

## COVID-19 Vaccine, Viral Vector (Janssen)

### 80:12 • Vaccines (AHFS primary)

#### Special Alerts:

**National Alert Network (NAN) Alert Regarding Influenza and COVID-19 Vaccine Mix-ups:** On October 15, 2021, the National Alert Network (NAN) issued an alert to make vaccine providers aware of reports of accidental mix-ups between the influenza (flu) and COVID-19 vaccines. The alert is based on 16 cases reported to the Institute for Safe Medication Practices (ISMP) error reporting programs. Most of the reports ISMP has received involve administration of one of the COVID-19 vaccines instead of an influenza vaccine; in 3 cases, patients received an influenza vaccine instead of a COVID-19 vaccine. Because most of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, possible contributing factors include increased demand for vaccination services, the ability to administer the flu and COVID-19 vaccines during the same visit, syringes located next to each other, unlabeled syringes, distractions, and staffing shortages. The alert provides recommendations for preventing such vaccine mix-ups. For additional information, consult the NAN alert at <https://www.ismp.org/sites/default/files/attachments/2021-10/NAN-20211015.pdf>.

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■ COVID-19 vaccine (Janssen), also known as the Johnson & Johnson COVID-19 vaccine, is a recombinant, replication-incompetent, viral vector (i.e., adenovirus serotype 26 [Ad26] vector) vaccine used to stimulate active immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

#### Uses

##### ■ Prevention of Coronavirus Disease 2019 (COVID-19)

COVID-19 vaccine (Janssen) is an adenovirus-vectored vaccine being investigated and used for the prevention of coronavirus disease 2019† (COVID-19) caused by SARS-CoV-2. Although efficacy and safety of COVID-19 vaccine (Janssen) have not been definitely established, the vaccine is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals ≥18 years of age. The Janssen COVID-19 vaccine can be used for primary vaccination† or as a single homologous booster dose† in individuals who have completed primary vaccination with this vaccine or as a single heterologous booster dose† in individuals who have completed primary vaccination with another authorized or approved COVID-19 vaccine.

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations and clinical considerations for the use of COVID-19 vaccines, including dosage and administration, specific populations and situations, and cautionary information.

There currently are 3 different COVID-19 vaccines available for use in the US, including a viral-vectored vaccine (Janssen COVID-19 vaccine) and 2 nucleoside-modified mRNA vaccines (Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine). COVID-19 vaccination is currently recommended for individuals ≥5 years of age in the US for prevention of COVID-19; however, the age groups approved or authorized to receive vaccination vary by vaccine product. In most situations, ACIP states that the mRNA vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination because of the risks associated with the Janssen vaccine; however, the Janssen COVID-19 vaccine may be offered in certain situations.

#### Emergency Use Authorization

On February 27, 2021, FDA issued an EUA that permits use of COVID-19 vaccine (Janssen) to prevent COVID-19 in individuals ≥18 years of age. Since then, the EUA has been amended and reissued several times as the scope of authorization changed. The EUA for the Janssen COVID-19 vaccine now permits use as:

- A single-dose (0.5 mL) primary series in adults ≥18 years of age.
- A single homologous booster dose (0.5 mL) administered at least 2 months after completion of the primary series of the COVID-19 vaccine (Janssen) in adults ≥18 years of age.
- A single heterologous booster dose (0.5 mL) after completion of primary vaccination with another authorized or approved COVID-19 vaccine in adults ≥18 years of age. When a heterologous booster dose is used, the dosing interval is the same as that authorized for a booster dose of the vaccine product used for primary vaccination.

FDA issued the EUA for COVID-19 vaccine (Janssen) after concluding that emergency use of the vaccine for the prevention of COVID-19 met the criteria for issuance of an EUA for the following reasons: SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness; based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Janssen COVID-19 vaccine may be effective in preventing COVID-19 and, when used under the conditions described in the authorization, the known and potential benefits outweigh the known and potential risks; and there are no adequate, approved, and available alternatives to the emergency use of the vaccine to prevent COVID-19. The EUA requires that the vaccine be administered by vaccination providers as authorized, and that vaccination providers participate and comply with the terms and training required by CDC's COVID-19 vaccination program.

Issuance of the EUA for COVID-19 vaccine (Janssen) was based on FDA review of safety and efficacy data from an ongoing phase 3 clinical trial that enrolled 43,783 adults randomized 1:1 to receive the vaccine or saline control. (See Clinical Experience under Uses.)

The EUA requires that vaccination providers administering the Janssen COVID-19 vaccine comply with certain mandatory requirements. These requirements include providing the recipient or caregiver with information consistent with the EUA fact sheet and ensuring that all vaccination administration errors and all serious adverse events potentially attributable to the vaccine are reported as specified in the EUA fact sheet.

For additional information, consult the Janssen COVID-19 vaccine EUA letter of authorization (<https://www.fda.gov/media/146303/download>), EUA fact sheet for healthcare providers (<https://www.fda.gov/media/146304/download>), and EUA fact sheet for recipients and caregivers (<https://www.fda.gov/media/146305/download>).

#### Clinical Experience

Efficacy, safety, and immunogenicity of a single dose of COVID-19 vaccine (Janssen) for the prevention of COVID-19 are being evaluated in an ongoing multicenter, randomized, double-blind, placebo-controlled, phase 3 clinical trial in adults 18 years of age or older (NCT04505722; ENSEMBLE; study COV3001). At the time of FDA's review of the vaccine for the EUA, the efficacy analysis population had been followed for a median of 8 weeks and data indicated that efficacy of a single dose of the Janssen COVID-19 vaccine in preventing protocol-defined moderate to severe/critical COVID-19 in individuals who were seronegative or had an unknown serostatus at baseline was 66.9% when cases occurring at least 14 days after vaccination were considered and 66.1% when cases occurring at least 28 days after vaccination were considered. Efficacy of a single dose of the vaccine in preventing protocol-defined severe/critical COVID-19 was 76.7 or 85.4% when cases occurring at least 14 or 28 days, respectively, after vaccination were considered.

This phase 3 trial enrolled adults ≥18 years of age who were randomized 1:1 to receive a single IM dose of the Janssen COVID-19 vaccine (0.5-mL dose containing  $5 \times 10^{10}$  virus particles of recombinant Ad26) or saline placebo, and randomization was stratified by age (18–59 years of age, 60 years of age or older) and presence or absence of comorbidities associated with an increased risk of progression to severe COVID-19. The study protocol allowed for inclusion of participants with stable preexisting medical conditions, defined as disease not requiring substantial change in therapy during the 3 months prior to enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. The co-primary efficacy end points were first occurrence of moderate to severe/critical COVID-19 (as defined in the protocol) with onset of symptoms at least 14 days after vaccination and onset at least 28 days after vaccination. Final determinations of severe/critical COVID-19 cases were made by an independent adjudication committee.

At the time of FDA's review for the EUA, the co-primary efficacy analysis population of 39,321 adults (19,630 received the Janssen COVID-19 vaccine and 19,691 received placebo) included 38,059 participants seronegative for SARS-CoV-2 at baseline and 1262 participants with unknown serostatus. Demographic and baseline characteristics were similar among participants who received the Janssen COVID-19 vaccine and those who received placebo.

At the time of FDA's review for the EUA, 116 cases of confirmed moderate to severe/critical COVID-19 had occurred in the vaccine group and 348 cases had occurred in the placebo group at least 14 days after vaccination and 66 and 193 cases had occurred in the vaccine and placebo groups, respectively, at least 28 days after

vaccination. This corresponded to 66.9% vaccine efficacy in prevention of moderate to severe/critical COVID-19 when considering cases occurring at least 14 days after vaccination and 66.1% vaccine efficacy when considering cases occurring at least 28 days after vaccination. When central laboratory-confirmed and blind-adjudicated cases of severe/critical COVID-19 were evaluated, 14 and 60 such cases had occurred in the vaccine and placebo groups, respectively, at least 14 days after vaccination and 5 and 34 cases had occurred in the vaccine and placebo groups, respectively, at least 28 days after vaccination. This corresponded to 76.7% vaccine efficacy in prevention of severe/critical COVID-19 when considering cases occurring at least 14 days after vaccination and 85.4% vaccine efficacy when considering cases occurring at least 28 days after vaccination. There were no deaths related to COVID-19 reported in recipients of the Janssen COVID-19 vaccine compared with 5 COVID-19-related deaths in placebo recipients.

#### Booster Doses.

Efficacy and safety of the Janssen COVID-19 vaccine as a booster dose following initial vaccination were evaluated across 5 clinical trials in which participants received 2 doses of the vaccine administered at least 2 months apart. A pooled assessment of approximately 9000 participants did not identify any new safety concerns with the booster dose as compared to the safety profile of the single-dose primary vaccination. Within a phase 2 study, adult participants received a booster dose approximately 2 months after primary vaccination. The immunogenicity analysis population included 39 participants. The effectiveness of a booster dose was evaluated through measurement of neutralizing antibodies to a SARS-CoV-2 strain. Administration of a booster dose resulted in geometric mean increases in neutralizing antibody titers of approximately 8-fold above pre-primary vaccination levels and about 2-fold above pre-booster baseline levels. Additional analysis in a limited number of participants demonstrated that the increase in IgG antibodies after booster administration was not lower when the booster was received 6 months after the primary vaccination as compared to 2 months. Efficacy and safety of the Janssen COVID-19 vaccine as a heterologous booster dose after completion of the primary vaccination series with another authorized or approved COVID-19 vaccine are being evaluated in an ongoing phase 1/2 trial. At the time of the FDA EUA review for authorization of booster doses, 458 participants 19–85 years of age who had no history of a prior SARS-CoV-2 infection were evaluated; participants had completed primary vaccination with a COVID-19 vaccine (Moderna, Janssen, or Pfizer-BioNTech) and were randomized 1:1:1 to receive a booster dose of the Moderna COVID-19 vaccine, Janssen COVID-19 vaccine, or Pfizer-BioNTech COVID-19 vaccine. A booster response to the Janssen COVID-19 vaccine based on neutralizing antibody titers against a pseudovirus expressing the SARS-CoV-2 spike protein was demonstrated regardless of primary vaccine received.

## Dosage and Administration

### ■ General

#### Pretreatment Screening

- Screen all individuals for contraindications and precautions to vaccination.

#### Patient Monitoring

- Monitor all individuals who receive a COVID-19 vaccine for immediate adverse reactions according to CDC (ACIP) guidelines. ACIP states that the following individuals should be observed for 30 minutes after receiving the vaccine: those with a history of immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapy; those with a contraindication to a different type of COVID-19 vaccine; those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine; and those with a history of anaphylaxis due to any cause. All other individuals should be observed for 15 minutes. A longer period of observation may be indicated for some individuals based on clinical concern (e.g., vaccine recipient develops pruritus and swelling at the injection site during the observation period).
- Instruct vaccine recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after the observation period is complete. (See Hypersensitivity Reactions under Cautions.)

#### Premedication and Prophylaxis

- Antipyretics or analgesics (e.g., acetaminophen, nonsteroidal anti-inflammatory agents) may be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in individuals receiving a COVID-19 vaccine is *not* currently recommended because information regarding possible impact on antibody response to the vaccine is not available at this time.
- Premedication with antihistamines prior to vaccination to prevent allergic reactions is *not* recommended; antihistamines do not prevent anaphylaxis and may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)

#### Dispensing and Administration Precautions

- Appropriate medications and supplies for managing immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines. Healthcare personnel who are trained and qualified

to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination sites at all times. Vaccination locations that anticipate vaccinating large numbers of people (e.g., mass vaccination clinics) should plan adequate staffing and supplies (including epinephrine) for assessment and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)

- Syncope (vasovagal or vasodepressor reaction; fainting) may occur following administration of parenteral vaccines; such reactions usually occur within 15 minutes following vaccine administration and are reported most frequently in adolescents and young adults. Take appropriate measures to decrease the risk of injury if the vaccine recipient becomes weak or dizzy or loses consciousness (e.g., instruct the vaccine recipient to sit or lie down during and for 15 minutes after vaccination). If syncope occurs, observe the individual until symptoms resolve.

#### Other General Considerations

- At the time of vaccine administration, provide the vaccine recipient or caregiver with a vaccination record card that documents the name of the vaccine and date when the vaccine was given.
- Provide vaccine recipients or their caregiver with information on CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in individuals who have received a COVID-19 vaccine. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)
- Prior to vaccination, counsel vaccine recipient or their caregiver about local and systemic adverse effects that may occur following vaccination.
- Individuals who receive COVID-19 vaccines should follow current CDC guidance to protect themselves and others. This may include wearing a mask in certain settings with substantial or high levels of viral transmission; following application federal, state, local, tribal, or territorial laws, rules, and regulations; and following CDC travel guidance and any applicable local business or workplace guidance. (See Limitations of Vaccine Effectiveness under Cautions.)

### ■ Administration

COVID-19 vaccine (Janssen) is administered *only* by IM injection into the deltoid.

#### IM Injection

COVID-19 vaccine (Janssen) is supplied as a suspension in multiple-dose vials. Although the Janssen COVID-19 vaccine is *initially* stored frozen by the manufacturer, the vaccine is shipped and stored refrigerated at a temperature of 2–8°C. (See Stability.)

*The Janssen COVID-19 vaccine should not be diluted.*

After removal from refrigeration, unused vials (i.e., unpunctured) may be stored for up to 12 hours at room temperature (9–25°C). After the first dose of Janssen COVID-19 vaccine is withdrawn from the multiple-dose vial, the vial should be held in a refrigerator (2–8°C) for up to 6 hours or at room temperature (up to 25°C) for up to 2 hours and *must* be discarded if not used within these time frames after first vial entry. The date and time of first use should be recorded on the vial label.

Before withdrawing each dose, the vaccine vial should be gently swirled in an upright position for 10 seconds and should *not* be shaken.

The Janssen COVID-19 vaccine should appear as a colorless to slightly yellow, clear to very opalescent suspension and should *not* be used if it is discolored or contains particulates.

To administer a dose, withdraw 0.5 mL of the vaccine from the vial using aseptic technique and an appropriate syringe and needle, and administer immediately. Each multiple-dose vial of Janssen COVID-19 vaccine provides five 0.5-mL doses. Because the vaccine does not contain preservatives, it is critical that any vaccine remaining in the vial that does not constitute a full 0.5-mL dose be discarded and should *not* be pooled with vaccine from other vials to obtain a dose.

### ■ Dosage

For primary vaccination or booster doses, COVID-19 vaccine (Janssen) is administered as a single 0.5-mL dose. The 0.5-mL dose contains  $5 \times 10^{10}$  virus particles of recombinant, replication-incompetent Ad26 (see Description).

A single dose of the Janssen COVID-19 vaccine is considered a complete vaccination series. Individuals should generally not receive more than one complete primary vaccination series for active immunization against COVID-19 (i.e., a single dose of Janssen COVID-19 vaccine or a 2-dose regimen of an mRNA vaccine [Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine]).

Individuals are considered fully vaccinated against COVID-19 if at least 2 weeks have elapsed since they received a single dose of the Janssen COVID-19 vaccine.

ACIP states that, in limited, *exceptional* situations when an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the vaccination series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), a single dose of Janssen COVID-19 vaccine administered at least 28 days after the first dose of mRNA COVID-19 vaccine may be considered, provided certain measures are taken. (See Hypersensitivity Reactions under Cautions.) An individual who receives a single dose of the Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine under such exceptional circumstances should be considered to have received valid, single-dose vaccination with Janssen COVID-19 vaccine (not a mixed vaccination series) and is considered fully vaccinated against

COVID-19 if at least 2 weeks have elapsed since the single dose of Janssen COVID-19 vaccine.

For booster doses, ACIP states that use of an mRNA COVID-19 vaccine is preferred in individuals  $\geq 18$  years of age even for those who received the Janssen COVID-19 vaccine for their single-dose primary series. However, if an mRNA vaccine cannot be given, offering the Janssen COVID-19 vaccine as a booster is preferable to not providing any COVID-19 vaccine booster. In individuals 12–17 years of age, only the Pfizer BioNTech COVID-19 vaccine can be used for the booster dose.

### Adult Dosage

#### Primary Vaccination.

The FDA EUA that permits use of COVID-19 vaccine (Janssen) for the prevention of COVID-19† (see Emergency Use Authorization under Uses) states that adults  $\geq 18$  years of age should receive a single 0.5-mL dose of the vaccine as primary vaccination.

#### Booster Doses.

Each booster dose of the Janssen COVID-19 vaccine is 0.5 mL. The dose and volume are the same when given as a homologous (same as the primary series) or heterologous (different from the primary series) booster. The FDA EUA permits administration of a single homologous booster dose† of 0.5 mL of the Janssen COVID-19 vaccine at least 2 months (8 weeks) after completion of the primary vaccine series in individuals  $\geq 18$  years of age. The FDA EUA permits administration of a single heterologous booster dose† of 0.5 mL of the Janssen COVID-19 vaccine following completion of primary vaccination with another authorized or approved COVID-19 vaccine in individuals  $\geq 18$  years of age. When a heterologous vaccine product is used for the booster dose, the dosing interval should be the same as that authorized for a booster dose of the vaccine product used for primary vaccination. For example, those who received an mRNA primary series should receive a Janssen COVID-19 vaccine booster dose at least 5 months after completing the primary series.

## Cautions

### ■ Contraindications

- Known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including polysorbate. (See Description.)
- History of thrombosis with thrombocytopenia syndrome (TTS) following receipt of Janssen COVID-19 vaccine or another adenovirus-vectored COVID-19 vaccine (e.g., AstraZeneca COVID-19 vaccine, which is not authorized for use in the US).

### ■ Warnings/Precautions

#### Sensitivity Reactions

##### Hypersensitivity Reactions.

At the time that FDA's safety analysis of data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial evaluating COVID-19 vaccine (Janssen) was performed for the EUA, urticaria (nonserious) occurring within 7 days following vaccination had been reported in 5 individuals who received the vaccine and 1 individual who received placebo.

A serious adverse hypersensitivity event (not classified as anaphylaxis) was reported in one vaccinated individual; the reaction consisted of urticaria beginning 2 days following vaccination and angioedema of the lips beginning 4 days following vaccination without respiratory distress. This event was considered likely related to the vaccine.

Severe allergic reactions, including anaphylaxis, have been reported in clinical studies following administration of the Janssen COVID-19 vaccine.

If a hypersensitivity reaction, including anaphylaxis, occurs following COVID-19 vaccination, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Because anaphylactic reactions have been reported rarely following administration of COVID-19 vaccines, ACIP has issued interim guidance with contraindications and precautions for use of COVID-19 vaccines pending further investigation. For the purposes of this interim guidance, ACIP states that an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis occurring within 4 hours following administration. Vaccination providers should attempt to determine whether reactions reported following COVID-19 vaccination are consistent with immediate allergic reactions or are reactions commonly observed following vaccination, such as vasovagal reactions or postvaccination adverse effects.

**History of polysorbate allergy:** ACIP considers this a **contraindication** to vaccination with COVID-19 vaccine (Janssen). ACIP states that use of an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) can be considered in such individuals. However, polysorbates are structurally related to polyethylene glycol (PEG), an ingredient in mRNA COVID-19 vaccines, and there is potential for cross-reactive hypersensitivity with PEG. Consultation with an allergist-immunologist should be considered to help determine if the individual with polysorbate allergy can safely receive an mRNA COVID-19 vaccine.

### Known contraindication to vaccination with mRNA COVID-19 vaccines

**(including known PEG allergy):** ACIP considers this a **precaution** to vaccination with COVID-19 vaccine (Janssen) and states that consideration can be given to using the Janssen COVID-19 vaccine in such individuals. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA COVID-19 vaccines and the Janssen COVID-19 vaccine (including PEG and polysorbate 80, respectively), consultation with an allergist-immunologist should be considered to help determine if the individual can safely receive the Janssen COVID-19 vaccine. If a decision is made to administer the Janssen COVID-19 vaccine to individuals with a contraindication to mRNA COVID-19 vaccines, the vaccine should be administered *only* in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

**History of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, or subcutaneous vaccines or therapies):** ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination. ACIP states that a history of allergic reaction to subcutaneous immunotherapy for allergies (i.e., allergy shots) is **not** a precaution or contraindication to vaccination.

**History of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components (one of which is a vaccine component), but it is not known which component elicited the reaction:** ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination.

**History of allergic reactions (including severe allergic reactions) not related to COVID-19 vaccines or other vaccines or injectable therapies:** ACIP states that allergic reactions related to food, pets, insects, venom, or environmental allergies and allergic reactions to oral medications (including the oral equivalents of injectable medications) are **not** a contraindication or precaution to COVID-19 vaccination. Latex allergy is **not** a contraindication or precaution since vial stoppers of COVID-19 vaccines are not made with natural rubber latex. In addition, allergies to eggs or gelatin are **not** a contraindication or precaution since COVID-19 vaccines do not contain eggs or gelatin.

If a precaution for COVID-19 vaccination is identified, ACIP recommends that a risk assessment be performed to help decide whether the individual should be vaccinated. The risk assessment should consider the risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation), risk of severe disease or death due to COVID-19 (e.g., because of age or underlying medical conditions), the unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in individuals with a history of immediate allergic reactions to other vaccines or injectable therapies, and ability to be vaccinated in a setting where appropriate medical care is immediately available to treat anaphylaxis if it occurs.

ACIP states that the following individuals should be monitored for 30 minutes after vaccination: those with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy, those with a contraindication to a different type of COVID-19 vaccine, those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of anaphylaxis due to any cause not considered a contraindication; all other individuals should be observed for 15 minutes. In addition, vaccine recipients should be instructed to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site.

Appropriate medications and supplies to assess and manage immediate allergic reactions (e.g., sufficient quantities of epinephrine in prefilled syringes or autoinjectors) *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. Early recognition of the clinical signs and symptoms of anaphylaxis is important since such reactions require immediate treatment. Individuals with suspected anaphylaxis should be immediately treated with IM epinephrine.

ACIP interim guidance regarding early recognition of clinical signs and symptoms of anaphylaxis and guidance regarding preparation for and management of anaphylaxis at COVID-19 vaccination sites, including recommendations for medications and supplies to have immediately available and specific recommendations regarding therapeutic management of anaphylaxis, are available at the CDC website at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html> and <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

When confronted with a complex COVID-19 vaccine safety question concerning an individual patient that is not readily addressed by ACIP guidance, US healthcare personnel and health departments can request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>).

### Thrombotic Events

At the time of FDA's safety analysis of the Janssen COVID-19 vaccine for the initial EUA, there had been 6 reports of deep-vein thrombosis in individuals who received the vaccine (2 serious events; 5 events within 28 days of vaccination) and 2 such events in placebo recipients (1 serious; 2 within 28 days of vaccination). In addition, there were 4 reports of pulmonary embolism (3 serious; 2 within 28 days of vaccination) in vaccine recipients versus 1 report in placebo recipients (serious;

within 28 days of vaccination) and 1 report of transverse sinus thrombosis (serious; within 28 days of vaccination) in vaccine recipients versus none in placebo recipients. A causal relationship between these thromboembolic events and the vaccine could not be established based on the phase 3 trial data. However, following issuance of the initial EUA for the Janssen COVID-19 vaccine, there were rare reports of thrombosis involving large blood vessels occurring with thrombocytopenia; post-authorization experience supports a causal relationship between the vaccine and transverse sinus thrombosis with thrombocytopenia.

#### **Thrombosis with Thrombocytopenia.**

Thrombosis in an unusual location (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) occurring with new-onset thrombocytopenia (also known as thrombosis with thrombocytopenia syndrome [TTS]) and with onset of symptoms approximately 1–2 weeks after vaccination has been reported rarely in recipients of the Janssen COVID-19 vaccine during post-authorization surveillance.

In response to reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in a few recipients of the Janssen COVID-19 vaccine, FDA and CDC initiated a temporary pause in use of the vaccine in the US out of an abundance of caution to allow time for investigation of these cases, inform vaccine recipients and healthcare providers of possible symptoms, and inform healthcare providers about appropriate management of this extremely rare adverse event. The temporary pause in use of the vaccine was lifted 10 days later after a thorough safety review was completed. At the time the pause was initiated (April 13, 2021), 6 cases of CVST had been reported in vaccine recipients, including one fatality; all 6 cases were reported in females 18–48 years of age and occurred within 6–13 days after vaccination.

After extensive evaluation of data for the post-authorization cases of TTS and analyses of the risks and benefits of vaccination with the Janssen COVID-19 vaccine (both population- and individual-level risks and benefits), FDA and CDC determined that the known and potential benefits of the vaccine outweigh its known and potential risks in adults 18 years of age or older. At the time of CDC's safety data analysis (April 21, 2021), a total of 15 cases of TTS had been reported and confirmed, including 3 fatalities. These post-authorization cases all occurred in females 18–59 years of age (median age 37 years; 13 of the 15 reported cases occurred in women 18–49 years of age), symptom onset was 6–15 days after vaccination (median 8 days), and the clinical course shared features with autoimmune heparin-induced thrombocytopenia. Some of these women had underlying medical conditions or risk factors for hypercoagulability (e.g., obesity, oral contraceptive use, hypothyroidism, hypertension); none of these women had a documented history of previous thrombotic events, known diagnosis of an underlying clotting disorder, or a family or personal history of clotting disorders. A single case of CVST with thrombocytopenia was reported during the phase 3 clinical trial of the Janssen COVID-19 vaccine (a male in the 18–49 years of age group). Data for the initial 12 cases of TTS reported to VAERS that occurred in recipients of the Janssen COVID-19 vaccine have been published; data that include the 15 TTS cases evaluated as part of CDC's safety analysis are provided in meeting materials from the April 23, 2021 ACIP meeting available at <https://www.cdc.gov/vaccines/acip/meetings/index.html>. At the time of CDC's safety analysis, the reporting rate to VAERS was 7 cases of TTS per million doses of the Janssen COVID-19 vaccine administered to women 18–49 years and 0.9 cases per million doses administered to women 50 years of age or older.

Data accumulated as of May 7, 2021 indicated that more than 8.7 million doses of the Janssen COVID-19 vaccine had been administered in the US and a total of 28 cases of TTS had been reported to VAERS and confirmed (22 cases in females and 6 cases in males). Analyses of all 28 cases of TTS indicated that the median age was 40 years (range: 18–59 years of age), median time from vaccination to symptom onset was 9 days (range 4–15 days), a total of 3 deaths had occurred, CVST occurred in 19 of the 28 cases, nadir platelet counts were less than 50,000/mm<sup>3</sup> in 18 of the 28 cases, and results of enzyme-linked immunosorbent assay (ELISA) for platelet-activating antibodies against platelet factor 4 (PF4) were positive in 24 of the 26 patients tested.

On December 14, 2021, FDA authorized revisions to the Janssen COVID-19 vaccine fact sheet for healthcare providers. A contraindication was added for individuals with a history of TTS following receipt of the Janssen COVID-19 vaccine or another adenovirus-vectored COVID-19 vaccine. Cases of TTS have been reported across a wide age range of adults ≥18 years of age; females between 30–49 years have the highest reporting rate (approximately 1 case/100,000 doses administered). Overall, approximately 15% of TTS cases have been fatal.

FDA and CDC are continuing to closely monitor reports of TTS in recipients of the Janssen COVID-19 vaccine. Current evidence supports a causal relationship between TTS and the Janssen COVID-19 vaccine. Specific risk factors for TTS following vaccination with the Janssen COVID-19 vaccine and the level of potential excess risk due to vaccination are still under investigation. Do not administer the Janssen COVID-19 vaccine to any individual who developed TTS following the Janssen COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccine.

ACIP states that women 18–50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine).

ACIP advises that individuals who have a history of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia such as heparin-induced thrombocytopenia (HIT) should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine.

Healthcare providers should be alert to and maintain a high index of suspicion for signs and symptoms of TTS (e.g., severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, new or easy bruising) occurring approximately 1–2 weeks after vaccination in individuals who have received the Janssen COVID-19 vaccine. Based on data regarding the US patients who developed TTS after receiving the Janssen COVID-19 vaccine and data regarding patients in Europe who developed immune thrombotic thrombocytopenia after receiving a different adenovirus-vectored COVID-19 vaccine not available in the US (i.e., AstraZeneca COVID-19 vaccine), the clinical course shares features with autoimmune HIT and may be associated with platelet-activating antibodies against PF4.

When managing thrombotic events and thrombocytopenia that occur following vaccination with the Janssen COVID-19 vaccine, use of heparin and its derivatives should be avoided (may be harmful); use of other anticoagulants and high-dose immune globulin IV (IGIV) should be considered. Consultation with hematology specialists is strongly recommended. Information regarding diagnosis and management of suspected cases of TTS in recipients of the Janssen COVID-19 vaccine is provided in the CDC Health Alert Network (HAN) notification at <https://emergency.cdc.gov/han/2021/han00442.asp> and is available from the American Society of Hematology (ASH) at <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>.

Vaccine recipients should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurologic symptoms (including severe or persistent headaches or blurred vision), easy bruising, or a diffuse rash consisting of petechiae (pinpoint-like spots) beyond the vaccination site within a few weeks after receiving the Janssen COVID-19 vaccine. These symptoms are distinct from the commonly reported adverse effects that may be experienced in the first few days following vaccination (e.g., headache, fatigue, muscle aches, nausea) that usually are mild to moderate in severity and last 1–2 days.

If TTS occurs following vaccination, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Immune Thrombocytopenia**

Reports of adverse events following use of the Janssen COVID-19 vaccine under EUA suggest an increased risk of immune thrombocytopenia (ITP) during the 42 days following vaccination. Individuals with a history of ITP should discuss the risk of ITP with their healthcare provider and the potential need for platelet monitoring following vaccination with the Janssen COVID-19 vaccine.

#### **Guillain-Barré Syndrome**

An increased risk of Guillain-Barré syndrome (GBS) following use of the Janssen COVID-19 vaccine has been suggested based on reports of adverse events during use under the EUA; the increased risk period is the first 42 days following vaccination.

Vaccine recipients should be instructed to seek immediate medical attention if they develop worsening weakness or tingling sensations or difficulty with walking, facial movements (e.g., speaking, chewing or swallowing), vision (e.g., double vision or inability to move eyes) or bladder control/bowel function.

If GBS occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Other Adverse Events**

Other adverse effects with a numerical imbalance between vaccine recipients and placebo recipients at the time that FDA's safety analysis of the phase 3 trial of the Janssen COVID-19 vaccine was performed for the EUA included 4 reports of seizures in vaccine recipients (1 serious; 4 within 28 days of vaccination) versus 1 seizure event in placebo recipients and 6 reports of tinnitus in vaccine recipients (not serious; all 6 within 28 days of vaccination, including 3 within 2 days of vaccination) versus none in placebo recipients. A causal relationship between these events and the vaccine could not be established.

#### **Concomitant Illness**

The decision to administer or delay vaccination in an individual with a current or recent febrile illness depends on the severity of symptoms and etiology of the illness.

ACIP states that a moderate or severe acute illness is a precaution for administration of vaccines and states that a risk assessment should be performed with potential deferral of vaccination. Deferring vaccination until an individual has recovered avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.

#### **Individuals with Current SARS-CoV-2 Infection.**

ACIP recommends that COVID-19 vaccination be deferred in individuals with known *current* SARS-CoV-2 infection until they have recovered from the acute illness (if symptomatic) and until criteria for discontinuance of isolation have been met. While

there is no recommended minimum interval between SARS-CoV-2 infection and COVID-19 vaccination, current evidence suggests that the risk of reinfection is low in the months after initial infection, but may increase with time due to waning immunity.

#### **Individuals with Prior SARS-CoV-2 Infection.**

Available data suggest that COVID-19 vaccines can be given safely to individuals with evidence of prior SARS-CoV-2 infection.

Data are not available to date regarding the safety and efficacy of administering COVID-19 vaccines to individuals who have received passive antibody therapy with investigational SARS-CoV-2-specific monoclonal antibodies or investigational COVID-19 convalescent plasma as part of treatment of COVID-19. (See SARS-CoV-2 Antibody Therapies under Drug Interactions.)

#### **Individuals with a History of Multisystem Inflammatory Syndrome.**

Data are not available to date regarding the safety and efficacy of COVID-19 vaccines in adults or children with a history of multisystem inflammatory syndrome (MIS-A or MIS-C, respectively). The mechanisms of MIS-A and MIS-C are not well understood, but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear whether those with a history of MIS-A or MIS-C are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to COVID-19 vaccination. ACIP recommends weighing these theoretical concerns against the known risks of COVID-19 following reinfection and the benefits of protection following COVID-19 vaccination.

ACIP states that individuals with a history of MIS-A or MIS-C may choose to be vaccinated. When making decisions regarding COVID-19 vaccination in those with a history of MIS-C, the benefits of vaccination are thought to outweigh the risks (MIS-like illness or myocarditis) if the following criteria are met: achievement of clinical recovery (including return to normal cardiac function), 90 days have passed since the diagnosis of MIS-C, the individual resides in an area of high or substantial community transmission of SARS-CoV-2 (or otherwise have an increased risk for exposure and transmission), and the onset of MIS-C preceded any COVID-19 vaccination. Those with a history of MIS-C that do not meet the previous criteria and those with a history of MIS-A may consider vaccination based on achievement of clinical recovery, increased personal risk of severe COVID-19 (e.g., age, underlying conditions), and timing of immunomodulatory therapies.

If MIS-A or MIS-C associated with a confirmed SARS-CoV-2 infection develops after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Healthcare providers and health departments can also request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>).

If MIS-A or MIS-C occurs following COVID-19 vaccination, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Individuals with Underlying Medical Conditions**

ACIP states that individuals with altered immunocompetence or certain underlying medical conditions may receive COVID-19 vaccination if they have no contraindications to the vaccine. Current FDA-approved or FDA-authorized COVID-19 vaccines are not live vaccines, so they may be safely administered to immunocompromised individuals.

US healthcare personnel and health departments can request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>) if they have concerns about vaccinating individuals with certain underlying medical conditions.

#### **Individuals with Altered Immunocompetence.**

Although some individuals with altered immunocompetence (e.g., HIV infection) have been included in the ongoing randomized, double-blind, placebo-controlled, phase 3 trial evaluating the Janssen COVID-19 vaccine, the number of such individuals has been insufficient to evaluate safety of the vaccine in such populations.

An additional primary dose of an mRNA COVID-19 vaccine is recommended in moderately or severely immunocompromised individuals. Janssen COVID-19 vaccine is not authorized for use as an additional primary dose, and individuals who have received a single-dose Janssen primary vaccine should not receive an additional primary dose but should receive a booster. A single booster dose with any FDA authorized or approved mRNA COVID-19 vaccine is recommended in moderately or severely immunocompromised individuals  $\geq 18$  years of age who received the single dose primary vaccination with the Janssen COVID-19 vaccine. Individuals with altered immunocompetence should be counseled about the unknown safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses and the need to continue following all current CDC guidelines for fully vaccinated individuals (e.g., wearing a mask, staying 6 feet apart from those outside their household) to protect themselves from COVID-19.

#### **Individuals with Autoimmune Conditions.**

ACIP states that individuals with autoimmune conditions may receive any authorized COVID-19 vaccine, unless they have a contraindication to the vaccine.

#### **Individuals with a History of Thrombosis or Risk Factors for Thrombosis.**

Some experts advise that an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) should be offered to individuals who

have had an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., HIT) that resolved within the past 90 days. The Janssen COVID-19 vaccine is contraindicated in any individual who developed TTS following the Janssen COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccine. (See Thrombosis with Thrombocytopenia under Cautions.)

Clinicians should consider that venous thromboembolism (VTE) is common and that the biologic mechanisms for VTE (as well as arterial thrombi) differ from the underlying immune-mediated mechanism for HIT. Based on current knowledge, experts believe that individuals with risk factors for VTE (e.g., inherited or acquired thrombophilia including factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S, or antithrombin deficiency) or a history of other types of thrombosis (including CVST) not associated with thrombocytopenia are unlikely to be at increased risk for TTS. In addition, although the risk of thrombosis is increased during pregnancy and the postpartum period and with certain hormonal contraceptives (e.g., estrogen-progestin oral contraceptive, transdermal system, or vaginal ring), experts believe that these factors do not make individuals more susceptible to TTS after receipt of the Janssen COVID-19 vaccine. ACIP states that such individuals can receive any FDA-authorized COVID-19 vaccine, including the Janssen COVID-19 vaccine.

ACIP states that administration of anticoagulants or aspirin prior to vaccination with the Janssen COVID-19 vaccine is not recommended. (See Anticoagulants and Aspirin under Drug Interactions.)

#### **Individuals with Liver Disease.**

The American Association for the Study of Liver Diseases (AASLD) has released a consensus statement regarding use of COVID-19 vaccines in individuals who have chronic liver disease or are liver transplant recipients.

Although safety and efficacy data regarding use of COVID-19 vaccines in individuals with chronic liver disease are limited and additional studies are needed, safety and efficacy of the vaccines in such individuals are expected to be similar to the general population.

The AASLD consensus statement should be consulted for additional guidance on use of COVID-19 vaccines in individuals with chronic liver disease.

#### **Individuals with a History of Guillain-Barré Syndrome.**

ACIP states that individuals with a history of GBS may receive COVID-19 vaccination, unless they have a contraindication to the vaccine. A history of GBS is not usually considered a contraindication or precaution to vaccination with most vaccines.

#### **Individuals with a History of Bell's Palsy.**

Although a causal relationship has not been established, several cases of Bell's palsy have been reported in COVID-19 vaccine clinical trials.

Data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial evaluating the Janssen COVID-19 vaccine identified 2 cases of Bell's palsy (facial paralysis) in the vaccine group and 2 cases in the placebo group. FDA stated that, although the cases of Bell's palsy were unlikely to be related to the vaccine, a causal relationship cannot be definitively excluded.

ACIP states that, in the absence of a causal relationship between COVID-19 vaccines and Bell's palsy, individuals with a history of Bell's palsy may receive COVID-19 vaccination, unless they have a contraindication to the vaccine.

If Bell's palsy occurs following COVID-19 vaccination, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Individuals with Increased Bleeding Risk.**

Individuals who have bleeding disorders or are receiving anticoagulant therapy should be advised about the risk of hematoma from IM injections.

ACIP states that IM vaccines may be given to individuals who have bleeding disorders if a clinician familiar with the patient's bleeding risk determines that the preparation can be administered IM with reasonable safety. In these cases, a fine needle (23 gauge or smaller) should be used to administer the vaccine and firm pressure applied to the injection site (without rubbing) for at least 2 minutes. In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for administration shortly after a dose of such therapy.

Individuals receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for IM administration. If possible, IM vaccines could be scheduled prior to use of an anticoagulant so that the patient's risk of bleeding is not increased by the drug's therapeutic action.

#### **Individuals Vaccinated Outside the US**

Some individuals in the US may have previously received vaccination against COVID-19 in another country using a vaccine that is not authorized by the FDA and/or is not listed for emergency use by the World Health Organization (WHO). ACIP provides guidance on COVID-19 vaccination in such individuals.

#### **Limitations of Vaccine Effectiveness**

COVID-19 vaccine (Janssen) may not protect all vaccine recipients against COVID-19. The risk of SARS-CoV-2 infection cannot be fully eliminated in fully vaccinated individuals while there is continued widespread community transmission of COVID-19.

Use of COVID-19 vaccines for outbreak management or for postexposure prophylaxis to prevent SARS-CoV-2 infection in individuals with a specific known exposure to the virus is unlikely to be effective and is not currently recommended. ACIP states that, because the median incubation period of SARS-CoV-2 infection is 4–5 days, it is unlikely that a dose of a COVID-19 vaccine would provide an adequate immune response within the incubation period for effective postexposure prophylaxis.

The FDA-approved or FDA-authorized COVID-19 vaccines are both efficacious and effective against symptomatic SARS-CoV-2 infection, including severe forms of disease. A substantial amount of data is available that has evaluated the effectiveness of COVID-19 vaccines in real world conditions. Multiple analyses have demonstrated effectiveness of a 2-dose mRNA COVID-19 vaccine series against symptomatic and asymptomatic infections, severe disease, hospitalization, and death. Real world studies that have evaluated the efficacy of COVID-19 vaccines specifically against the Delta variant or during times of substantial Delta circulation have reported effectiveness against SARS-CoV-2 infection, symptomatic disease, and hospitalization. Breakthrough infections have been observed but at a much lower rate than infections in unvaccinated individuals; vaccine effectiveness against severe disease remains high, including against the Delta variant, and generally symptoms and duration of SARS-CoV-2 infections have been attenuated. Literature examining the effectiveness of COVID-19 vaccines against infection, symptomatic disease, and clinical outcomes can be accessed in the International Vaccine Access Center's VIEW-Hub resource library (<https://view-hub.org/resources>).

Based on the unknown duration of vaccine-induced protection and unknown efficacy against emerging SARS-CoV-2 variants, individuals who receive COVID-19 vaccination and are considered fully vaccinated should be counseled to follow current guidance for fully vaccinated individuals to protect themselves and others. This may include wearing a mask and physically distancing in certain settings and venues if required by federal, state, local, tribal, or territorial laws, rules, and regulations and following CDC travel guidance and any applicable workplace or school guidance. CDC has issued interim public health recommendations for individuals who are fully vaccinated against COVID-19; these recommendations (available at the CDC website at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>) should be consulted for information on precautionary measures that fully vaccinated individuals should take in certain social situations and/or following exposure to someone with suspected or confirmed COVID-19.

If COVID-19 breakthrough infection occurs in an individual who has received one or more doses of a COVID-19 vaccine, COVID-19 treatment guidelines, such as those from the National Institutes of Health (<https://www.covid19treatmentguidelines.nih.gov/>) or Infectious Diseases Society of America (<https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>), should be consulted for treatment decisions, including use of SARS-CoV-2-specific monoclonal antibodies, convalescent plasma, antivirals, or corticosteroids.

### ***Duration of Immunity***

The duration of protection against SARS-CoV-2 infection following vaccination with a single dose of COVID-19 vaccine (Janssen) has not been fully evaluated. The immunogenicity of COVID-19 vaccines has been demonstrated through 6 to 8 months after completion of the primary vaccine series. However, waning antibody levels and reduced neutralization of variants has been documented, which has contributed to current ACIP recommendations for booster doses. In comparison to mRNA COVID-19 vaccines, Janssen COVID-19 vaccine produces lower neutralizing titers, after 2–3 months after primary vaccination.

### ***Improper Storage and Handling***

Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccine recipients. All vaccines should be inspected on delivery and monitored during storage to ensure that the recommended storage temperatures are maintained.

COVID-19 vaccine (Janssen) must be shipped, stored, and handled under specific conditions at all times, according to specifications in the EUA fact sheet for healthcare providers and guidance from the manufacturer and CDC. Vaccine that has been mishandled or has not been stored at the recommended temperatures should not be administered. (See Stability.)

If there are concerns about mishandling or defective or damaged vaccine, the manufacturer should be contacted at 800-565-4008 or 908-455-9922 for guidance.

### ***EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting***

Safety and efficacy of COVID-19 vaccine (Janssen) have not been established.

Some data are available regarding adverse effects associated with use of the Janssen COVID-19 vaccine. (See Common Adverse Effects under Cautions.) Additional adverse effects, some of which may be serious, may become apparent with more widespread use of the vaccine.

All vaccine recipients should be monitored for immediate adverse reactions according to CDC (ACIP) guidelines. (See General under Dosage and Administration.)

Vaccine recipients or their caregivers should be provided with information on, and encouraged to participate in, CDC's voluntary smartphone-based tool (v-safe) that

uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects. Information on v-safe is available at <https://www.cdc.gov/vsafe>.

**It is mandatory that vaccination providers administering COVID-19 vaccine (Janssen) report all vaccine administration errors (even if not associated with an adverse event) and serious adverse events (irrespective of attribution to vaccination) that occur following vaccination and also report all cases of multisystem inflammatory syndrome (MIS) and COVID-19 that result in hospitalization or death in vaccine recipients to VAERS.** VAERS reports can be completed and submitted online at <https://vaers.hhs.gov/reportevent.html> or faxed to 877-721-0366; the words "Janssen COVID-19 Vaccine EUA" should be included in the description section of the report. Information on submitting a VAERS report can be obtained by calling 800-822-7967 or emailing [info@vaers.org](mailto:info@vaers.org). To the extent feasible, a copy of the VAERS form should also be provided to the manufacturer (Janssen) at [JNJvaccineAE@its.jnj.com](mailto:JNJvaccineAE@its.jnj.com) (email), 215-293-9955 (fax), or 800-565-4008 (phone).

The FDA fact sheet for healthcare providers for the Janssen COVID-19 vaccine available at the FDA website and at <http://www.janssencovid19vaccine.com> should be consulted for requirements and instructions regarding reporting of adverse reactions and vaccination errors.

### ***Specific Populations***

#### ***Pregnancy.***

Data are insufficient to date regarding use of COVID-19 vaccine (Janssen) in pregnant women to inform vaccine-associated risks during pregnancy. In a reproductive developmental toxicity study in female rabbits, there was no evidence of vaccine-related adverse effects on female fertility, embryofetal development, or postnatal development up to postnatal day 28 when 1 mL of the Janssen COVID-19 vaccine was given by IM injection 7 days prior to mating and on gestation days 6 and 20 (i.e., during early and late gestation, respectively).

Observational data suggest that, while the absolute risk is low, pregnant women with COVID-19 are at increased risk of severe illness, including illness resulting in admission to an intensive care unit, mechanical ventilation, ECMO, or death. Additionally, such women are at increased risk of preterm birth and may be at increased risk of adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.

Although data are limited regarding the safety of the Janssen COVID-19 vaccine during pregnancy, a different adenovirus-vectored vaccine (i.e., Ebola virus vaccine not available in the US) has been used in a large-scale vaccination trial that included pregnant women who were vaccinated during any trimester and no adverse pregnancy-related outcomes, including infant outcomes, were identified that were determined to be related to the vaccine. The Janssen COVID-19 vaccine contains a replication-incompetent adenovirus viral vector and cannot cause SARS-CoV-2 infection in the pregnant woman or her fetus.

FDA states that pregnancy is not a contraindication for use of the Janssen COVID-19 vaccine, and pregnant women should discuss their options with their healthcare providers.

ACIP states that vaccination against COVID-19 is recommended for pregnant women. These experts state that evidence regarding the safety and efficacy of COVID-19 vaccines available from both animal and human studies indicates that the benefits of vaccination against COVID-19 during pregnancy outweigh any known or potential risks. For purposes of decisions regarding administration of both the primary vaccination series and a booster dose, ACIP recommends that pregnant and recently pregnant women (up until at least 42 days following the end of pregnancy) should be considered in the same group as individuals with underlying medical conditions.

ACIP and the American College of Obstetricians and Gynecologists (ACOG) state that pregnant and postpartum women <50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine (see Thrombosis with Thrombocytopenia under Cautions) and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine). ACOG states that women who choose not to receive the Janssen COVID-19 vaccine should be strongly encouraged to receive a different FDA-authorized COVID-19 vaccine.

ACOG recommends that pregnant women be vaccinated against COVID-19. When recommending the COVID-19 vaccination to pregnant women, ACOG suggests that clinicians review the available data on risks and benefits of vaccination, including the risks of not getting vaccinated, in the context of the individual patient's current health status and risk of exposure (e.g., possibility for exposure at work or home) and the possibility for exposing high-risk household members. In addition, the individual patient's values and perceived risk of various outcomes should be taken into account and autonomous decision-making should be respected and supported.

ACIP and ACOG state that a conversation between the pregnant woman and her clinical team may assist with decisions regarding use of COVID-19 vaccines available under an EUA; however, such a conversation is not required and written permission is not needed prior to vaccination. When making a decision, these experts recommend that the pregnant woman and her healthcare provider consider the level of COVID-19 transmission in the community, the individual's personal risk of contracting COVID-19, the increased risk of severe COVID-19 in the pregnant woman and

potential risks to the fetus, the known and potential benefits of vaccination, efficacy of the vaccine, adverse effects of the vaccine, and the limited but growing data about use of the vaccine during pregnancy.

Adverse effects similar to those reported in non-pregnant individuals can occur following COVID-19 vaccination in pregnant women. Pregnant women who experience fever following COVID-19 vaccination should be counseled to take acetaminophen; acetaminophen also may be offered as an option for pregnant women experiencing other postvaccination symptoms.

Administration of other vaccines (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP], influenza vaccine) in pregnant women should be deferred for 14 days after COVID-19 vaccination. (See Vaccines under Drug Interactions.) ACOG states that Rh<sub>0</sub>(D) immune globulin should not be withheld when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Immune Globulins and Antibody Therapies under Drug Interactions.)

A pregnancy exposure registry to monitor pregnancy outcomes in women exposed to the Janssen COVID-19 vaccine during pregnancy has been established. Women who are vaccinated with the Janssen COVID-19 vaccine during pregnancy are encouraged to enroll in the registry at <https://c-viper.pregistry.com>.

Individuals who receive a COVID-19 vaccine during pregnancy and those who become pregnant within 30 days after receiving a COVID-19 vaccine should be encouraged to participate in CDC's v-safe program. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Females and Males of Reproductive Capacity.**

Routine pregnancy testing is *not* recommended before receiving a COVID-19 vaccine.

ACIP states that vaccination against COVID-19 is recommended for women currently trying to get pregnant and those who might become pregnant in the future. Women trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.

ACOG recommends COVID-19 vaccination for all eligible individuals, including those who may consider future pregnancy.

There is no evidence that any COVID-19 vaccines approved or authorized by FDA affect current or future fertility. Because the Janssen COVID-19 vaccine contains a replication-incompetent adenoviral vector that cannot cause infection or alter the DNA of vaccine recipients, it cannot cause infertility. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility.

#### **Lactation.**

Data are not available to assess whether COVID-19 vaccine (Janssen) administered to a woman who is breast-feeding has any effects on the breast-fed infant or milk production.

FDA states that breast-feeding is not a contraindication to use of the Janssen COVID-19 vaccine, and women who are breast-feeding should discuss their options with their healthcare providers.

ACIP states that FDA-authorized COVID-19 vaccines administered to breast-feeding women cannot cause SARS-CoV-2 infection in the women or their infants; therefore, breast-feeding women can receive COVID-19 vaccination. ACIP states that lactating women <50 years of age should be informed about the rare risk of TTS after receipt of the Janssen COVID-19 vaccine (see Thrombosis with Thrombocytopenia under Cautions) and the availability of other FDA-authorized COVID-19 vaccines (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine).

ACOG recommends that lactating women be vaccinated against COVID-19. ACOG also states that theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine and there is no need to avoid breast-feeding or to discontinue breast-feeding in those who receive a COVID-19 vaccine.

Although there is some evidence that antibodies that develop following vaccination with mRNA COVID-19 vaccines are present in breast milk, additional data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection in breast-fed infants.

#### **Pediatric Use.**

Safety and efficacy of COVID-19 vaccine (Janssen) have not been assessed in individuals <18 years of age.

The FDA EUA permits use of the Janssen COVID-19 vaccine *only* in individuals ≥18 years of age.

#### **Geriatric Use.**

Individuals ≥65 years of age have been included in clinical trials evaluating COVID-19 vaccine (Janssen), and data from such individuals contribute to the overall assessment of safety and efficacy of the vaccine.

At the time that FDA's safety analysis of data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial was performed for the EUA, 19.5% of participants were ≥65 years of age and 3.7% were ≥75 years of age. No overall

differences in safety or efficacy were observed between adults ≥65 years of age and younger individuals.

#### **Common Adverse Effects**

Data regarding the safety of COVID-19 vaccine (Janssen) are available from several clinical trials, including the ongoing randomized, double-blind, placebo-controlled, phase 3 trial (NCT04505722; ENSEMBLE; study COV3001) evaluating a single dose of the vaccine. At the time that FDA's safety analysis was performed for the EUA, a total of 43,783 study participants ≥18 years of age had been followed for 2 months (21,895 in the vaccine group). A subset of 6736 participants (3356 in the vaccine group and 3380 in the placebo group) were followed for solicited local and systemic adverse effects within 7 days following vaccination and unsolicited adverse effects within 28 days following vaccination.

**Primary vaccination:** Solicited local adverse effects reported in vaccine recipients included injection site pain (48.6%), erythema (7.3%), and swelling (5.3%). Onset of local adverse effects generally occurred within the first 1–2 days after vaccination, and the median duration of symptoms was 2 days. However, pain was reported to last longer than 7 days in 2.3% of vaccine recipients and erythema and swelling lasted longer than 7 days in 0.5–0.8% of vaccine recipients. Solicited systemic adverse effects reported in vaccine recipients included headache (38.9%), fatigue (38.2%), myalgia (33.2%), nausea (14.2%), and fever (9%). Onset of systemic adverse effects generally occurred within the first 1–2 days after vaccination, and the median duration of symptoms was 1–2 days. Use of antipyretics/analgesics within 7 days following vaccination was reported in 19.9% of vaccine recipients versus 5.7% of placebo recipients. Solicited adverse local and systemic reactions generally were reported more frequently in vaccine recipients 18–59 years of age than in individuals <60 years of age. At the time of FDA's safety analysis for the EUA, serious adverse events (excluding those related to confirmed COVID-19) had been reported in 0.4% of vaccine recipients and 0.4% of placebo recipients. Severe allergic reactions, including anaphylaxis, have been reported rarely. (See Hypersensitivity Reactions under Cautions.)

**Booster dose:** Solicited local adverse effects reported in vaccine recipients 18–55 years of age included injection site pain (59.6%) and erythema (1.1%). Solicited local adverse effects reported in vaccine recipients ≥65 years of age included injection site pain (20.8%). Solicited systemic adverse effects reported in vaccine recipients 18–55 years of age included headache (41.6%), fatigue (51.7%), myalgia (36%), nausea (10.1%), and fever (5.6%). Solicited systemic adverse effects reported in vaccine recipients ≥65 years of age included headache (27.1%), fatigue (33.3%), myalgia (10.4%), and nausea (2.1%).

## **Drug Interactions**

### **Anticoagulants and Aspirin**

Administration of an anticoagulant or aspirin is not recommended prior to receipt of the Janssen COVID-19 vaccine or any other FDA-authorized COVID-19 vaccine. Individuals taking anticoagulants or aspirin as part of their routine medications do not need to discontinue or alter dosage of these drugs prior to vaccination with the Janssen COVID-19 vaccine.

### **Antiviral Agents**

Use of antiviral agents at any interval before or after COVID-19 vaccination is unlikely to impair development of vaccine-induced protective antibody responses.

### **Hormonal Contraceptives**

Although certain hormonal contraceptives (e.g., estrogen-progestin oral contraceptive, transdermal system, or vaginal ring) may increase the overall general risk of thrombosis, experts believe that such contraceptives do not make individuals more susceptible to TTS after receipt of the Janssen COVID-19 vaccine. ACOG states that there is no recommendation to discontinue or change hormonal contraceptive methods in women who have received or plan to receive the Janssen COVID-19 vaccine.

### **Immune Globulins and Antibody Therapies**

Individuals receiving immune globulin (e.g., immune globulin IV [IGIV], Rh<sub>0</sub>(D) immune globulin) and antibody therapies *not* specific for SARS-CoV-2 may receive a COVID-19 vaccine, either concurrently with or at any interval before or after the immune globulin or antibody therapy since such products are unlikely to substantially impair immune responses to the COVID-19 vaccine. ACIP states that there is no recommended minimum interval between receipt of antibody therapies not specific for SARS-CoV-2 and COVID-19 vaccination.

### **SARS-CoV-2 Antibody Therapies**

Limited data are available regarding the safety and efficacy of administering COVID-19 vaccines to individuals who have received passive antibody therapy with investigational SARS-CoV-2-specific monoclonal antibodies (e.g., bamlanivimab and etesevimab, casirivimab and imdevimab) or investigational COVID-19 convalescent plasma. Based on the estimated half-life of SARS-CoV-2 antibody therapies as well as the anticipated period of protection, individuals who have received passive antibody products as part of post-exposure prophylaxis or treatment for COVID-19 should temporarily defer COVID-19 vaccination as a precautionary measure to avoid any

potential inference of the antibody therapy with vaccine-induced responses; COVID-19 vaccination should be deferred for 30 days and 90 days in patients who receive passive antibody products for post-exposure prophylaxis and COVID-19 treatment, respectively. However, COVID-19 vaccination is not contraindicated in individuals who have received passive antibody therapy within the past 90 days, and COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated.

If an individual who has received one or more doses of COVID-19 vaccine subsequently develops COVID-19, ACIP states that prior receipt of a COVID-19 vaccine should not affect treatment decisions, including the use of SARS-CoV-2-specific monoclonal antibodies or COVID-19 convalescent plasma, or the timing of such treatment.

### ■ Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., cancer chemotherapy, corticosteroids, radiation) may have diminished or suboptimal antibody responses to vaccines, including the Janssen COVID-19 vaccine.

Although data are not currently available to establish safety and efficacy in individuals receiving immunosuppressive therapy, ACIP states that such individuals may receive a COVID-19 vaccine if they have no contraindications to vaccination. (See Individuals with Altered Immunocompetence under Cautions.)

Data are insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised individuals, ACIP states that COVID-19 vaccination should ideally be completed at least 2 weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccination series (i.e., a single dose of Janssen COVID-19 vaccine or a 2-dose regimen of Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) in advance, individuals on immunosuppressive therapy can still receive COVID-19 vaccination. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the individual's risks related to their underlying condition. The level of immunocompromise and timing of vaccination with the primary series, additional primary dose, booster dose, and revaccination is best determined with the individual's clinical team.

Based on currently available information, ACIP states that revaccination after immune competence is regained is not recommended in individuals who received COVID-19 vaccination during chemotherapy or treatment with other immunosuppressive drugs.

Based on general best practices for vaccination, ACIP states that COVID-19 vaccines may be administered to individuals receiving corticosteroids given topically or by local injection (e.g., intra-articular, intrabursal, or tendon injections) without regard to the timing of corticosteroid administration.

### ■ Vaccines

Data are not available to date to assess concomitant administration of COVID-19 vaccines, including the Janssen COVID-19 vaccine, with other vaccines.

Although ACIP previously recommended that COVID-19 vaccines should be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines, these experts currently state that COVID-19 vaccines and other vaccines may be administered without regard to timing, including on the same day or within 14 days of each other.

Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar whether vaccines are administered concomitantly or alone. However, it is not known whether reactogenicity of COVID-19 vaccines is increased when administered concomitantly with other vaccines, including those known to be more reactogenic (e.g., adjuvanted vaccines, live vaccines). Decisions to administer a COVID-19 vaccine concomitantly with other vaccine(s) should be based on whether routine immunizations with the other vaccines have been delayed or missed, the individual's risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profiles of the vaccines.

ACIP states that COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration on the same day. If a COVID-19 vaccine is administered concomitantly with other vaccines, each parenteral vaccine should be given at a different injection site and, if possible, the injection sites should be separated by at least 1 inch. ACIP states that, although the deltoid muscle can be used for more than one IM injection in adolescents and adults, COVID-19 vaccines and vaccines that are likely to cause a local reaction (e.g., tetanus toxoid-containing vaccines, adjuvanted vaccines) should be administered in different limbs, if possible.

## Description

COVID-19 vaccine (Janssen) is a viral vector vaccine composed of a recombinant, replication-incompetent, human adenovirus type 26 (Ad26) vector encoding the SARS-CoV-2 spike (S) protein in a stabilized conformation. The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins.

Following IM injection of the Janssen COVID-19 vaccine, the Ad26 vector enters human cells and expresses the S antigen of SARS-CoV-2 (without virus propagation). An immune response to the S antigen is then elicited to protect against SARS-CoV-2 infection.

Data from an ongoing phase 1/phase 2 clinical trial in healthy adults 18 years of age or older indicate that a single dose of Janssen COVID-19 vaccine containing  $5 \times 10^{10}$  virus particles (i.e., recombinant Ad26) elicited SARS-CoV-2 neutralizing antibody when tested against wild-type virus and a SARS-CoV-2 S-binding antibody response that was detected by day 15 after the dose and was increased when evaluated at day 57. The vaccine dose elicited cellular responses in study participants that were consistent with a Th-1 phenotype. A second dose of the vaccine given 56 days after the first dose resulted in increased naturalizing antibody titers.

COVID-19 vaccine (Janssen) available for use under the FDA EUA is provided as a suspension in multiple-dose vials. Each 0.5-mL dose of COVID-19 vaccine (Janssen) contains  $5 \times 10^{10}$  virus particles (i.e., recombinant Ad26). Each dose of the vaccine also contains citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD), polysorbate 80, and sodium chloride. Each dose may also contain residual amounts of host cell proteins and/or host cell DNA.

The Janssen COVID-19 vaccine does not contain preservatives; vial stoppers are not made with natural rubber latex.

## Advice to Patients

- Prior to administration of COVID-19 vaccine (Janssen), the vaccine recipient or their caregiver must be provided with information consistent with the Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age or Older and given a copy of the fact sheet or directed to the manufacturer's website at <http://www.janssencovid19vaccine.com> to obtain the fact sheet.
- Give the vaccine recipient or their caregiver a vaccination card that provides the name of the vaccine (Janssen COVID-19 vaccine) and the date the vaccine was administered.
- Provide the vaccine recipient or their caregiver with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects; live telephone follow-up is provided if a medically important health impact is reported. Information on v-safe is available at <https://www.cdc.gov/vsafe>.
- Inform vaccine recipients or their caregivers that FDA authorized the emergency use of the Janssen COVID-19 vaccine, which is an investigational vaccine that has not received FDA approval, for use in individuals  $\geq 18$  years of age. Advise them that an ongoing clinical trial has shown that a single dose of the vaccine can prevent COVID-19; however, the duration of protection following vaccination is unknown and the vaccine may not protect everyone who receives it.
- Provide vaccine recipients or their caregivers with information on available alternative vaccines and the risks and benefits of those alternatives.
- Inform vaccine recipients or their caregivers about the significant known and potential risks and benefits of the Janssen COVID-19 vaccine, and the extent to which such risks and benefits are unknown. Inform them that local adverse effects (injection site pain, swelling, redness) and systemic adverse effects (headache, fatigue, muscle aches, nausea, fever) have been reported in recipients of the Janssen COVID-19 vaccine.
- Importance of vaccine recipient informing the vaccination provider of any allergies or fever. Advise vaccine recipients or their caregivers that there is a remote chance that the vaccine could cause a severe allergic reaction and such reactions would usually occur within a few minutes to 1 hour after receiving the vaccine dose and may include difficulty breathing, swelling of the face and throat, fast heartbeat, bad rash all over the body, and dizziness and weakness.
- Inform vaccine recipients or their caregivers that blood clots involving blood vessels in the brain, abdomen, and legs along with low platelet counts have occurred rarely in individuals who received the Janssen COVID-19 vaccine and that symptoms began approximately 1–2 weeks following vaccination. While these events have been reported in a wide range of ages, reports of blood clots with low levels of platelets have been highest among women between 30–49 years of age (about 1 case/100,000 doses given). Cases have been fatal in about 1 out of every 7 cases. Advise vaccine recipients or their caregivers to immediately seek medical attention if shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, easy bruising, or tiny blood spots under the skin at sites beyond the vaccine injection site occur following vaccination with the Janssen COVID-19 vaccine. Advise patients that they should not receive the Janssen COVID-19 vaccine if they previously developed a blood clot with low platelet counts following the Janssen COVID-19 vaccine or the AstraZeneca COVID-19 vaccine (not authorized in the US).
- Inform vaccine recipients or their caregivers that cases of Guillain-Barré syndrome have occurred in some individuals who received the Janssen COVID-19 vaccine; symptoms typically begin within 42 days following receipt of the vaccine. Advise vaccine recipients or their caregivers to immediately seek medical attention if any of these symptoms develop following vaccination: weakness or tingling sensations (especially in arms or legs) that is worsening and spreading to other parts of the body; difficulty walking; difficulty with facial



movements (speaking, chewing, or swallowing); double vision or inability to move eyes; or difficulty with bladder control or bowel function.

- Importance of vaccine recipient informing the vaccination provider if they previously received any other COVID-19 vaccine, have any medical conditions (e.g., bleeding disorders, immunocompromising diseases), or are receiving anticoagulants or immunosuppressive therapy.
- Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed.

**Overview<sup>®</sup> (see Users Guide). It is *essential* that the Emergency Use Authorization (EUA) prescribing information contained in the Fact Sheet for Healthcare Providers that is available at the FDA website and at <http://www.janssencovid19vaccine.com> be consulted for more detailed information on dosage and administration, cautions, precautions, and contraindications, and for complete information on the conditions for use of the vaccine for the prevention of coronavirus disease 2019 (COVID-19) under the EUA, including mandated record keeping and reporting requirements.**

## Preparations

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Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

COVID-19 vaccine (Janssen) is not commercially available. Allocation of the vaccine for use under the EUA is being directed by the US government. The vaccine will be supplied directly from the manufacturer or authorized US distributor(s) and distributed to emergency response stakeholders as directed by the US government, including the CDC and/or other designee.

### COVID-19 Vaccine, Viral Vector (Janssen)

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**Parenteral  
Suspension, for IM use**

5 × 10<sup>10</sup> virus particles  
(recombinant Adenovirus type 26)  
per 0.5-mL dose

**Janssen COVID-19 Vaccine,  
Janssen**

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<sup>†</sup> Use is not currently included in the labeling approved by the US Food and Drug Administration.

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