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

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).

Class: 80:12 • Vaccines (AHFS primary)

Brands*:

**also available generically*

Special Alerts:

On April 23, 2021, after a thorough safety review, the FDA and CDC announced that the temporary pause in the use of the Janssen COVID-19 vaccine (also known as the Johnson & Johnson COVID-19 vaccine) in the US was lifted and use of the vaccine should resume. The pause had been initiated on April 13, 2021 out of an abundance of caution to allow time for FDA and CDC to investigate cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia that had been reported rarely following administration of the vaccine. The pause in use of the vaccine also helped ensure that vaccine recipients and healthcare providers were aware of possible symptoms and that healthcare providers were informed about appropriate management of this extremely rare adverse event. At the time the pause was initiated, more than 6.8 million doses of the Janssen COVID-19 vaccine had been administered in the US and there were 6 cases of CVST 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.

FDA and CDC evaluated available data and assessed the risk of thrombosis involving large blood vessels (e.g., the cerebral venous sinuses, portal vein, lower extremity veins, pulmonary artery) occurring with thrombocytopenia (also known as thrombosis with thrombocytopenia syndrome [TTS]) in recipients of the Janssen COVID-19 vaccine. 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 cases all occurred in females 18–59 years of age (median age 37 years), symptom onset was 6–15 days after vaccination (median 8 days), and the clinical course shared features with autoimmune heparin-induced thrombocytopenia. After extensive evaluation of these TTS cases and analyses of the risks and benefits of vaccination with the Janssen COVID-19 vaccine, FDA and CDC determined that the known and potential benefits of the vaccine outweigh its known and potentials risks in adults 18 years of age or older.

Vaccinees should be instructed to immediately seek 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 3 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.

Healthcare providers should 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 adenoviral-vectored COVID-19 vaccine not available in the US (i.e., AstraZeneca COVID-19 vaccine), the pathogenesis of such adverse effects after vaccination may be associated with platelet-activating antibodies against platelet factor 4 (PF4). FDA and CDC are alerting clinicians that heparin and its derivatives should be avoided when managing thrombotic events and thrombocytopenia that occur following vaccination with the Janssen COVID-19 vaccine and that other anticoagulants and high-dose immune globulin IV should be considered. Consultation with hematology specialists is strongly recommended. Information for clinicians regarding diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia is available from the American Society of Hematology at https://www.hematology.org/covid- 19/vaccine-induced-immune-thrombotic-thrombocytopenia. Additional background information regarding the cases of TTS reported to date in individuals who received the Janssen COVID-19 vaccine is provided in meeting materials from the April 23, 2021 meeting of CDC's Advisory Committee on Immunization Practices (ACIP) that are available at https://www.cdc.gov/vaccines/acip/meetings/index.html.

Individuals and healthcare providers should report adverse events that occur following vaccination with the Janssen COVID-19 vaccine to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are cautioned that COVID-19 Vaccine (Janssen) is not an approved vaccine for coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, but rather, is being investigated for and is currently available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals 18 years of age or older. The American Society of Health-System Pharmacists, Inc. makes no representations or warranties, express or implied, including, but not limited to, any implied warranty of merchantability and/or fitness for a particular purpose, with respect to the information contained in the accompanying monograph, and specifically disclaims all such warranties. Readers of this information are advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information contained in the monograph in any and all practice settings. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The entire monograph for a drug should be reviewed for a thorough understanding of the drug's actions, uses and side effects. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Uses

Prevention of Coronavirus Disease 2019 (COVID-19)

- Being investigated and used for prevention of COVID-19† caused by SARS-CoV-2. One of various COVID-19 vaccines being evaluated for prevention of COVID-19.
- Although efficacy and safety not definitely established, COVID-19 vaccine (Janssen) is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals ≥18 years of age.
- On February 27, 2021, FDA issued an EUA that permits use of the Janssen COVID-19 vaccine in individuals ≥18 years of age. This EUA requires that the vaccine be administered by vaccination providers using a single-dose regimen as described in the EUA (see Dosage and Administration) and that vaccination providers participate and comply with terms and training required by CDC's COVID-19 vaccination program, including monitoring and complying with CDC and/or emergency response stakeholder vaccine management requirements concerning obtaining, tracking, and handling the vaccine and reporting vaccine administration data to CDC and state/local jurisdiction's Immunization Information System (IIS) or other designated systems.
- FDA issued the EUA for the Janssen COVID-19 vaccine after concluding that emergency use of the vaccine for 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 vaccine may be effective in preventing COVID-19 and, when used under the conditions described in the authorization, known and potential benefits outweigh known and potential risks; and there are no adequate, approved, and available alternatives to emergency use of the vaccine to prevent COVID-19.
- Issuance of the EUA for the Janssen COVID-19 vaccine was based on FDA review of safety and efficacy data from an ongoing phase 3 clinical trial in adults indicating that a single dose of the vaccine was 66.9% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days after vaccination and 66.1% effective in preventing such infections at least 28 days after vaccination. In addition, efficacy of a single dose of the vaccine in preventing severe/critical COVID-19 was 76.7 or 85.4% when cases occurring at least 14 or 28 days, respectively, after vaccination were considered.
- The EUA for the Janssen COVID-19 vaccine authorizes that distribution of the vaccine will be controlled by the US government for use consistent with the terms and conditions of the EUA. (See Restricted Distribution under Preparations.)
- To mitigate risks of this unapproved vaccine, the EUA includes certain mandatory requirements (e.g., providing the recipient or caregiver with information consistent with the EUA fact sheet for recipients and caregivers, 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 healthcare providers). (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)
- Consult the Janssen COVID-19 vaccine EUA letter of authorization, EUA fact sheet for healthcare providers, and EUA fact sheet for recipients and caregivers for additional information.
- CDC's Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Janssen COVID-19 vaccine for prevention of COVID-19

in individuals ≥18 years of age. ACIP also issued interim recommendations regarding allocation of supplies of COVID-19 vaccines and interim considerations for phased implementation of COVID-19 vaccination and sub-prioritization among recommended populations in the US (available at the CDC website at https://www.cdc.gov/vaccines/covid-19/phased-implementation.html and https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html).

- There currently are 3 different COVID-19 vaccines available for use in the US under FDA EUAs, 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). ACIP does not state a preference for any specific currently authorized COVID-19 vaccine when the vaccines are used within the scope of their respective EUAs and states that individuals should be encouraged to receive the earliest vaccine available to them. However, currently available COVID-19 vaccines are *not* interchangeable with each other. (See Dosage under Dosage and Administration.)

Dosage and Administration

General

- *Must* have appropriate medications and supplies immediately available to assess and manage immediate allergic reactions in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine, including COVID-19 vaccine (Janssen). Healthcare personnel trained and qualified to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination locations 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.)
- Prior to administration of the Janssen COVID-19 vaccine, screen all individuals for contraindications and precautions to vaccination. Do not give the vaccine to those with a contraindication. (See Contraindications and see Warnings/Precautions under Cautions.)
- *Monitor all vaccine recipients for immediate adverse reactions according to CDC (ACIP) guidelines.* When administered to individuals with no contraindications to vaccination with the Janssen COVID-19 vaccine, ACIP states observe those who have a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy and those who have a history of anaphylaxis due to any cause not considered a contraindication for 30 minutes, and observe all other individuals for 15 minutes. A longer period of observation may be indicated in some individuals based on clinical concern (e.g., pruritus and swelling confined to the injection site develop during observation period). Instruct vaccine recipients 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. (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 risk of injury if a patient becomes weak or dizzy or loses consciousness (e.g., vaccinees should sit or lie down during and for 15 minutes after vaccination). If syncope occurs, observe patient until symptoms resolve.
- At the time that the Janssen COVID-19 vaccine is administered, give vaccine recipient or their caregiver a vaccination record card that provides the name of the vaccine (Janssen COVID-19 vaccine) and the date the vaccine was administered.
- Provide vaccine recipient or their caregiver with information on, and encourage participation in, CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in COVID-19 vaccine recipients. (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. (See Cautions and see Advice to Patients.)
- Antipyretics or analgesics (e.g., acetaminophen, NSAIAs) may be taken to treat postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in vaccinees is not currently recommended since information not available regarding possible impact on antibody response to COVID-19 vaccines. 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 delay diagnosis and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)
- Counsel individuals who receive the Janssen COVID-19 vaccine to continue following all current guidance to protect themselves and others. This includes wearing a mask, staying ≥6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands frequently, following CDC travel guidance, and following any applicable workplace or school guidance. This recommendation is based on the currently limited information on the extent to which vaccination may reduce viral transmission in the general population and unknown duration of vaccine-induced protection. (See Limitations of Vaccine Effectiveness under Cautions.)

Administration

IM Administration

Administer *only* by IM injection into the deltoid.

The Janssen COVID-19 vaccine is supplied as a suspension in multiple-dose vials.

Although the vaccine is *initially* stored frozen by the manufacturer, it is shipped and stored refrigerated at a temperature of 2–8°C. Do *not* refreeze the vaccine. (See Storage under Stability.)

Do not dilute the Janssen COVID-19 vaccine.

Swirl vials of vaccine gently in an upright position for 10 seconds before withdrawing a dose; do *not* shake.

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

To administer a dose, withdraw 0.5 mL of Janssen COVID-19 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 should be discarded and *not* pooled with vaccine from other vials to create a dose.

Data not available regarding concomitant administration with other vaccines. ACIP recommends that the Janssen COVID-19 vaccine *not* be administered simultaneously with or within 14 days of any other vaccine. (See Vaccines under Interactions.)

Dosage

Administer the Janssen COVID-19 vaccine as a single 0.5-mL dose. Each 0.5-mL dose contains 5×10^{10} virus particles of recombinant, replication-incompetent Ad26.

The Janssen COVID-19 vaccine is *not* interchangeable with any other COVID-19 vaccine.

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

Safety and efficacy regarding use of the Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine *not* established. However, 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), may consider giving a single dose of the Janssen COVID-19 vaccine at least 28 days after the dose of mRNA COVID-19 vaccine. (See Hypersensitivity Reactions under Cautions.) In such exceptional circumstances, consider the individual to have received valid, single-dose vaccination with Janssen COVID-19 vaccine, not a mixed vaccination series.

Report all vaccine administration errors and deviations from currently recommended dosage and vaccination schedule to the vaccinee and the Vaccine Adverse Event Reporting System (VAERS). Information on preventing and reporting COVID-19 vaccine administration errors and recommendations for specific actions to take if an administration error or deviation from recommended vaccination schedule occurs are available at the CDC website at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Adults

Prevention of COVID-19

IM: FDA EUA that permits use for prevention of COVID-19† (see Prevention of Coronavirus Disease 2019 [COVID-19] under Uses) states that adults ≥18 years of age should receive a single 0.5-mL dose of the vaccine.

Cautions

Contraindications

- Known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including polysorbate. (See Actions.)

Warnings/Precautions

Sensitivity Reactions

Hypersensitivity Reactions

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, urticaria (nonserious) reported within 7 days following administration in 5 individuals who received COVID-19 vaccine (Janssen) and 1 individual who received placebo.

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

Severe allergic reactions, including one case of anaphylaxis, reported in an ongoing open-label study in South Africa.

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

Because anaphylactic reactions reported rarely following administration of COVID-19 vaccines, ACIP issued interim guidance with contraindications and precautions for use of COVID-19 vaccines pending further investigation. For 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. If reactions occur following vaccination with a COVID-19 vaccine, the vaccination provider should attempt to determine whether the reactions are consistent with immediate allergic reactions or are reactions commonly observed following vaccination (e.g., vasovagal reactions, postvaccination adverse effects).

History of polysorbate allergy: This a **contraindication** to vaccination with Janssen COVID-19 vaccine. ACIP states consider use of an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) 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. Therefore, consider consultation with an allergist-immunologist to help determine if an individual with polysorbate allergy can safely receive an mRNA COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) when making such decisions.

Known contraindication to vaccination with mRNA COVID-19 vaccines (including known PEG allergy): ACIP considers this a **precaution** to vaccination with Janssen COVID-19 vaccine 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 Janssen COVID-19 vaccine (including PEG and polysorbate 80, respectively), consider consultation with an allergist-immunologist to help determine if the individual can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) when making such decisions. If a decision is made to administer the Janssen COVID-19 vaccine to individuals with a contraindication to mRNA COVID-19 vaccines, administer the vaccine *only* in an appropriate setting under supervision of a healthcare provider experienced in management of severe allergic reactions. Although safety and efficacy of administering the Janssen COVID-19 vaccine after an mRNA COVID-19 vaccine not established, ACIP states that in those *exceptional* situations when an individual 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 a contraindication), may consider administering a single dose of Janssen COVID-19 vaccine at a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. (See Dosage under Dosage and Administration.)

History of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, or sub-Q vaccines or therapies): ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination. ACIP states that history of allergic reaction to sub-Q 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 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. 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 performing a risk assessment to help decide whether the individual should be vaccinated. The risk assessment should consider 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), 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.

When a COVID-19 vaccine, including the Janssen COVID-19 vaccine, is administered to individuals without a contraindication to such vaccines, ACIP states observe those with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy and those with a history of anaphylaxis due to any cause not considered a contraindication for 30 minutes after the vaccine dose and observe all other individuals for 15 minutes. Instruct vaccine recipients 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 clinical signs and symptoms of anaphylaxis is important since such reactions require immediate treatment. Immediately treat individuals with suspected anaphylaxis 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/clinicalconsiderations/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 or 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).

Concomitant Illness

Base decision to administer or delay vaccination in an individual with a current or recent febrile illness 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 recommends that a risk assessment 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 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. ACIP states COVID-19 vaccination should be offered to individuals regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

Data not available to date regarding 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 Specific Drugs under Interactions.)

Individuals with Current SARS-CoV-2 Infection

ACIP recommends deferring COVID-19 vaccination 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. There is no recommended minimum interval between SARS-CoV-2 infection and COVID-19 vaccination, but evidence to date suggests that risk of reinfection is low in the months after initial infection, but may increase with time due to waning immunity. If vaccine supply is limited, ACIP states that individuals with recent documented acute SARS-CoV-2 infection may choose to temporarily delay COVID-19 vaccination, if desired, recognizing that risk of reinfection and need for vaccination may increase with time following the initial infection.

ACIP states that viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purpose of COVID-19 vaccination decision-making is *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Recent Exposure to SARS-CoV-2 Infection

ACIP states that COVID-19 vaccines not currently recommended for outbreak management or for postexposure prophylaxis in individuals with a specific known exposure to SARS-CoV-2; postexposure vaccination is unlikely to be effective in preventing disease following such exposures. (See Limitations of Vaccine Effectiveness under Cautions.)

Individuals in the community or outpatient setting with a known COVID-19 exposure: ACIP states that such individuals should not seek COVID-19 vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other individuals to SARS-CoV-2 during the vaccination visit.

Individuals residing in congregate healthcare settings (e.g., long-term care facilities) or congregate non-healthcare settings (e.g., correctional and detention facilities, homeless shelters) with a known COVID-19 exposure: ACIP states that such individuals may receive COVID-19 vaccination since exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time in these settings and healthcare personnel and other staff are already in close contact with residents in these settings. Individuals providing vaccination services should employ appropriate infection prevention and control procedures.

Residents in congregate settings (healthcare and non-healthcare) with a known COVID-19 exposure waiting for results of SARS-CoV-2 testing: ACIP states that such individuals may receive COVID-19 vaccination if they do not have symptoms consistent with COVID-19. Individuals providing vaccination services should employ appropriate infection

prevention and control procedures. Viral testing to assess for acute SARS-CoV-2 infection solely for the purpose of COVID-19 vaccination decision-making is *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Underlying Medical Conditions

ACIP states that individuals with altered immunocompetence or certain underlying medical conditions may receive COVID-19 vaccine if they have no contraindications to vaccination. ACIP does not state a preference for any specific COVID-19 vaccine in such individuals. Clinical trials of COVID-19 vaccines have demonstrated safety and efficacy profiles in individuals with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, that are similar to safety and efficacy profiles in individuals without comorbidities.

Individuals with Altered Immunocompetence

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy (see Specific Drugs under Interactions), may have diminished immune responses to vaccines, including the Janssen COVID-19 vaccine.

Although some individuals with altered immunocompetence (e.g., stable HIV infection) were included in the ongoing phase 3 trial evaluating the Janssen COVID-19 vaccine, the number of such individuals was insufficient to evaluate safety of the vaccine in such populations.

ACIP states that individuals with HIV infection or other immunocompromising conditions and individuals receiving immunosuppressive therapies may be at increased risk for severe COVID-19 and, although data are not currently available to establish safety and efficacy in such individuals, they may receive any authorized COVID-19 vaccine if they have no contraindications to vaccination. However, counsel such individuals about the unknown safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses and need to continue following all current guidelines to protect themselves from COVID-19.

Antibody testing to assess for immunity to SARS-CoV-2 following COVID-19 vaccination in individuals with altered immunocompetence is *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Autoimmune Conditions

ACIP states that individuals with autoimmune conditions may receive any authorized COVID-19 vaccine, unless they have a contraindication to vaccination. Although data not currently available regarding safety and efficacy of COVID-19 vaccines in individuals with autoimmune conditions, such individuals were not excluded from clinical trials evaluating the mRNA COVID-19 vaccines and these trials showed no imbalances in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in trial participants who received COVID-19 vaccine compared with those who received placebo.

Individuals with Liver Disease

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

Although safety and efficacy data regarding use of COVID-19 vaccines in individuals with chronic liver disease are limited and additional studies needed, safety and efficacy of the vaccines in such individuals expected to be similar to the general population. AASLD states that individuals with chronic liver disease receiving antiviral treatment for HBV or HCV infection and those receiving medical therapy for primary biliary cholangitis or autoimmune hepatitis should not discontinue such therapy when receiving COVID-19 vaccination. In addition, consider COVID-19 vaccination for patients with hepatocellular carcinoma undergoing locoregional or systemic therapy without interruption of treatment.

Although solid organ transplant recipients, including liver transplant recipients, not included in clinical trials of COVID-19 vaccines and efficacy and safety in such individuals not known, AASLD states that liver transplant candidates should receive COVID-19 vaccination prior to transplantation, whenever possible, to help ensure an adequate immune response. The best time for COVID-19 vaccination in previously unvaccinated liver transplant recipients is likely to be ≥3 months after transplant; however, vaccination may be given as early as 6 weeks after transplant if indicated based on ongoing community spread of SARS-CoV-2, especially in those at highest risk with other comorbid factors associated with severe COVID-19.

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

Individuals with a History of Guillain-Barré Syndrome

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, a single case of Guillain-Barré syndrome (GBS) occurred in a vaccine recipient 16 days after the vaccine dose and a single case occurred in a placebo recipient 10 days after the dose. FDA stated that, although the case of GBS was unlikely to be related to the vaccine, a causal relationship cannot be definitively excluded.

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.

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.)

Individuals with a History of Bell's Palsy

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, there had been 2 reported 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, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Individuals with Increased Bleeding Risk

Advise individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their caregiver 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, use a fine needle (23 gauge or smaller) to administer the vaccine and apply firm pressure to the injection site (without rubbing) for ≥2 minutes. In individuals receiving therapy for hemophilia, schedule IM vaccines for administration shortly after a dose of such therapy.

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

Thromboembolic Events and Other Adverse Events

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, there had been 6 reports of deep-vein thrombosis in individuals who received the Janssen COVID-19 vaccine (2 serious; 5 within 28 days) and 2 such events in placebo recipients (1 serious; 2 within 28 days). In addition, there were 4 reports of pulmonary embolism (3 serious; 2 within 28 days) in vaccine recipients versus 1 report in placebo recipients (serious; within 28 days) 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 not established based on the phase 3 trial data. However, thrombosis involving large blood vessels (e.g., the cerebral venous sinuses, portal vein, lower extremity veins, pulmonary artery) occurring with thrombocytopenia reported rarely during post-authorization surveillance (see Special Alert at the beginning of the monograph) and evaluation of these cases suggest a causal relationship between the Janssen COVID-19 vaccine and thrombosis with thrombocytopenia is plausible.

Other adverse effects with a numerical imbalance between vaccine recipients and placebo recipients 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, including 3 events within 2 days) versus none in placebo recipients. A causal relationship between these events and the vaccine could not be established.

Limitations of Vaccine Effectiveness

May not protect all vaccine recipients against 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.

FDA states that data are too limited to date to assess the effect of the Janssen COVID-19 vaccine for prevention of asymptomatic SARS-CoV-2 infection; additional evaluations are needed, including data from clinical trials and from use of the vaccine after issuance of the EUA.

FDA states that data are too limited to date to assess effect of the Janssen COVID-19 vaccine against transmission of SARS-CoV-2 from individuals who become infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake; however, it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission of the virus. Additional evaluations are needed, including data from clinical trials and from use of the vaccine after issuance of the EUA, to assess the effect of the vaccine in preventing virus shedding and transmission, particularly in individuals with asymptomatic infection.

Based on currently limited information on the extent to which vaccination may reduce viral transmission in the general population and unknown duration of vaccine-induced protection, counsel individuals who receive COVID-19 vaccination to follow current guidance to protect themselves and others. This includes wearing a mask, staying ≥6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands frequently, following CDC travel guidance, and following any applicable workplace or

school guidance. CDC issued interim public health recommendations for individuals who are fully vaccinated against COVID-19 (defined as at least 2 weeks after a single dose of the Janssen COVID-19 vaccine or at least 2 weeks after completion of a 2-dose vaccination series of the Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine); consult these recommendations (available at the CDC website at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html) for information on precautionary measures that fully vaccinated individuals should take in various social situations and/or following exposure to someone with suspected or confirmed COVID-19.

Withholding COVID-19 vaccination due to concerns about efficacy against current or future SARS-CoV-2 viral variants not recommended.

If an individual is fully vaccinated and tests positive for SARS-CoV-2, healthcare providers and local health departments are encouraged to request that the specimen be held and the case reported to the state health department. CDC will work with the state health department to collect information about the case. In addition, report information about such cases to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Duration of Immunity

Duration of protection against SARS-CoV-2 infection following vaccination with a single dose of the Janssen COVID-19 vaccine not fully evaluated.

Because available trial data have a limited length of follow-up to date, it is not possible at this time to assess sustained efficacy over a period longer than 2 months.

ACIP states that the need for and timing of booster doses of COVID-19 vaccines not established. Additional vaccine doses beyond those recommended for a complete, valid vaccination series (see Dosage under Dosage and Administration) are *not* recommended at this time. Recommendations on revaccination or additional doses of COVID-19 vaccines may be updated when additional information is available.

Improper Storage and Handling

Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccinees. Inspect all vaccines on delivery and monitor during storage to ensure that recommended storage temperatures are maintained.

The Janssen COVID-19 vaccine 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. Do not administer vaccine that has been mishandled or has not been stored at the recommended temperatures. (See Storage under Stability.)

Contact the manufacturer at 800-565-4008 for guidance if there are concerns about mishandling or defective or damaged vaccine.

EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting

Safety and efficacy not established. FDA issued an EUA that permits use of the Janssen COVID-19 vaccine for prevention of COVID-19† in individuals ≥18 years of age when administered according to the single-dose regimen specified in the EUA. (See Prevention of Coronavirus Disease 2019 [COVID-19] under Uses.)

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

Monitor all vaccine recipients for immediate adverse reactions according to CDC (ACIP) guidelines. (See General under Dosage and Administration.)

Provide vaccine recipients or their caregivers 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. Reports to v-safe that indicate a medically important health impact are followed up by the CDC v-safe call center to collect additional information to complete a VAERS report. Information on v-safe is available at https://www.cdc.gov/vsafe.

It is mandatory that vaccination providers administering the Janssen COVID-19 vaccine 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. Can complete and submit VAERS reports online at https://vaers.hhs.gov/reportevent.html or by faxing to 877-721-0366; include the words "Janssen COVID-19 Vaccine EUA" in description section of the report. Obtain information on submitting a VAERS report by calling 800-822-7967 or emailing info@vaers.org. To the extent feasible, also provide a copy of the VAERS form to the manufacturer (Janssen) at JNJvaccineAE@its.jnj.com (email), 215-293-9955 (fax), or 800-565-4008 (phone).

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

Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals

Results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests) not affected by prior COVID-19 vaccination.

Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins (spike or nucleocapsid). Because COVID-19 vaccines, including the Janssen COVID-19 vaccine, encode the spike protein of the virus, a positive test for spike protein IgM/IgG could indicate either prior infection *or* vaccination. Use a test that specifically evaluates IgM/IgG to the nucleocapsid protein to assess for evidence of prior infection in an individual who has received COVID-19 vaccination.

Antibody testing *not* currently recommended to assess for immunity to COVID-19 following COVID-19 vaccination. Antibody tests currently authorized for use under EUAs have variable sensitivity and specificity, as well as positive and negative predictive values, and are not authorized for assessment of immune response in individuals who have received COVID-19 vaccination. In addition, the serologic correlates of protection against SARS-CoV-2 not established, and antibody testing does not evaluate cellular immune response, which may also play a role in vaccine-mediated protection. If antibody testing is performed following COVID-19 vaccination, do *not* administer additional doses of the same or different COVID-19 vaccine beyond those recommended based on results of antibody testing.

Interpretation of Tuberculosis Tests in Vaccinated Individuals

ACIP states do *not* delay COVID-19 vaccination in situations when an immune-based method of tuberculosis testing (i.e., intradermal tuberculin skin test [TST] or serum interferon gamma release assay [IGRA]) is required or indicated.

If TST or IGRA required according to administrative policies (e.g., healthcare employment, admission to long-term care facilities), perform such testing before or during same visit that COVID-19 vaccine is administered. If such testing cannot be done prior to or at the same time as vaccine administration, ACIP recommends delaying testing until ≥4 weeks after completion of COVID-19 vaccination. If a tuberculosis testing requirement or policy cannot be modified to accept a delay in TST or IGRA testing during the COVID-19 pandemic, it should be understood that a false-negative TST or IGRA cannot be excluded; in such situations, consider repeating a negative TST or IGRA test ≥4 weeks after completion of COVID-19 vaccination. In addition, if TST was performed as the initial test, consider the possibility that boosting could be a factor if results of a repeat TST are positive.

ACIP states COVID-19 vaccines can be given to individuals who have active tuberculosis disease or an illness being evaluated as active tuberculosis disease; however, consider that a moderate or severe acute illness usually is a precaution for vaccination (see Concomitant Illness under Cautions). If TST or IGRA is being considered for medical diagnosis of latent tuberculosis infection (e.g., during contact investigation after exposure to contagious tuberculosis disease), a decision to delay such testing until ≥4 weeks after completion of COVID-19 vaccination is at the discretion of the responsible medical provider and local tuberculosis program overseeing the contact investigation. If a decision is made to not delay TST or IGRA testing (e.g., in individuals at high risk for progression to tuberculosis disease) and test results are negative, ACIP states consider retesting ≥4 weeks after completion of the vaccination series.

Specific Populations

Pregnancy

Data insufficient to date regarding use of the Janssen COVID-19 vaccine in pregnant women to inform vaccine-associated risks during pregnancy. A developmental toxicity study in female rabbits did not reveal evidence of vaccine-related adverse effects on female fertility, embryofetal development, or postnatal development.

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 (ICU), mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death. Additionally, such women might be at an increased risk of adverse pregnancy outcomes, such as preeclampsia, coagulopathy, and preterm birth.

Although data are limited regarding 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.

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

ACIP states that, based on current knowledge, COVID-19 vaccines are unlikely to pose a risk to pregnant women or the fetus; therefore, pregnant women may choose to be vaccinated. ACIP states that any authorized COVID-19 vaccine can be administered to pregnant women; ACIP does not state a preference for any specific COVID-19 vaccine in such women.

ACOG recommends that COVID-19 vaccines not be withheld from pregnant women. In the interest of patient autonomy, these experts recommend that pregnant women be free to make their own decision regarding COVID-19 vaccination.

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 prior to vaccination. When making a decision, pregnant women and their healthcare providers should consider the level of COVID-19 transmission in the community, the individual's personal risk of contracting COVID-19, risks of COVID-19 to the individual and potential risks to the fetus, efficacy of the vaccine, adverse effects of the vaccine, and lack of 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. Advise pregnant women who experience fever following COVID-19 vaccination to take acetaminophen; may also offer acetaminophen as an option for pregnant women experiencing other postvaccination symptoms.

Defer administration of other vaccines (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP], influenza vaccine) in pregnant women for 14 days after COVID-19 vaccination. (See Vaccines under Interactions.) ACOG states do not withhold $Rh_o(D)$ immune globulin when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Specific Drugs under Interactions.)

Pregnancy exposure registry established to monitor pregnancy outcomes in women exposed to the Janssen COVID-19 vaccine during pregnancy. Encourage women who are vaccinated with the Janssen COVID-19 vaccine during pregnancy to enroll in the registry at https://c-viper.pregistry.com.

Encourage women who receive a COVID-19 vaccine during pregnancy and those who become pregnant within 30 days after receiving a COVID-19 vaccine 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 *not* recommended before receiving a COVID-19 vaccine.

ACIP states that women trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.

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

There is no evidence that any of the authorized COVID-19 vaccines affect future fertility.

Lactation

Not known whether the Janssen COVID-19 vaccine administered to a woman who is breast-feeding has any effects on the breast-fed infant or milk production.

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

ACIP states that COVID-19 vaccines are not thought to be a risk for breast-feeding women or their infants and any authorized COVID-19 vaccine can be administered to breast-feeding women. ACIP does not state a preference for any specific COVID-19 vaccine in such women.

ACOG states offer COVID-19 vaccines to lactating women, similar to other individuals. ACOG also states that theoretical concerns regarding safety of vaccinating lactating women do not outweigh potential benefits of the vaccine; there is no need for individuals who receive a COVID-19 vaccine to avoid initiating breast-feeding or to discontinue breast-feeding.

Pediatric Use

Safety and efficacy of the Janssen COVID-19 vaccine not assessed in individuals <18 years of age.

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

Geriatric Use

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

At the time of FDA's safety and efficacy analysis of data from the ongoing phase 3 trial 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 observed between those ≥65 years of age and younger adults.

Common Adverse Effects

Solicited local adverse effects reported in vaccine recipients included injection site pain (48.6%), erythema (7.3%), and swelling (5.3%). Onset usually within first 1–2 days after vaccination with median duration of 2 days. However, local adverse effects reported to last >7 days in some 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 usually within first 1–2 days after vaccination with median duration of 2 days.

Use of antipyretics/analgesics within 7 days following vaccination reported in 19.9% of vaccine recipients versus 5.7% of placebo recipients.

Solicited adverse local and systemic reactions reported more frequently in vaccinees 18–59 years of age than in vaccinees ≥60 years of age.

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, serious adverse events (excluding those related to confirmed COVID-19) reported in 0.4% of vaccine recipients and 0.4% of placebo recipients.

Severe allergic reactions, including anaphylaxis, reported rarely. (See Hypersensitivity Reactions under Cautions.)

Interactions

Vaccines

Data not available to date to assess concomitant administration of COVID-19 vaccine (Janssen) with other vaccines.

ACIP recommends giving the vaccine alone, with a minimum interval of 14 days before or after administration of any other vaccine. However, the Janssen COVID-19 vaccine and other vaccines may be administered within a shorter period if benefits of vaccination outweigh potential unknown risks of concomitant administration (e.g., tetanus toxoid-containing vaccination as part of wound management; rabies vaccination for postexposure prophylaxis; measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to or at time of admission or onboarding). If administered within 14 days of another vaccine, ACIP states there is no need to repeat doses of either vaccine.

Specific Drugs

Drug	Interaction	Comments
COVID-19 convalescent plasma	Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine	To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment
Immune globulin and antibody therapies *not* specific for SARS-CoV-2 (e.g., immune globulin IV [IGIV], Rh_o[D] immune globulin)		May give COVID-19 vaccine concurrently with or at any interval before or after immune globulin or antibody therapies *not* specific for SARS-CoV-2
Immunosuppressive agents (e.g., cancer chemotherapy, corticosteroids, radiation)	Possible decreased or suboptimal antibody responses to vaccines, including the Janssen COVID-19 vaccine Data insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies	ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccine if they have no contraindications to vaccination Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥2 weeks before initiation of immunosuppressive therapies; if this is not possible, individuals on immunosuppressive therapy can still receive COVID-19 vaccination; consider individual's risks related

		to their underlying condition if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination Revaccination after immune competence regained not recommended in individuals who received COVID-19 vaccine during chemotherapy or treatment with other immunosuppressive agents If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of corticosteroids, or timing of such treatment
SARS-CoV-2-specific monoclonal antibodies (bamlanivimab, bamlanivimab and etesevimab, casirivimab and imdevimab)	Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine	To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment

Stability

Storage

Parenteral

Suspension, for IM Use

Supplied as a suspension in multiple-dose vials that are *initially* stored frozen by the manufacturer and are then shipped at a temperature of 2–8°C.

After receipt, store multiple-dose vials of the vaccine in a refrigerator at 2–8°C, protect from light, and do *not* freeze.

If the vaccine is still frozen upon receipt, thaw in a refrigerator at 2–8°C. If the vaccine needs to be used immediately, may thaw appropriate number of vials at room temperature (up to 25°C). If thawing at room temperature is necessary, 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 thawed vaccine.

Consult EUA fact sheet for healthcare providers for the Janssen COVID-19 vaccine and information provided by CDC and the manufacturer for information on storage, handling, and stability of the vaccine. Storage and handling information contained in the EUA fact sheet for healthcare providers supersedes storage and handling information on vaccine vials and carton labels.

After removal from refrigeration, may store unused (i.e., unpunctured) vials for up to 12 hours at room temperature (9–25°C).

After withdrawing first dose of vaccine from a multiple-dose vial, vial may 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 times after first vial entry.

Expiration dates are not marked on vials and cartons of the Janssen COVID-19 vaccine. Scan the QR code on the vial or carton to reach an online resource that provides the expiration date based on the lot number printed on the packaging. Alternatively, obtain expiration dates by entering the lot number at the manufacturer's website at https://vaxcheck.jnj. Because it is possible that expiration dates may be extended as more stability data become available, contact the manufacturer prior to discarding vaccine to determine if the expiration date has been extended.

Actions

- 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.
- Following IM injection, the Ad26 vector in the vaccine enters human cells and expresses the S antigen of SARS-CoV-2 (without virus propagation). The S antigen elicits an immune response to provide protection against SARS-CoV-2 infection.
- Data from clinical trial in healthy adults ≥18 years of age indicate that a single dose of Janssen COVID-19 vaccine containing 5×10^{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 (detected by day 15 after the dose and increased by day 57). The vaccine dose elicited cellular responses in study participants 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 5×10^{10} virus particles (i.e., recombinant Ad26). Each dose also contains citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate 80, and sodium chloride and may contain residual amounts of host cell proteins and/or host cell DNA.
- 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 ≥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.
- Inform vaccine recipients or their caregivers that they have the option to accept or refuse the vaccine.
- 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.

- 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.

Preparations

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. FDA issued an emergency use authorization (EUA) for the Janssen COVID-19 vaccine that permits use of the vaccine for the prevention of COVID-19† in individuals ≥18 years of age. 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)

Parenteral

Suspension, for IM use

5×10^{10} virus particles (recombinant Adenovirus type 26) per 0.5-mL dose	**Janssen COVID-19 Vaccine**, Janssen

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