed a primary COVID-19 vaccination series
- An individual is considered **UP TO DATE** on COVID-19 vaccinations, if they have completed a primary vaccination series along with any recommended booster doses for which they are eligible.
- ***The Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine*** for primary and booster vaccinations based on the latest risk-benefit analyses (e.g., evidence on vaccine effectiveness, vaccine safety, and rare adverse events). However, there are certain situations and subpopulations for which the Janssen vaccine may be offered:
  - When there is a contraindication to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
  - When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines,
  - When a person wants to receive the Janssen COVID-19 vaccine despite the safety concerns identified.

  Those who are considering receipt of the Janssen COVID-19 vaccine should be counseled about the need for a booster dose and the rare risk of thrombosis with thrombocytopenia syndrome (TTS) which can occur typically within two weeks after receipt of the vaccine.

INMATE VACCINATION

- ***A primary vaccination series and any recommended booster doses should be offered to all inmates.***
- ***Moderately or severely immunocompromised inmates*** are at increased risk for severe COVID-19, since they may not mount a protective immune response after the first two doses of the vaccine series. In addition, immune protection by primary vaccination may wane over time making this population more susceptible to severe SARS-CoV-2 infection. Therefore, ***a 3-dose primary vaccination series is recommended if mRNA COVID-19 vaccines are administered, followed by a booster dose at least 3 months after the third primary series dose.***
  - ***Conditions and treatments causing moderate to severe immunocompromise include:***
    - Active treatment for solid tumor and hematologic malignancies
    - Receipt of solid-organ transplant and taking immunosuppressive therapy
    - Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
    - Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)

- Advanced or untreated HIV infection (i.e., CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

➢ ***For moderate or severely immunocompromised inmates who received a single primary vaccine dose of the Janssen COVID-19 vaccine***, a second (additional) dose using an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech [30 mcg dose] or Moderna [100 mcg dose]) should be provided at least four weeks days later followed by a booster dose at least two months after the second dose.

- The Janssen COVID-19 vaccine is not authorized for use as an additional primary vaccine dose.
- For the booster dose, an mRNA COVID-19 vaccine is preferred over the Janssen vaccine.
- The BOP COVID-19 Vaccine dashboard may be used to assist institutions in identifying eligible patients based on current CDC guidance.

➢ Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the inmate's medical condition and response to vaccine. Whenever possible, COVID-19 vaccines should be administered at least two weeks before initiation or resumption of immunosuppressive therapies.

➢ The inmate's clinical team is best positioned to determine the degree of immune compromise, appropriate timing for administration of the primary series and booster doses, and in the case of hematopoietic stem cell transplant and CAR-T-cell recipients, the need for COVID-19 revaccination.

- ***Quarantine-specific considerations:***

➢ Inmates admitted to ***intake or exposure quarantine*** may be vaccinated as long as they do not have symptoms or signs of COVID-19. Using these types of quarantines as an opportunity to vaccinate and achieve immunity can be beneficial in limiting transmission and outbreaks.

➢ Inmates in a ***transfer quarantine or those who are scheduled for a BOP intrasystem transfer*** may elect to initiate a primary vaccination series. The type of vaccine used should remain a clinical decision that is made between patient and provider.

➢ Inmates pending immediate release (e.g., full term releases or court-ordered transfers) may be vaccinated. Per the CDC's guidance, vaccine providers may begin the primary vaccination series even if there is uncertainty about how and when a person will receive their remaining doses.

➔ *Institutions will provide inmates their CDC COVID-19 vaccination card as proof of vaccination upon release.*

➔ *CDC guidance for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, including discussion on vaccinating patients in quarantine, is available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*

- ***Vaccine management at the BOP Federal Transfer Center in Oklahoma City (OKL) and BOP holdover sites, including bus hubs and detention centers.***
  - Vaccination series may be initiated during transfers even if there is uncertainty about how the patient will receive their remaining doses.

2. CONTRAINDICATIONS AND PRECAUTIONS

CONTRAINDICATIONS:

- ***Do not administer COVID-19 vaccines to any person with a history of a known severe allergic reaction (e.g., anaphylaxis)*** after a previous dose or to a component of a COVID-19 vaccine OR ***with a*** known (diagnosed) allergy to a component of the vaccine.
  - Both Pfizer-BioNTech and Moderna COVID-19 vaccine components include mRNA as the active ingredient and a variety of inactive ingredients, such as lipids (e.g., polyethylene glycol [PEG]), and buffers.
  - Janssen COVID-19 vaccine components include a recombinant, replication-incompetent human adenovirus vector, which encodes for production of the SARS-CoV-2 spike (S) protein as the active ingredient and a variety of inactive ingredients, such as buffers (e.g., polysorbate).
- Do not administer the Janssen COVID-19 vaccine if an individual developed thrombosis with thrombocytopenia syndrome (TTS) following receipt of a previous Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors).
- For additional information on product-specific vaccine components, refer to the:
  - FDA fact sheet for the Pfizer-BioNTech COVID-19 vaccine at:
    https://www.fda.gov/media/153715/download (grey cap, no dilution)
    https://www.fda.gov/media/153713/download (purple cap, must dilute)
  - FDA Emergency Use Authorization (EUA) fact sheet for the Moderna COVID-19 vaccine at:
    https://www.fda.gov/media/144637/download
  - FDA Emergency Use Authorization (EUA) fact sheet for the Janssen COVID-19 vaccine at:
    https://www.fda.gov/media/146304/download
  - CDC guidance on the Interim Considerations for Clinical Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (Appendix C. Ingredients included in COVID-19 vaccines) at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*

PRECAUTIONS:

- Individuals with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy OR with a non-severe, immediate allergic reaction after a previous dose of COVID-19 vaccine should be assessed clinically to determine whether they can either be vaccinated or if vaccination should be deferred. In these situations, clinical assessment may include referral to an allergist-immunologist. If vaccine is administered, a 30-minute observation period should be performed after vaccination.
  - An **IMMEDIATE ALLERGIC REACTION** is defined as: any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
- Because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen vaccine, individuals with a contraindication to mRNA COVID-19 vaccines such as a severe allergic

reaction (e.g., anaphylaxis) after a previous dose or to a component of the mRNA vaccine also have a precaution to the Janssen COVID-19 vaccine, and vice versa. Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination.

- Persons who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least four weeks after the mRNA COVID-19 vaccine dose to receive the Janssen COVID-19 vaccine.
- ***For specific recommendations for the following precautions, refer to the CDC guidance:*** *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications*
  - PEG and polysorbate allergies
  - Patients who develop myocarditis or pericarditis after receipt an mRNA COVID-19 vaccine
  - History of thrombosis and thrombocytopenia

VACCINATION SHOULD BE DEFERRED FOR:

- ***Patients with current SARS-CoV-2 infection until recovery from acute illness (if the person had symptoms) and criteria have been met to discontinue medical isolation.*** This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection between doses. There is no recommended minimal interval between infection and vaccination; however, current evidence suggests the risk of reinfection is low in the months after initial infection but may increase with time due to waning immunity.
- ***Multisystem inflammatory syndrome in adults (MIS-A) due to SARS-CoV-2 infection or after COVID-19 vaccination is rare and merits a conversation between the patient and their provider to assist with decision-making about the use and timing of a COVID-19 vaccine.*** Considerations to discuss include whether cardiac function has returned to normal, if there is an increased personal risk of severe COVID-19, and the timing of immunomodulatory therapies. The disease mechanism of MIS-A is not well understood but includes a dysregulated immune response to SARS-CoV-2 infection. If MIS-A occurs after a COVID-19 vaccination, individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection. The risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or COVID-19 vaccination among persons with a history of MIS-A is unknown. These theoretical concerns should be weighed against the known risks of COVID-19 from reinfection and the benefits of protection from a COVID-19 vaccine.
- ***Patients with moderate or severe illness of any type with or without fever should defer vaccination until the illness has improved.***

NEITHER CONTRAINDICATIONS NOR PRECAUTIONS:

- ***Individuals with a history of anaphylaxis due to any cause that is not related to a vaccine or injectable therapy*** may proceed with vaccination provided a 30-minute observation period is completed.
- ***Individuals with other allergies (e.g., to oral medications, including the oral equivalent of an injectable medication; food; and pets) or a family history of allergies*** may proceed with vaccination followed by a 15-minute observation period.
- ***For mRNA COVID-19 vaccines: Individuals with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose*** should receive the second dose using the same vaccine product as the first dose at the recommended interval and preferably in the opposite arm. Delayed-onset local reactions have been reported beginning a few days through the second week after the first dose and are sometimes large.

3. TIMING OF COVID-19 VACCINES WITH OTHER VACCINES

COVID-19 vaccines may be administered without regard to timing of other vaccines or non-COVID-19 antibody therapies (e.g., intravenous immunoglobulin). This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

- In persons who previously received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least two weeks after vaccination,
- When deciding whether to co-administer vaccine(s), providers should consider the reactogenicity profile of all the vaccines, whether the patient is at risk for a vaccine-preventable disease (e.g., occupational exposure), and whether they are behind or at risk of becoming behind on recommended vaccines.
- If multiple vaccines are administered at a single visit:
  - The deltoid muscle can be used for more than one intramuscular injection; however, **injection sites should be separated by one (1) inch or more**, if possible.
  - Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

4. VACCINATION OF INDIVIDUALS WITH UNDERLYING MEDICAL CONDITIONS

COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Information on groups with specific underlying medical conditions is included below. As with the general population, mRNA vaccines are preferred over the Janssen COVID-19 vaccine in each of these groups.

- ***Persons with a history of myocarditis or pericarditis prior to COVID-19 vaccination:*** Persons with a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the patient's clinical team. All cases of myocarditis or pericarditis following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- ***Persons with autoimmune conditions:*** Persons with autoimmune conditions may receive any currently FDA-approved or authorized COVID-19 vaccine. However, if an individual is immunocompromised because of medications, such as high-dose corticosteroids or biologic agents, they should follow vaccine schedules for those who are moderately or severely immunocompromised.
- ***Persons with a history of Guillain-Barré syndrome (GBS):*** Reports of adverse events following use of the Janssen COVID-19 vaccine suggest an increased risk of GBS during the 42 days following vaccination with the highest risk observed in males aged 50-64 years. No increased risk of GBS has been identified with mRNA COVID-19 vaccines during use under EUA.
  - *For additional information on GBS, refer to the CDC Clinical Considerations for Janssen COVID-19 Vaccine* https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-Janssen

- ***Persons with a history of Bell's palsy:*** Rare cases of Bell's palsy were reported following vaccination among participants in COVID-19 vaccine clinical trials. Available data were insufficient for the FDA to conclude whether these cases were causally related to vaccination. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to VAERS.
- ***Persons with a dermal filler:*** Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection following administration of a dose of an mRNA COVID-19 vaccine. The swelling is temporary and resolves with medical treatment. Individuals should contact their healthcare provider for evaluation if they experience swelling at or near a dermal filler site following vaccination.

5. VACCINATION OF INDIVIDUALS WHO ARE PREGNANT, BREASTFEEDING/LACTATING, OR TRYING TO GET PREGNANT

COVID-19 vaccination is recommended for women who are pregnant, lactating, trying to get pregnant now, or who might become pregnant in the near future. mRNA vaccines are preferred for all vaccine-eligible populations, including for persons who are pregnant or lactating.

- ***There is no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems.*** There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.
- ***Pregnant and recently pregnant women with COVID-19 are at increased risk for severe illness*** (e.g., hospitalization, intensive care unit admission, mechanical ventilation, death) when compared with non-pregnant women. Additionally, pregnant women with COVID-19 are at increased risk for preterm birth and stillbirth and might be at increased risk for other pregnancy complications. Therefore, COVID-19 vaccination is recommended for all women who are pregnant.
  - A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that ***the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy***. A conversation between the patient and their healthcare provider may assist with decisions about the use of a COVID-19 vaccine during pregnancy. If a woman becomes pregnant following a dose of a COVID-19 vaccine, subsequent doses should be administered as indicated for maximum protection.
  - Women who choose to receive COVID-19 vaccine are encouraged to enroll in v-safe, a smartphone-based tool through which a pregnancy registry has been established. For more information, refer to *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html*.
- ***Breastfeeding/Lactating women:*** There are limited data on the safety of COVID-19 vaccines in these women or their effects on the breastfed infant, milk production, and secretion, because this population was not included in clinical trials. However, the COVID-19 vaccines (i.e., mRNA vaccines and the Janssen vaccine) cannot cause infection in either the lactating woman or the infant. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination were present in breastmilk samples. More data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection for neonates and infants.

➔ *Additional information regarding COVID-19 vaccination and pregnancy can be found on the CDC's Interim Clinical Considerations for the Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*

6. Tuberculosis (TB) and Syphilis Testing Considerations

- TB testing should not be delayed because of COVID-19 vaccine administration. Testing for TB infection using the tuberculin skin test (TST) may be performed before, during, or after the same patient encounter as COVID-19 vaccination.
- For additional guidance regarding the management of testing due to a suspected TB exposure or TB disease and for other types of TB testing (e.g., interferon gamma release assays [IGRAs]), refer to the CDC guidance, the BOP *Tuberculosis Clinical Guidance*, Regional IP&Cs and/or Regional Medical Directors.
- Falsely reactive Rapid Plasma Reagin (RPR) test results have been reported with certain RPR tests for at least five months following COVID-19 vaccination in some individuals. Treponemal testing for syphilis such as Treponema pallidum particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue.

7. Patient Education and Consent

- Review the manufacturer-specific COVID-19 vaccine fact sheet with the patient and have them sign the BOP COVID-19 immunization consent/declination form (Refer to *Section 9. Documentation* for more information on vaccine consent).
  - Consent forms for employees and inmates (English and Spanish) are located in BEMR and also on the COVID-19 Vaccine Resources Page on Sallyport.
  - Current COVID-19 vaccine fact sheets for recipients can be found at:
    - Pfizer- BioNTech COVID-19 Vaccine: *https://www.fda.gov/media/153716/download* (English) and https://www.fda.gov/media/144625/download (Spanish)
    - Moderna COVID-19 Vaccine: *https://www.fda.gov/media/144638/download* (English) and *https://www.fda.gov/media/144712/download* (Spanish)
    - Janssen COVID-19 Vaccine: *https://www.fda.gov/media/146305/download* (English) and *https://www.fda.gov/media/146762/download* (Spanish)
- Before vaccination, providers should counsel recipients about the following:
  - **mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary series and booster vaccination.** The recommendation is based on updated risk-benefit analyses, particularly the concern surrounding the risk of TTS and its symptoms which typically occur within two weeks after Janssen COVID-19 vaccine receipt. Immediate medical care should be sought in the event of shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, and easy bruising or tiny blood spots under the skin beyond the site of the injection.
  - Expected local post-vaccination symptoms (e.g., pain; swelling; erythema at the injection site; and for mRNA COVID-19 vaccines, also localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic post-vaccination symptoms (e.g., fever, fatigue, headache, chills, myalgia, and arthralgia). Most systemic post-vaccination symptoms are mild to moderate in severity and resolve within 1-3 days of onset or after vaccination.

- Use of the following medications is generally ***not recommended for purposes of preventing post-vaccination symptoms***, unless they are part of an individual's routine medication:
  - Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) - these can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
  - Aspirin or anticoagulants
  - Antihistamines – some experts, however, advise antihistamine use as a means of preventing mild allergic reactions in patients who might be at higher risk for allergic reactions.
- Immunocompromised persons should be counseled about the potential for a reduced immune response to COVID-19 vaccines and need to follow all current prevention measures to protect themselves against COVID-19.
- Continue all current guidance for protection of oneself and others to include wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands, and following quarantine and isolation procedures.

8. On-Site Vaccine Receipt and Storage

Refer to the CDC COVID-19 Quick Reference Guidance for Health Care Professionals for additional storage considerations.

Pfizer-BioNTech COVID-19 Vaccine

- There are two approved formulations of the Pfizer-BioNTech COVID-19 vaccine. Either formulation may be used for COVID-19 vaccination in the BOP.
  - A multidose vial with a purple cap, which **MUST BE DILUTED** prior to use
  - A multidose vial with a gray cap, which **IS NOT DILUTED** prior to use.

Pfizer-BioNTech COVID-19 Vaccine (purple cap - MUST DILUTE)

- Vaccine allotments will be shipped using one of two methods:
  - ***Directly from the manufacturer at ultra-low temperature (ULT)*** (-70˚C [-94°F], range -60°C to -80°C [-76°F to -112°F]) to select BOP institutions in full package quantities per institution requests.
  - ***Directly from the BOP Central Fill and Distribution (CFAD) site at frozen temperature (-15°C to -25°C [5°F to -13°F]) to the BOP institution that requested an allotment in partial package quantities (i.e. micro-distribution).***
- Upon receipt, institutions should immediately inspect vaccine for damage, then place into refrigeration storage temperatures (2˚C to 8˚C [36°F to 46°F]). Placement in refrigeration must occur as soon as feasible. If there is a delay of more than 2 hours from receipt to refrigeration, Central Office must be notified.
  *Once thawed, the vaccine **CANNOT** be re-frozen.*
- ***The undiluted, refrigerated vaccine must be used within 30 days of removal from ULT storage, and institutions must keep up with the 30 day timeline***.
  - Vaccine not used after 30 days must be maintained in a separate area and labeled "DO NOT USE" (see Section *13. Disposal*).

PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP - DO NOT DILUTE)

- Vaccine will be shipped by the CFAD or directly from the manufacturer in a refrigerated state between 2°C to 8°C (36°F to 46°F) to each institution in multiples of 300 doses, or in partial package quantities (i.e. micro-distribution).
- Upon receipt, sites will immediately inspect vaccine for damage, then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator.
- Vaccine has a 10 week refrigerated expiration date, which should be marked on the carton upon arrival.
- ***When stored refrigerated, unpunctured vaccine vials must be used within 10 weeks, and institutions must keep up with the 10 week timeline.***
  - Vaccine not used within 10 weeks must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal*).

MODERNA COVID-19 VACCINE

- Vaccine allotments will be shipped using one of two methods:
  - Directly from the vaccine distributor in full package quantities (140 doses)
  - Directly from the BOP Central Fill and Distribution (CFAD) site in partial package quantities at frozen temperature (-50°C to -15°C [-58°F to -5°F]) to the BOP institution that requested an allotment in partial package quantities (i.e. micro-distribution).
- Vaccine is supplied in two, multi-dose vial types: a 5.5 ml vial and 7.5 ml vial. The number of doses in each will vary depending on the number of booster doses administered and the syringes used.
- Upon receipt, sites will immediately inspect vaccine for damage, then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator. During storage, minimize exposure to room light.
  - *Once thawed, the vaccine **CANNOT** be re-frozen.*
- If frozen prior to administration, thaw
  - 5.5 ml vials in a refrigerator (2°C to 8°C [36°F to 46°F]) for 2 hours ***OR*** at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour.
  - 7.5 ml vials in a refrigerator (2°C to 8°C [36°F to 46°F]) for 3 hours ***OR*** at room temperature between 15°C to 25°C (59°F to 77°F) for 1.5 hours.
    - When thawed, the vaccine should be handled with care and protected from shocks, drops, and vibration.
    - Thawed vaccine vials can be handled in room light conditions.
- ***When stored refrigerated, the unpunctured vaccine vials must be used within 30 days, and institutions must keep up with the 30 day timeline.***
  - Vaccine not used after 30 days must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal*).

JANSSEN COVID-19 VACCINE

- Vaccine initially will be stored frozen by the manufacturer and shipped either by McKesson (the vaccine distributor) or the CFAD in a refrigerated state between 2°C to 8°C (36°F to 46°F) directly to each institution.
- Upon receipt, sites will immediately inspect vaccine for damage, then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator.

- If vaccine is still frozen upon receipt and needed immediately, thaw at room temperature (maximally 25°C [77°F]).
  - A carton of 10 vials will take approximately 2 hours to thaw whereas an individual vial will take approximately 1 hour to thaw.
    - *Once thawed, the vaccine **CANNOT** be re-frozen.*
- ***When stored refrigerated, unpunctured vaccine vials must be used within the expiration date of the vaccine, and institutions must keep up within this timeline.***
  - Vaccine not used by the expiration date must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal*).

9. On-Site Vaccine Preparation

Pfizer-BioNTech COVID-19 Vaccine (purple cap - MUST DILUTE)

- Remove thawed vaccine from the refrigerator and allow it to come to room temperature for at least 30 minutes prior to administration.
  - *Undiluted vaccine must NOT be out of the refrigerator for **more than 2 hours**.*
- Verify the vaccine, vaccine formulation and expiration date located on the vial.
- ***Reconstitute with 1.8 ml of 0.9% sodium chloride diluent prior to use.*** Prepare to add diluent to the vaccine vial in the following manner:
  - Invert the vaccine vial gently 10 times to mix. *DO NOT SHAKE*.
  - Visually inspect the liquid in the vaccine vial prior to dilution. It should be a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if the liquid is discolored or if other particles are observed.
  - Obtain the diluent vial (i.e., sterile 0.9% Sodium Chloride Injection, USP).
  - Cleanse the vaccine and diluent vial stoppers with an alcohol swab.
  - Withdraw only 1.8 ml from the sodium chloride vial and inject that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 gauge needle found in the shipped ancillary kits. ***ONLY*** reconstitute vaccine that will be used within 6 hours.
  - Equalize pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.
  - Engage the needle safety device (if present) prior to disposal in a sharps container.
  - Discard the remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.
  - Gently invert the vial containing the vaccine and diluent 10 times to mix. *DO NOT SHAKE.*
  - Visually inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
  - Label the vial and record the date and time of dilution on the label.
  - ***The vaccine vial now contains 6 (six) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial***.
- Store the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures, between 2˚C to 25˚C (35˚F to 77˚F).
  - ***Reconstituted vaccine must be used within 6 hours.***

PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP - DO NOT DILUTE)

- Remove thawed vaccine from the refrigerator and allow it to come to room temperature for at least 30 minutes before vaccine administration.
- Verify the vaccine, vaccine formulation, and expiration date located on the vial.
  - *Vaccine may be stored at room temperature [8˚C to 25˚C (46˚F to 77˚F) for a total of 12 hours prior to the first puncture.*
- Gently invert the vaccine vial 10 times to mix. **DO NOT SHAKE** and **DO NOT DILUTE** the vaccine.
- Visually inspect the liquid in the vaccine vial. Prior to mixing, it may contain white to off-white opaque amorphous particles. After mixing, the vaccine should appear as a white to off-white suspension with no visible particles. Do not use if the liquid is discolored or if other particles are observed.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3mL of the vaccine, preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3mL of vaccine.
- **After the first dose has been withdrawn**, the vaccine vial should be held between 2°C to 25°C (35°F to 77°F).
- Record the date and time of first use on the vaccine vial label.
  - *Vials should be discarded 12 hours after the first puncture.*

MODERNA COVID-19 VACCINE

- Remove the multi-dose vaccine vial from refrigeration and allow it to come to room temperature for at least 15 minutes before vaccine administration. Swirl the vaccine vial gently and between each withdrawal. **DO NOT SHAKE** and **DO NOT DILUTE** the vaccine.
- Visually inspect the vaccine vial before vaccine administration.
  - The vaccine is a white to off-white suspension, and it may contain white or translucent product-related particulates.
  - If other particulate matter and/or discoloration are present, the vaccine should NOT be administered.
  - Thawed vaccine vials can be handled in room light.
- Verify the vaccine and expiration date by accessing the manufacturer's website here: *https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup*. Document the lot number and the expiration date provided by the website.
- **After the first dose has been withdrawn**, the vaccine vial should be held between 2°C to 25°C (36°F to 77°F).
- Record the date and time of first use on the vaccine vial label.
  - ***Punctured vials must be used within 12 hours.***
- **Unpunctured** vials may be stored
  - Refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
  - Between 8°C to 25°C (46°F to 77°F) for a total of 24 hours to include usage time.
- Refrigerated vials not used after 30 days, unpunctured vials stored between 8°C to 25°C [46°F to 77°F] not used after 24 hours, and punctured vials not used after 12 hours, must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal*).
- ***Special considerations for transportation:*** **Once thawed,** the Moderna vaccine is sensitive to movement and institutions should refer to the following CDC guidance on transporting Moderna vaccine: *https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf*

JANSSEN COVID-19 VACCINE

- Visually inspect the vaccine vial for particulate matter and discoloration before vaccine administration.
  - The vaccine is a colorless to slightly yellow, clear to very opalescent suspension.
  - If particulate matter and/or discoloration are present, the vaccine should NOT be administered.
- Verify the vaccine and check the expiration date by:
  - Calling the manufacturer at 1-800-565-4008, *or*
  - Going to *www.vaxcheck.jnjexternal iconexternal icon* and entering the lot number
- Document the lot number and the expiration date provided.
- As the expiration date approaches, check the expiration date again by using the above process. Never use expired vaccine.
  - Do not discard expired vaccine and refer to *Section 13. Disposal* for guidance.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. *DO NOT SHAKE*.
- Record the date and time of first use on the vaccine vial label.
  - ***Punctured vials stored refrigerated*** *(between 2°C to 8°C [36°F to 46°F]) must be used within 6 hours*
  - ***Punctured vials stored at room temperature*** *(maximally 25°C [77°F]) must be used within 2 hours.*
  - ***Unpunctured*** *vials may be stored at room temperature (between 9°C to 25°C [47°F to 77°F]) for no more than* ***12 hours****.*
- Unpunctured, refrigerated vials not used after 3 months; unpunctured vials out of refrigeration (i.e., stored between 8°C to 25°C [46°F to 77°F]) not used within 12 hours; punctured vials kept at room temperature (maximally 25°C [77°F]) and not used within 2 hours; and punctured vials kept between 2°C to 8°C (36°F to 46°F) and not used within 6 hours must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal).*

10. ADMINISTRATION

- For all multi-dose COVID-19 vaccine vials (i.e., Pfizer-BioNTech, Moderna, and Janssen):
  - Pierce the stopper at a different site each time a new dose is withdrawn.
  - Remove air bubbles while the needle is still inside the vaccine vial.
  - If the amount of vaccine remaining in a vial cannot provide a full dose, discard the vaccine vial and contents (see *Section 13. Disposal*).
  - Do not pool excess vaccine from multiple vaccine vials.
- Refer to the table on the following pages for a summary of administration procedures.

SUMMARY OF ADULT ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 1 OF 2)					
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**

Pfizer-BioNTech COVID-19 Vaccine
 	
mRNA vaccine
	Suspension
	
	Multi-dose vial (contains six doses)
		Dose/ Volume
		
		Primary series (2 or 3 doses) and booster
			30 mcg/0.3 ml	IM	***Purple cap-MUST DILUTE***
					Gray cap-DO NOT DILUTE
					• Refer to *Section 9* for on-site vaccine prep instructions.
					• Egg, cell, latex and preservative free.
					• Refer to *Section 2* for contraindications, precautions and special populations.
					• **Primary series doses**
					  • Interval between 1st and 2nd dose: **3-8 weeks**
					  Use shorter interval if immunocompromised, age ≥ 65 years, at increased risk for severe disease, or moderate to high levels of viral community or facility transmission present. Otherwise, use longer interval if age ≤ 64 years.
					  • Interval between 2nd and 3rd dose: **≥ 4 weeks**
					• **Booster dose:** Any mRNA vaccine may be given
					  • ≥ 5 months after the 2nd dose ***OR***
					  • If immunocompromised, ≥ 3 months after the 3rd dose.

Moderna COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vial** (Number/volume of doses withdrawn will vary if booster doses used)	**Dose/ Volume** *Primary series (2 or 3 doses)*	100 mcg/0.5 ml	IM	***No reconstitution required*** • **Withdraw a maximum of 20 doses** (booster and/or primary series) from each vial – **DO NOT** puncture the vial stopper more than 20 times. • Use unpunctured, refrigerated vaccine **within 30 days.** • Use unrefrigerated (8°C to 25°C [46°F to 77°F]) and unpunctured vaccine vials **within 24 hours.** • After 1st dose withdrawn, use vaccine **within 12 hours.** • Egg, cell, latex and preservative free. • Contraindications, Precautions, and Special Populations: same as for Pfizer-BioNTech COVID-19 vaccine. • **Primary series doses:** • Interval between 1st and 2nd dose: **3-8 weeks** with same interval considerations as Pfizer-BioNTech COVID-19 vaccine. • **Booster dose:** same as for Pfizer-BioNTech COVID-19 vaccine.
		Dose/ Volume *Booster*	50 mcg/0.25 ml		

SUMMARY OF ADULT ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 2 OF 2)					
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**
Janssen COVID-19 Vaccine Recombinant, non-replicating viral vector	Suspension **Multi-dose vial** (contains five, 0.5 ml doses)	**Dose**	$5x10^{10}$ virus particles	IM	***No reconstitution required**** • **Use refrigerated vaccine within 3 months.** • Visually inspect each dose in the dosing syringe before use. • Before withdrawing each dose, swirl gently in upright position for 10 seconds. **Do NOT shake.** • Use unrefrigerated (9°C to 25°C [47°F to 77°F]) and unpunctured vaccine vials **within 12 hours.** • After 1st dose withdrawn, use vaccine **within either 6 hours or 2 hours** depending on storage temperatures. • Egg, cell, latex and preservative free. • Refer to *Section 2* for contraindications, precautions and special populations. • **Primary series doses in the immunocompromised:** see text**.** • **Booster dose:** Give an mRNA vaccine booster dose at least 2 months after the primary vaccine series.
		Volume	0.5 ml		

- ***Ancillary supply kits are ordered automatically based on the number of vaccine orders and will arrive before or along with the vaccine***.
  - The kits contain syringes, needles for reconstitution (if needed) and administration, diluent (if needed), vaccination cards, and a limited amount of PPE supplies (i.e., face shields and gowns).
  - Gloves and sharps containers are not included in the kits.
  - Sharps sent in the kits should be stored, inventoried and disposed of in accordance with BOP policy.
- ***Vaccine administration procedure***
  - ***To prevent syncope,*** have the patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
  - Administer the reconstituted vaccine intramuscularly (22-25 g, 1-1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also may be used.
    - *See Appendix 3. Administering Vaccines: Dose, Route, Site, and Needle Size*
  - Note: A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

11. COVID-19 Vaccine Scheduling & Interchangeability

➔ *For an algorithm for COVID-19 vaccine schedules, refer to Appendix 4. Vaccine Schedule and Dose Algorithm for Adult Patients*

- ***The mRNA COVID-19 vaccine primary series is given in two or three doses (30 mcg/0.3 mL each for Pfizer-BioNTech, 100 mcg/0.5 mL each for Moderna) scheduled 3-8 weeks apart (Pfizer-BioNTech) or 4-8 weeks apart (Moderna).***
  - ***Use the shorter interval*** for those who are immunocompromised, 65 years of age and older, or in need of rapid protection due to concerns about the risk of severe disease or when SARS-CoV-2 transmission levels in the community and/or facility are high (i.e., Level 2 or 3 Operations as per the Modified Operation Matrix).
  - ***Use the longer interval*** for those who are less than 65 years of age, particularly males under the age of 40 years. Data have shown that a longer interval may increase vaccine effectiveness and immunogenicity while decreasing the risk of myocarditis and pericarditis.
  - ***If immunocompromised, schedule a third dose*** at least four weeks after the second dose.
  - If an immunocompromised person received two different mRNA COVID-19 vaccine products for the first two doses of their primary mRNA vaccination series, the product used for the second dose should be used for the third dose to complete the vaccine series.
- ***The Janssen COVID-19 vaccine primary series is given as:***
  - One Janssen COVID-19 dose, ***OR***
  - If immunocompromised, one (1) Janssen COVID-19 dose followed by an mRNA COVID-19 vaccine at least four weeks later. If the Moderna COVID-19 vaccine is administered for the second dose, the 100 mcg/0.5 mL formulation should be used.
- ***Primary vaccination doses of COVID-19 vaccines*** should be given as close to the recommended interval as possible.
  - Persons should not be scheduled to receive primary series vaccination doses earlier than recommended; however, doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. When not feasible to adhere to the recommended interval:
    - Doses administered any time ***after*** the recommended interval and are considered valid.
    - Doses administered prior to the 4-day grace period ***should be repeated at the proper interval*** with the repeat dose spaced from the date of the dose given early in error.
- In most circumstances, individuals initiating a primary mRNA COVID-19 vaccination series by a particular manufacturer should complete their vaccination series using the same product.
  - If the mRNA vaccine product administered for the first dose of the primary vaccination series cannot be determined or is not available, an alternative mRNA COVID-19 vaccine may be administered at a minimum interval of four weeks between doses to complete the mRNA COVID-19 primary vaccination series.
  - In limited, exceptional situations where a first dose of an mRNA COVID-19 vaccine was received but the series cannot be completed with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), a single dose of the Janssen COVID-19 vaccine may be considered at a minimum interval of four weeks after the mRNA COVID-19 vaccine dose. Persons who receive the Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose primary COVID-19 vaccination—not a mixed vaccination series.

- ***Booster doses should be administered to all inmates.***
  - In most circumstances, mRNA vaccines (Pfizer-BioNTech or Moderna) are preferred over the Janssen vaccine for booster vaccination.
  - Recipients who received a primary series of mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna) may receive a booster dose at least:
    - Five months after the second primary series dose, ***OR***
    - If immunocompromised, three months after the third primary series dose.
  - Recipients who received a primary series of the Janssen vaccine should receive a booster dose at least two months after the last primary vaccination series dose.
  - Booster doses given in error earlier do not need to be repeated.

12. Persons Vaccinated Outside the United States

- Recommendations for persons vaccinated outside of the United States depend on the vaccine(s) received for the primary vaccination series, whether the primary vaccination series was completed, and whether a booster dose was received.
  - ***For persons vaccinated with any FDA-approved or authorized COVID-19 vaccines,*** the Pfizer-BioNTech or Moderna COVID-19 vaccines may be used to complete vaccination.
  - ***For persons who received at least one COVID-19 vaccine that was not FDA approved or authorized***, the Pfizer-BioNTech or Moderna COVID-19 vaccines may be used to complete vaccination.
- For specific recommendations, refer to the CDC guidance: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#appendix-e

13. Documentation

Inmate Vaccine Administration Documentation

Administration will be documented in the BEMR immunization flow sheet. Select the COVID-19 immunization administered from the drop-down menu. Record the dose number, location, lot number, dosage, route, expiration date, and provider.

- If vaccine was not given, record the reason(s) (e.g., medical contraindication, refusal).
- Utilize the comments section as needed, to include documenting diluent lot# and expiration date.
- Enter the second or third primary vaccine dose date in the scheduler, if applicable.
- Upon exiting, do not forget to save the immunization flow sheet data.
  - *Institutions will **provide inmates** a completed CDC COVID-19 vaccination card as proof of vaccination upon release. A formal medical records request is not required.*
- ***For inmates who received COVID-19 vaccination elsewhere*** (i.e., not in the BOP), enter vaccination information into BEMR as "History Of" along any available information to include manufacturer name, dose number, vaccination date(s) and location.
  - Scan any supporting documentation into BEMR or provide information in the comment box regarding source of information. Once scanned, CDC COVID-19 Vaccination Cards should be returned to the inmate.
  - In order to accurately reflect vaccination status on the COVID-19 vaccination dashboard, the dose number and vaccination date must be entered when entering a vaccination history into BEMR. If an inmate received a 2-dose or 3-dose series, ***all doses must be entered separately***.

- ***If vaccination history is not reliable,*** obtain a signed declination of the BOP-offered COVID-19 vaccination and include prior vaccination as the reason for declination. There should also be an explanation as to why the reported vaccination history does not seem reliable (e.g., can't remember the name of the vaccine, estimated date, or location of administration.)
- If a vaccination has already been documented in the flow sheet, it should not be charted again

EMPLOYEE VACCINE ADMINISTRATION DOCUMENTATION.

When BOP has provided the vaccination, this will be documented in the Vaccine Administration Management System (VAMS) – a system developed by the CDC for COVID-19 vaccine management – no later than 24 hours after vaccine administration. Employees should also be provided with completed CDC COVID-19 vaccination cards after being vaccinated.

COVID-19 VACCINE CONSENT FORMS

- Document the publication date of the fact sheet.
- Document the vaccine and dose being given and have the patient sign consent or declination.
- The person administering the immunization signs and dates the form.
- Disposition of the completed, signed consent forms
  - ***Inmates:*** Scan a separate inmate consent form for each administered or declined dose of vaccine into the Document Manager in BEMR.
  - ***Employees:*** Provide a hard copy of the signed employee consent form to employee records for filing after any vaccination has been completed (including second and booster doses where applicable) or the employee's refusal of the primary vaccination series has been documented. For employees receiving single-dose vaccines (i.e., the Janssen COVID-19 vaccine), ensure that all other vaccine dose information has been crossed out, initialed, and dated.

➔ ***Documentation of vaccine consent or declination must be obtained from every inmate***.

SCHEDULING ADDITIONAL DOSES OF VACCINE

- Vaccines are readily available at all facilities. Vaccine administration should be made available for "walk-ins" or during sick-call clinics. Alternatively, facilities should plan for clinic availability and be able to offer vaccination on a daily/weekly basis.
- ***For inmates, using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.***
- The COVID-19 vaccine dashboard is a tool that may be used to monitor when additional vaccine doses should be given.
- ***For employees, each facility will determine a method for scheduling vaccination administration clinics*** and what reminders to use for determining when follow-up vaccine doses should be given (e.g., pre-determined clinic dates, use of the Manage Recipients page in VAMS to track dates for second doses, use of a spread sheet of due dates, and/or vaccine cards).

14. MEDICAL EMERGENCY OR ANAPHYLAXIS

Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat maybe all be signs of anaphylaxis.

- In the event of a medical emergency related to vaccination, ***immediately call a medical emergency.***
- ***Epinephrine 1:1000 IM/SQ and respiratory support should be immediately available.***
- BOP nursing and paramedic protocols are available on Sallyport for implementation and use in the management of allergic reactions and anaphylaxis when approved by the clinical director.

15. VACCINE ADVERSE REACTIONS.

Documentation of adverse events, even if it is uncertain whether the vaccine caused the event, should occur in the following two locations:

- BOP Adverse Events dashboard ***for inmates only***
- Federal Vaccine Adverse Event Reporting System (VAERS) *for* ***staff AND inmates*** at: *https://vaers.hhs.gov/reportevent.html*
  - Vaccination providers are required by the FDA to report to VAERs any of the following after COVID-19 vaccination:
    - Vaccine administration errors
    - Serious adverse events
    - Cases of MIS (a Multisystem Inflammatory Syndrome)
    - Cases of COVID-19 that result in hospitalization or death
  - Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event.
  - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

16. DISPOSAL

- Syringes and needles used for vaccination should be placed in hard, lockable biohazard containers and bagged in biohazard bags just as any other vaccine.
- Institutions must store nonviable vaccine vials (unpunctured and punctured) that are contaminated, expired or unused in a separate, designated area away from any vaccine that is in use. Label the vaccine vials "DO NOT USE".
  - Nonviable and unpunctured vaccine vials should be returned to the manufacturer following the normal pharmacy procedures for return of expired medications.
  - Nonviable and punctured vaccine vials should be disposed of in hot trash. This includes left over vaccine doses.
- For wasted vaccine, institutions must immediately notify the BOP Chief Pharmacist or their designee with details of the wastage.
  - It is important for providers to not miss any opportunity to vaccinate every eligible person, even if that means puncturing a multi-dose vials without having enough people available to use every dose. In these cases, unused doses are not considered waste and do not require reporting to BOP Chief Pharmacist or their designee.

APPENDIX 1. SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION

The checklist on the following pages can be used as an assessment tool for healthcare staff who administer the Pfizer-BioNTech, Moderna, and/or Janssen (Johnson & Johnson) COVID-19 vaccines.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 1 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
PATIENT EDUCATION				
				Welcomes patient, verifies identification, accommodates language/literacy barriers and special needs, and explains what vaccine will be given.
				Provides Emergency Use Authorization (EUA) fact sheet and answers questions.
				Reviews preference for mRNA COVID-19 vaccines, potential side effects, comfort measures, and after care instructions.
SCREENING/PREPAREDNESS				
				Screens patient for vaccine eligibility (based on EUA and package insert), history of adverse reactions, allergies, contraindications, and precautions.
				Ensures consent/declination form is signed and that the current EUA date is documented. Uses a separate consent form for each vaccine dose for inmates and one consent form for all primary series vaccine doses for employees.
				Verbalizes signs and symptoms of potential medical emergency or anaphylaxis.
				Able to initiate CPR and maintain airway, if necessary. Locates epinephrine.
				States procedure for responding to and reporting needle stick injuries.
VACCINE STORAGE AND HANDLING – GENERAL				
				Documents refrigerator temperatures with a temperature digital data logger twice daily on clinic days. Acknowledges that temperature data for vaccines is stored for at least 3 years.
				Does not store vaccines in dormitory style refrigerators.
				Ensures that food and beverages are not stored in a refrigerator with vaccines.
				Ensures refrigerator is plugged into a generator back-up plug, if available, and labeled with "Do not unplug" signage.
				Stores vaccines in original containers with lids closed until ready for administration.
				Positions vaccines 2-3 inches from walls, floor, ceiling and door of refrigerator and not directly under cooling vent, in deli or fruit or vegetable drawers, or refrigerator door.
				Uses appropriate storage coolers with temperature monitoring when moving vaccines to clinics outside of main storage.
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (PURPLE CAP-MUST DILUTE)				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days.
				Removes vaccine from refrigerator and allows to come to room temperature prior to dilution (30 minutes).
				Verifies vaccine, vaccine formulation, and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.
				Inverts vial gently 10 times to mix*. DOES NOT SHAKE the vial.*
				Obtains sterile 0.9% Sodium Chloride Injection, USP (i.e., diluent).
				Cleanses the vaccine and sodium chloride vial stoppers with an alcohol swab.
				Withdraws only 1.8 ml from the sodium chloride vial *and injects that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 or narrower gauge needle (from the shipped ancillary kits).* ***ONLY*** *reconstitutes vaccine that will be used within 6 hours.*

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 2 OF 5*)				
Self-Assessment		Supervisor/ Preceptor Review		SKILLS
Needs to Improve	Meets or Exceeds	Needs to Improve	Meets or Exceeds	
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (PURPLE CAP-MUST DILUTE) (CONTINUED)				
				Equalizes pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.
				Engages needle safety device (if present) prior to disposal in a sharps container.
				Discards remaining 0.9% sodium chloride solution regardless of fluid remaining. Does not reuse.
				Gently inverts the vial with the vaccine and diluent 10 times to mix. *DOES NOT SHAKE.*
				Labels the vial and records the date and time of dilution on the label. The vaccine vial now contains 6 (six) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial.
				Stores the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures between 2˚C to 25˚C (35˚F to 77˚F) for up to 6 hours.
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP-DO NOT DILUTE)				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 10 weeks.
				Removes vaccine from refrigerator and allows to come to room temperature prior to administration (30 minutes).
				Verifies vaccine, vaccine formulation, and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.
				Inverts vial gently 10 times to mix*. DOES NOT SHAKE the vial. DOES NOT DILUTE the contents.*
				Cleanses the vaccine vial stopper with an alcohol swab.
				Withdraws 0.3ml of vaccine.
				Stores the vial between 2°C to 25°C (35°F to 77°F) for up to 12 hours after first dose has been drawn.
				Records the date and time of the first use on the vial label.
VACCINE HANDLING AND PREPARATION, MODERNA COVID-19 VACCINE				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days and **may be moved from the storage location to clinic only once in an unfrozen state.**
				Acknowledges that a maximum of 20 doses (booster [0.25 ml] and/or primary series [0.5 ml] doses) can be withdrawn from the vial and understands that the vial stopper should not be punctured more than 20 times.
				Removes vaccine from refrigerator and verifies vaccine and expiration date. For any questions, contacts Central Office.
				Ensures the vaccine is thawed and that the vial has been allowed to come to room temperature for 15 minutes prior to drawing up vaccine for administration. Unpunctured vials are not stored any longer than 24 hours between 8°C to 25°C (46°F to 77°F).
				Swirls the vial gently and between each withdrawal*. DOES NOT SHAKE the vial and does not dilute the contents.*
				Visually inspects the vial for unexpected particulate matter and/or discoloration. The vaccine is a white to off-white suspension, and it may contain white or translucent product-related particulates. The vaccine should NOT be used if other particulate matter and/or discoloration are present.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 3 OF 5*)				
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE				
				Demonstrates knowledge that vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 3 months.
				Acknowledges that each multi-dose vaccine vial contains 5 (five) separate 0.5 ml vaccine doses.
				Removes vaccine from refrigerator, verifies vaccine and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.
				Ensures the vaccine is thawed prior to use. For use in clinic outside of main storage site, stores in appropriate temperature monitored storage cooler at (2°C to 8°C [36°F to 46°F].
				Gently swirls the multi-dose vial in an upright position for 10 seconds before withdrawing each dose of vaccine. *DOES NOT SHAKE the vial.*
				Stores the vial between 2°C to 8°C (36°F to 46°F) for up to 6 hours OR at room temperature (maximally 25°C [77°F]) for up to 2 hours after first dose has been drawn.
				Records the date and time of the first use on the vial label.
ADMINISTERING VACCINES				
				Demonstrates knowledge of the appropriate route (IM), site (deltoid), vaccine type and dose, and the type of syringe safety device being utilized (glide, snap or retraction device).
				Washes or disinfects hands before and in-between patient encounters. *If gloves are worn, they are changed and hand hygiene performed between patients.*
				Places the labeled, unexpired, multi-dose vaccine on a hard surface, cleanses the stopper with a clean alcohol wipe and allows to dry ***between each dose of vaccine***.
				Utilizes a new and appropriately sized needle and syringe for each dose of vaccine. Opens syringe packet carefully placing the safety cap on the package covering.
				Inserts needle into the multi-dose vaccine vial and pierces the stopper at a different site each time for each new dose.
				Inverts vial and syringe and withdraws the following amount of vaccine from the multi-dose vial: • *Pfizer-BioNTech:* 0.3 ml • *Moderna:* 0.5 ml for primary vaccine dose, 0.25 ml for booster dose • *Janssen:* 0.5 ml
				Does not pool excess vaccine doses from multiple vials to obtain a vaccine dose. Discards the vaccine vial and contents, if a full vaccine dose cannot be withdrawn from a given vaccine vial.
				Removes air bubbles from the vaccine vial while the needle is still inside the vial, withdraws needle from the vial, and verifies final vaccine dose.
				Positions patient so that muscles are relaxed and preps injection site with alcohol wipe, allowing it to dry.
				Holds the syringe and needle in the dominant hand and either bunches up muscle using the non-dominant hand or gently stretches the skin around the injection site.
				Inserts the needle at a 90-degree angle using a dart-like action to prevent accidental depression of the plunger during insertion of the needle. Aspiration is not necessary for IM injections in the deltoid site.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 4 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
ADMINISTERING VACCINES (CONTINUED)				
				Uses the thumb and forefinger of the non-dominant hand to hold the syringe and depresses the plunger with the dominant hand in a steady motion after the needle pierces the skin.
				Removes the needle at the same angle at which it was inserted once medication is completely injected. Engages the needle safety device appropriately.
				Disposes of the needle and syringe in a sharps container.
				Covers injection site with the gauze, using gentle pressure and applies a Band-Aid, if needed.
				Records the date and time of first use on the vial label.
				Identifies vials that can no longer be used by expiration date or the following: • *Pfizer-BioNTech (purple cap):* undiluted vaccine out of refrigeration for more than 2 hours, refrigerated undiluted vaccine not used after 30 days, or reconstituted vaccine not used within 6 hours. • *Pfizer-BioNTech (gray cap):* unpunctured vials out of refrigeration for more than 12 hours; punctured vials not used after 12 hours when stored between 2°C to 25°C (35°F to 77°F). • *Moderna*: vaccine out of refrigeration for more than 24 hours, punctured vials not used after 12 hours, refrigerated vaccine not used after 30 days, or unused vaccine from a vaccination clinic. • *Janssen*: unpunctured vials out of refrigeration for more than 12 hours; punctured vials not used after 6 hours when stored between 2°C to 8°C (36°F to 46°F) *OR* not used after 2 hours when stored at room temperature (maximally 25°C [77°F]).
				Maintains vials that can no longer be used in a separate area labeled *"DO NOT USE"* and demonstrates knowledge of BOP vaccine disposal procedures: • Nonviable, unpunctured vaccine vials are returned to the pharmacy. • Nonviable, punctured vaccine vials, are disposed of in hot trash. • For wasted vaccine doses, the BOP Chief Pharmacist or designee must be contacted with details concerning the wastage.
DOCUMENTATION				
				Documents the vaccine dose in the appropriate place (consent forms, BEMR, and VAMS) to include dose number, date, lot number, manufacturer, site, and name/initials. Provides vaccination cards to employees.
				Addresses future appointments through the BEMR scheduler for inmates. For employees, follows institution plans.
				Demonstrates the ability to properly document a vaccine adverse event (AE) in VAERS and in the BOP Medication Event dashboard, and identifies which healthcare personnel to notify in the case of an AE.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 5 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
				If an inmate received COVID-19 vaccination elsewhere (i.e., not in the BOP), knows to: • Make every effort to verify confirmation of the vaccination. • If written documentation is provided or if vaccination is verified verbally from a reliable primary source (e.g., clinic, pharmacy, government agency or office) or transfer paperwork, enter vaccination information into the BEMR system as "History Of" along with the manufacturer name, dose number, and vaccination date(s). • *If proof of vaccination is not provided and cannot be verified*, document declination of the BOP-offered COVID-19 vaccination, *including prior vaccination as the reason for declination,* before entering vaccination information into the BEMR system as "History Of" along with the vaccination date(s).

Employee Signature:	**Date:**
Supervisor Signature:	**Date:**

APPENDIX 2. COVID-19 VACCINE ADMINISTRATION SIGNATURE SHEET

BOP HEALTH SERVICES UNIT

Institution:	
Authorization is given for the checked (✓) categories of healthcare providers to use the checked (✓) COVID-19 vaccine(s) (below) for administration without individual patient medication orders. Healthcare providers who are authorized to administer vaccines should have demonstrated vaccine administration skills (see skill checklist). File a copy of this Signature Sheet in each authorized healthcare provider's credential file.	
	Registered Nurses
	Advanced Practice Providers
	Licensed Practical Nurses
	Paramedics
	Pharmacists
	Dentists
	Other:
The following COVID-19 vaccine(s) is/are approved for use in this facility, in accordance with FDA approval or the FDA EUA and package insert, if the specific vaccine brand(s) is/are checked (✓) below:	
	Pfizer-BioNTech COVID-19 Vaccine (Comirnaty® or under EUA)
	Moderna COVID-19 Vaccine (Spikevax® or under EUA)
	Janssen (Johnson & Johnson) COVID-19 Vaccine
	Other:

Signatures:		
IP&C Coordinator (Last, First) – PRINT	*Signature*	*Date*
Health Services Administrator (Last, First) – PRINT	*Signature*	*Date*
Clinical Director (Last, First) – PRINT	*Signature*	*Date*
Healthcare Provider (Last, First) – PRINT	*Signature*	*Date*

APPENDIX 3. ADMINISTERING COVID-19 VACCINES

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 1 OF3)				
VACCINE	**DOSE**	**ROUTE**	**INJECTION SITE**	**KEY POINTS**
Pfizer-BioNTech COVID-19 Vaccine (purple cap-MUST DILUTE)	0.3 mL	IM	Deltoid	• Reconstitution required with 1.8 ml of 0.9% sodium chloride diluent (mixing syringe 3-5 ml with 21 gauge 1.5" mixing needle). The 1.5", 21 gauge needles included in the ancillary kits are to be used. • Label reconstituted vials with date and time. • Each reconstituted multi-dose vial contains six (6) separate 0.3 ml vaccine doses. • Reconstituted vaccine must be used within 6 hours. • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Removes air bubbles from the vaccine vial while the needle is still inside the vial. • After 6 hours, label "DO NOT USE" and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.
Pfizer-BioNTech COVID-19 Vaccine (gray cap-DO NOT DILUTE)	0.3mL	IM	Deltoid	• No reconstitution needed. • Refrigerated vaccine must be used within 10 weeks. • Each multi-dose vial contains six (6) separate 0.3ml vaccine doses. • Unpunctured vials out of refrigeration must be used within 12 hours. • Once punctured, label the vial with the date and time and use within 12 hours (storing between 2°C to 25°C (35°F to 77°F) • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Remove air bubbles from the vaccine vial while the needle is still inside the vial. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 2 OF3)				
VACCINE	**DOSE**	**ROUTE**	**INJECTION SITE**	**KEY POINTS**
Moderna COVID-19 Vaccine	0.5 mL full dose/ 0.25 mL booster dose	IM	Deltoid	• No reconstitution needed. • The number of doses in each vial type (5.5 mL and 7.5 mL) will vary depending if booster doses are used and the syringe type. A maximum of 20 doses (booster and/or full dose) may be withdrawn. • Refrigerated vaccine must be used within 30 days. • Vials not refrigerated must be used within 24 hours. • Once punctured, label the vial with the date and time and use within 12 hours. • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Remove air bubbles from the vaccine vial while the needle is still inside the vial. • Vaccine moved from refrigerator storage to a vaccination clinic cannot be placed back in storage. • After beyond use or expiration date, label “DO NOT USE” and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.
Janssen COVID-19 Vaccine	0.5 ml	IM	Deltoid	• No reconstitution needed. • Refrigerated vaccine must be used within 3 months. • Each multi-dose vial contains five (5) separate 0.5 ml vaccine doses. • Unpunctured vials out of refrigeration must be used within 12 hours. • Punctured vials must be used within 6 hours, if stored between 2°C to 8°C (36°F to 46°F). If stored at room temperature (maximally 25°C [77°F]), vials must be used within 2 hours. • Label punctured vials with date and time. • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Removes air bubbles from the vaccine vial while the needle is still inside the vial • After beyond use or expiration date, label “DO NOT USE” and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 3 OF3)

Administer IM injections in the deltoid muscle, with a 22-25 gauge needle. Choose needle length based on person's age and body mass:

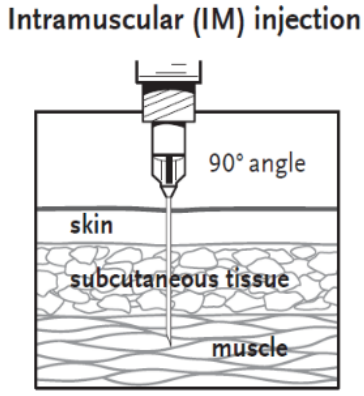
< 130 lbs.	1" length needle
130-152 lbs.	1" length needle
Female 153-200 lbs.	1-1½" length needle
Female 200+ lbs.	1½" length needle
Male 153-260 lbs.	1-1½" length needle
Male 260+ lbs.	1½" length needle

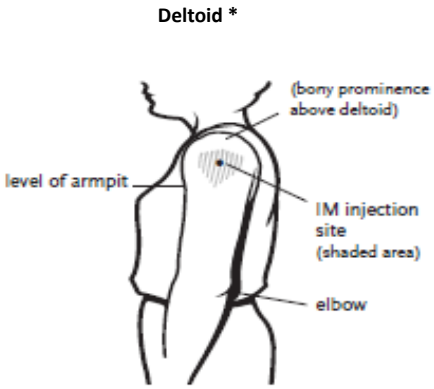
A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

NOTE: Each location will receive an ancillary kit and product information guide separate from the vaccine product. The kits will contain a variety of needles and syringes along with other supplies (e.g., diluent, if needed). When preparing and administering vaccine, staff will need to select the correct syringe size and needle gauge/length appropriate for the activity (vaccine preparation vs. vaccine administration) and for the patient's size. Guidance may be found in the ASPR/CDC "Product Information Guide for COVID-19 Vaccines and Associated Products" sent to the VPOCs and in BOP guidance.

How to administer an intramuscular vaccine*:

1. Use a needle long enough to reach into the muscle – for adults, 1-1½" needle.
2. The 1 ml syringe included in the ancillary kit is recommended for vaccine administration and not for mixing of the diluent with vaccine.
3. With the non-dominant hand, bunch up the muscle (for smaller muscle mass) or stretch the skin (for larger body mass).
4. With the dominant hand, insert the needle at a 90° angle to the skin with a quick thrust.
5. Push down on the plunger and inject the entire contents of the syringe. There is no need to aspirate.
6. Remove the needle and apply pressure to the injection site with a dry gauze. Hold in place for several seconds.
7. If there is any bleeding, cover the injection site with a bandage.
8. Engage the needle safety mechanism and put the used needle and syringe in a sharps container.





*References adapted from www.immunize.org/catg.d/Item # 2024 (9/19) and 3084 (8/20)

APPENDIX 4. COVID-19 VACCINE SCHEDULE AND DOSE ALGORITHM FOR ADULT PATIENTS