**SAMPLE PROTOCOL for ADMINISTRATION OF Janssen COVID-19 Vaccine**

**Under FDA Emergency Use Authorization (“EUA”) dated 2/27/2021 and as amended**

**May 14, 2021 (Version 2)**

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| The San Francisco Department of Public Health (SFDPH) is sharing this sample protocol for the administration of Janssen COVID-19 vaccine to assist local COVID-19 vaccination providers in developing their own procedures. This document is based on recommendations, sources, and knowledge, current as of the date above, but which are subject to change without notice. Users should consult FDA, CDC, and CDPH sources for initial and updated guidance.  |
| 5/14/2021 Updates* Thrombosis with Thrombocytopenia syndrome; additional counseling
* Interval between COVID-19 vaccine and other vaccines
* Use in pregnancy and breastfeeding
* Vaccination of persons with prior or current SARS-CoV-2 infection, MIS-C or MIS-A
* Additional warning on syncope; techniques to prevent syncope
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**Vaccine Components**

The vaccine does not contain thimerosal or preservative and the vial stopper does not contain latex.

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| **Active Ingredient*** Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein

**Additional Ingredients*** Polysorbate-80
* 2-hydroxypropyl-β-cyclodextrin
* Citric acid monohydrate
* Trisodium citrate dihydrate
* Sodium chloride, Sodium hydroxide, Hydrochloric acid, Ethanol, Water for injection
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**Authorized Use**

The vaccine is authorized to prevent COVID-19 in persons age **18 years** and older.

**Contraindications**

**Severe allergic reaction** (e.g., anaphylaxis) after a previous dose of Janssen COVID-19 vaccine, or to any of its components

**Immediate allergic reaction of any severity** to a previous dose of Janssen COVID-19 vaccine, or to any of its components (including polysorbate)

**Warnings and Precautions**

Ensure that medical treatment used to manage immediate allergic reactions (e.g. epinephrine) is immediately available in the event of acute anaphylactic reaction following administration.

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) history of **any immediate allergic reaction to other vaccines or injectable therapies** is a precaution to receiving any COVID-19 vaccine.

**Contraindication to mRNA vaccine is a precaution to receiving Janssen vaccine;** patient may be able to receive Janssen vaccine after consultation with an allergist-immunologist.

Immunocompromised persons may have a diminished immune response to this vaccine.

Syncope (fainting) may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.

**Thrombosis with Thrombocytopenia Syndrome (TTS)**

**Thrombosis with thrombocytopenia syndrome (TTS)** has occurred rarely following Janssen COVID-19 vaccine. Most cases have been in females age 18 through 49 years, though cases have occurred even more rarely in males and in females age 50 and above. Symptom onset has ranged from 3 to 15 days following vaccination. The clinical course shares features with the autoimmune form of heparin-induced thrombocytopenia (HIT). Most cases had clots in the cerebral venous sinuses, but clots have also occurred in vessels in the legs or abdomen.

Women age <50 years may receive Janssen vaccine but should be aware of the risk of TTS and of the availability of other FDA-authorized vaccines.

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations) **persons with recent history (within 90 days) of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered a different FDA-authorized vaccine.** Those with history of or risk factors for other thromboses are not thought to be at increased risk of TTS. Persons who routinely take aspirin or anticoagulants do not need to stop these medications prior to receiving Janssen vaccine.

Heparin should not be used to treat persons with TTS following the Janssen COVID-19 vaccine; review of [treatment guidance](https://www.hematology.org/covid-19/vaccine-induced-immunethrombotic-thrombocytopenia) and consultation with a hematology specialist is strongly recommended.

**Use in Pregnancy**

Data on the safety of COVID-19 vaccines in pregnant people are currently limited. Evidence from pregnancy registries have not identified any safety concerns to date; studies are ongoing. [Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), pregnant women are eligible for and can receive a COVID-19 vaccine.

Routinely testing for pregnancy prior to receipt of vaccine is not recommended.

Pregnant women who experience fever following vaccination may be offered acetaminophen, as fever has been associated with adverse pregnancy outcomes.

**Use during Breastfeeding**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), none of the COVID-19 vaccines can cause infection in either the mother or the infant; therefore, breastfeeding people can receive a COVID-19 vaccine.

**Pediatric Use**

Janssen COVID-19 vaccine is not authorized for persons younger than age 18 years.

**Use in Persons with Underlying Medical Conditions**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination. This includes persons with auto-immune conditions or a history of Bell’s palsy or Guillain-Barre syndrome.

**Use in Persons with Immunocompromise**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies can receive COVID-19 vaccine, unless otherwise contraindicated. Data are not currently available to establish safety and efficacy of vaccination in these groups, and so they should be counseled about the unknown safety profile and effectiveness in immunocompromised persons, the potential for reduced immune response to the vaccine, and the need to continue to follow all current guidance to protect themselves against COVID-19. If possible, vaccine should be administered at least 2 weeks prior to initiation of immunosuppressive therapy.

**Co-Administration with Other Vaccines**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html/Coadministration), COVID-19 vaccines and other vaccines may now be administered without regard to timing. Consideration should be given regarding administration of two highly reactogenic vaccines (e.g. COVID-19 vaccine plus a tetanus vaccine or an adjuvanted vaccine such as Shingrix, Fluad, or Heplisav-B). If multiple vaccines are administered at a single visit, administer the more reactogenic vaccines at different injection sites, e.g. in different limbs.

**Use in Persons with Prior or Current SARS-CoV-2 Infection, MIS-C or MIS-A**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html%22%20%5Cl%20%22CoV-19-vaccination), vaccination should be offered regardless of history of symptomatic or asymptomatic SARS-CoV-2 infection, including people with prolonged post-COVID-19 symptoms.

In people with known current SARS-CoV-2 infection, vaccination should be deferred until the person has recovered from the acute illness (if symptomatic) and criteria have been met to discontinue isolation.

Viral or serologic testing for acute or prior SARS-CoV-2 infection is not recommended for the purpose of vaccine decision-making.

Persons with a history of multisystem inflammatory syndrome (MIS-C or MIS-A) may be vaccinated after weighing [factors outlined by ACIP.](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#CoV-19-vaccination)

**Use in Persons After Prior Receipt of COVID-19 Passive Antibody Therapy**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), vaccination should be deferred at least 90 days after receipt of COVID-19 monoclonal antibodies or COVID-19 convalescent plasma, due to the possibility that treatment with a COVID-19 antibody-containing product could interfere with development of immune response to the vaccine dose.

**Use in Persons with Recent Known SARS-CoV-2 Exposure**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html), recent exposure to COVID-19 is not a contraindication to vaccination. However, individuals should not leave quarantine just to get a vaccine and thereby risk exposing others; if they cannot be vaccinated at their quarantine location, defer vaccination until their quarantine period has ended.

**Dosing and Schedule**

Administer intramuscularly (IM) as a **single dose of 0.5-mL**

**Interchangeability**

[Per ACIP](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) in limited, exceptional situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine ***may be considered*** at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose.

Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series.

(See Precautions for use of Janssen vaccine in people with a contraindication to mRNA vaccines.)

**Before Administering Vaccine**

Ensure that the recipient or caregiver has received a copy of the Janssen [Fact Sheet for Recipients and Caregivers](https://www.fda.gov/media/146305/download) or has been directed to <http://www.janssencovid19vaccine.com/> to obtain a copy.

Communicate to the recipient:

* That Janssen COVID-19 vaccine is not an FDA-approved vaccine, and has been authorized by FDA for emergency use
* That the recipient or their caregiver has the option to accept or refuse the vaccine.
* The significant known and potential risks and benefits of the vaccine, and the extent to which such risks and benefits are unknown
* Information about available alternative vaccines (if available) and the risks and benefits of those alternatives.

Written informed consent for vaccination is not required in order to receive vaccine under the EUA.

**Instructions for Dose Preparation**

The vaccine vial contains a colorless to slightly yellow, clear to opalescent suspension.

Visually inspect the vaccine vials for particulate matter and discoloration prior to administration; if either of these conditions exists, do not administer the vaccine.

Before drawing up the dose, swirl the multi-dose vial gently in an upright position for 10 seconds. **Do not shake.**

Each dose is 0.5-mL and each vial contains 5 doses.

**Do not pool doses from multiple vials.**

**Do not dilute the Janssen vaccine.**

**Administration**

Ensure the recipient is seated or lying down to receive the vaccine.

Techniques to prevent syncope:

* Ask patients about history of fainting or lightheadedness with needle sticks; if so, have them lie supine on a cot or mat for the injection.
* Ask patients if they’ve eaten today; if not, provide a drink and snack prior to the injection.

The deltoid muscle is the preferred site for IM administration. Inject into the central and thickest portion of the deltoid muscle.

[To avoid injury](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6347325/figure/f1-0650040/), do not inject too high or too low in the deltoid; identify an injection point 2-3 finger widths down from the acromion.

Cleanse the skin of the area to be injected using an alcohol wipe.

Use a sterile 22 to 25-gauge safety needle; 1” length for most adults and 1½” length for adults with very large arms. The needle should be inserted at a 90° angle.

For each dose, draw 0.5 mL into a sterile safety syringe and verify the final dosing volume of 0.5 mL. Cleanse the vial stopper between each withdrawal, using an alcohol wipe.

**Storage and Handling**

See [Fact Sheet for HCP](https://www.fda.gov/media/146304/download) or [CDC Janssen Storage and Handling Resources](https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html) for details.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. **Do not refreeze once thawed.**

**Storage before vial puncture:**

* Store unpunctured vials at standard refrigerator temperature between 36° to 46°F (2° to 8°C)
* During storage, protect from light
* **Do not freeze**
* Unpunctured vials can be stored at room temperature between 46° to 77°F for up to 12 hours.

**Storage after first puncture of the vial:**

* Hold punctured vials at standard refrigerator temperature between 36° to 46°F (2° to 8°C) for up to 6 hours
* Or, hold punctured vials at room temperature 46° to 77°F for up to 2 hours
* Discard vial if not used within these times

**After Administering Vaccine**

Observe all recipients after vaccination to monitor for the occurrence of immediate adverse reactions.

**30-min** observation period:

* History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
* History of anaphylaxis due to any cause
* Contraindication to an mRNA COVID-19 vaccine, but able to receive Janssen vaccine

**15-min** observation period: All other vaccinees

Counsel recipients:

* That since vaccination is not 100% effective, current guidance on preventing COVID-19 should continue to be followed.
* That they may treat post-vaccination symptoms with typical doses of acetaminophen, ibuprofen, or naproxen, but they should not take these medications to try to prevent symptoms
* That while the chance is remote, a syndrome of blood clots and low platelets may occur after Janssen COVID-19 vaccine. Recipients should seek medical attention promptly if, within 3-4 weeks of Janssen vaccine, they experience severe headache, visual changes, abdominal pain, nausea and vomiting, back pain, shortness of breath, leg pain or swelling, and petechiae, easy bruising, or bleeding.

Provide a vaccination document to the recipient or their caregiver with the administration date and brand administered.

**Reported Adverse Reactions**

**Local Reactions.** In clinical studies, redness, swelling, and pain at the injection site were mainly mild-moderate in severity, began on average 1 day after vaccination, and lasted on average for 2-3 days.

Up to 60% of vaccinees reported at least one local injection site reaction. Pain at the injection site was the most frequent; redness and swelling at the injection site were much less frequent.

**Systemic Reactions.** In clinical studies, systemic adverse reactions were mainly mild to moderate in severity, began within 1-2 days of vaccination, and lasted on average for 2 days.

Up to 60% of vaccinees reported at least one systemic reaction. The frequency of systemic adverse reactions was higher in recipients age 18 to 59 years compared with those age 60 years and older.

Fatigue, headache, and myalgia were the most common systemic reactions (~40%), followed by nausea in 15% and fever in 13%.

See [Fact Sheet for HCP](https://www.fda.gov/media/146304/download) or this [CDC page](https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/reactogenicity.html) for data on rates of reported adverse reactions.

See information above regarding TTS.

**Evaluating and Managing New-Onset Systemic Post-Vaccination Symptoms**

Post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases.

Note that cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

CDC has posted approaches to evaluating and managing new onset post-vaccination signs and symptoms [in healthcare providers](https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html) and in [long-term care facility residents](https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html). Additional guidance for other persons or settings may be forthcoming.

**Mandatory Reporting to the Vaccine Adverse Event Reporting System (VAERS)**

Vaccination providers are responsible for reporting certain types of events in vaccine recipients.

* All vaccine administration errors, whether or not the error is associated with an adverse event.
* Serious adverse events, whether or not the event is attributable to vaccination.
	+ Serious adverse events are defined as: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect; an important medical event that may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes above).
* Cases of multisystem Inflammatory Syndrome (MIS) in adults or children

Refer to the [Fact Sheet for HCP](https://www.fda.gov/media/146304/download) for details of reporting to VAERS.

**Reference Documents**

EUA Fact Sheet for Recipients/Caregivers <https://www.fda.gov/media/146305/download>

EUA Fact Sheet for Healthcare Providers <https://www.fda.gov/media/146304/download>

FDA website: Janssen Vaccine

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

CDC Janssen Vaccine Page <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>

Janssen COVID-19 vaccine Website <http://www.janssencovid19vaccine.com/>