COVID-19 VACCINES (Part 1 of 2)

Contraindications: COVID-19 vaccines are contraindicated in patients with a severe allergic reaction (eg, anaphylaxis) after a previous dose or to a component of the vaccine, or an immediate allergic reaction[1] of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine.

- Those with a contraindication to one mRNA COVID-19 vaccine should not receive doses of either mRNA vaccine.

Precautions: caution in patients with a history of an immediate allergic reaction[1] to any other vaccines or injectable therapies, contraindication to other COVID-19 vaccines, and patients with moderate to severe acute illness[2] (eg, current SARS-Cov-2 infection). The Janssen vaccine includes additional precautions for women aged <50yrs and patients with a history of or risk factors for thrombosis due to rare cases of thrombosis with thrombocytopenia syndrome (TTS) after vaccine administration. Both mRNA vaccines include additional warnings for adolescents, young adults, (predominantly males and aged ≥16yrs), and patients with a history of myocarditis or pericarditis due to increased risks of these conditions following the second dose.

- Those with a contraindication to mRNA vaccines (including due to a known polyethylene glycol allergy) have a precaution to Janssen COVID-19 vaccine. Those with a contraindication to Janssen vaccine (including due to a known polysorbate 80 allergy) have a precaution to mRNA vaccines. Consultation with an allergist-immunologist should be considered and vaccination with either COVID-19 vaccine should only be undertaken in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
- Those who have previously received 1 dose of mRNA vaccine with a contraindication to the 2nd dose should wait at least 28 days to receive the Janssen vaccine.

Underlying conditions: vaccines may be administered to patients with immunocompromising conditions, autoimmune conditions, history of Guillain-Barré syndrome, Bell's palsy, dermal filler use. However, immunocompromised patients, including those receiving immunosuppressants, may have a diminished immune response to the vaccines.

Prior SARS-CoV-2 infection: vaccines may be administered regardless of history of prior symptomatic or asymptomatic infection.

Pregnancy and lactation: any authorized COVID-19 vaccines may be administered, however, patients should be aware of the rare risk of TTS after administration of the Janssen vaccine.

Vaccine coadministration: COVID-19 vaccines and other vaccines may be administered without regard to timing; simultaneous administration on the same day and coadministration within 14 days are now accepted.

Passive antibody therapy: defer vaccination for ≥90 days for persons who received passive antibody therapy (eg, monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

***COVID-19 vaccines are not interchangeable.**

Developer	Vaccine	Status	Efficacy[17]	Dosing	Storage/Stability[4]	Side Effects[5,6]
mRNA[3]						
Pfizer-BioNTech	**BNT162b2**	EUA for ≥12yrs	**Prevention of symptomatic disease:** • ≥7 days after 2nd dose:[18] *12–15yrs:* 100% *16–64yrs:* 94.6% *≥65yrs:* 94.7% **Prevention of severe disease:** • 95–100%	30mcg (0.3mL) IM × 2 doses, 21 days apart[7,8]	**Ultra-Cold Freezer** (–80°C to –60°C/–112°F to –76°F): until expiration date **Thermal Shipper**[9] (–90°C to –60°C/–130°F to –76°F): up to 30 days from delivery **Freezer**[10] (–25°C to –15°C/–13°F to 5°F): up to 2wks **Refrigerator** (2°C to 8°C/35°F to 46°F): up to 1 month (up to 6hrs after dilution) **Room Temperature** (up to 25°C/up to 77°F): up to 2hrs	Inj site pain, swelling and/or erythema, fatigue, headache, myalgia, chills, arthralgia, fever, nausea, malaise, lymphadenopathy. *Rare:* severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (eg, rash, pruritis, urticaria, angioedema), myocarditis/pericarditis (esp. adolescents and young adults)
Moderna	**mRNA-1273**	EUA for ≥18yrs	**Prevention of symptomatic disease:** • ≥14 days after 2nd dose: *Overall:* 94.1% *18–64yrs:* 95.6% *≥65yrs:* 86.4% **Prevention of severe disease:** • ≥14 days after 2nd dose: 100%	100mcg (0.5mL) IM × 2 doses, 28 days apart[7,8]	**Freezer** (–50°C to –15°C/–58°F to 5°F): until expiration date **Refrigerator** (2°C to 8°C/36°F to 46°F): up to 30 days (up to 12hrs after vial puncture) **Room temperature** (8°C to 25°C/46°F to 77°F): up to 24hrs (up to 12hrs after vial puncture)	Inj site pain, swelling and/or erythema, fatigue, headache, myalgia, arthralgia, chills, nausea, vomiting, axillary swelling/tenderness, fever. *Rare:* severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (eg, rash, pruritis, urticaria, angioedema), myocarditis/pericarditis (esp. adolescents and young adults)
VIRAL VECTOR[11]						
Janssen (Johnson & Johnson)	**JNJ-78436735**	EUA for ≥18yrs	**Prevention of moderate to severe disease:** • ≥14 days after dose: *Overall:* 66.9% *US:* 74.4% *S. Africa*[12]: 52.0% *Brazil*[13]: 66.2% • ≥28 days after dose: *Overall:* 66.1% *US:* 72.0% *S. Africa*[12]: 64.0% *Brazil*[13]: 68.1% **Prevention of severe/critical disease:** • ≥14 days after dose: *Overall:* 76.7% *US:* 78.0% *S. Africa*[12]: 73.1% *Brazil*[13]: 81.9% • ≥28 days after dose: *Overall:* 85.4% *US:* 85.9% *S. Africa*[12]: 81.7% *Brazil*[13]: 87.6%	5×10^{10} viral particles (0.5mL) IM × 1 dose[8]	**Refrigerator** (2°C to 8°C/36°F to 46°F): up to 4.5mos (up to 6hrs after vial puncture) **Room temperature** (9°C to 25°C/47°F to 77°F): up to 12hrs (up to 2hrs after vial puncture)	Inj site pain, swelling and/or erythema, headache, fatigue, myalgia, nausea, fever. *Rare:* severe allergic reactions, including anaphylaxis, clotting events such as TTS (esp. women aged 18-49yrs)
AstraZeneca-Oxford	**AZD1222**	Phase 3 clinical trials in US	**Prevention of symptomatic disease:** • ≥15 days after 2nd dose: *Overall:* 76% *≥65yrs:* 85% **Prevention of severe/critical disease, including hospitalization:** • 100%	5×10^{10} viral particles (0.5mL) IM × 2 doses, 4-12wks apart[15]	**Refrigerator** (2°C to 8°C/36°F to 46°F): at least 6mos	

(continued)

COVID-19 VACCINES (Part 2 of 2)

Developer	Vaccine	Status	Efficacy[17]	Dosing	Storage/Stability[4]	Side Effects[5,6]
PROTEIN SUBUNIT[14]						
Novavax	**NVX-CoV2373**	Phase 3 clinical trials in US	**Prevention of mild/moderate/severe disease:** **US & Mexico trials:** • After 2nd dose: *Overall:* 90.4% *Predominantly variant strains*[19]: 93.2% *High risk groups*[20]: 91.0% **UK trial:** • 14 days after 1st dose: 83.4% • After 2nd dose: *Overall:* 89.7% *Original strain:* 96.4% *B.1.1.7 variant:* 86.3% **South Africa trial:** • Predominantly variant strains (mostly B.1.351): 48.6% overall • HIV-negative: 55.4%[16] **Prevention of moderate and severe disease:** US & Mexico trials: 100% **Prevention of severe disease, including all hospitalization and death:** • UK & South Africa trials: 100%	0.5mL IM × 2 doses, 21 days apart	**Refrigerator** (2°C to 8°C/36°F to 46°F): up to 6mos	

NOTES

Key: EUA = Emergency Use Authorization (given by FDA); IM = intramuscular

[1] Defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress, or anaphylaxis that occur within 4hrs following exposure to a vaccine or medication.

[2] If known current COVID-19 infection, vaccination should be deferred until person has recovered and has met criteria to discontinue isolation.

[3] Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2.

[4] Stability is for unopened vials unless otherwise specified. Frozen vaccines must be thawed and diluted before use, either in refrigerator or at room temperature, and should not be refrozen.

[5] mRNA vaccines: most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first 3 days of vaccination, and resolve with 1-3 days of onset. Symptoms are more frequent and severe following 2nd dose and among younger people compared with older (eg, >55yrs/Pfizer-BioNTech, ≥65yrs/Moderna). Those with prior SARS-CoV-2 infection may be more likely to experience symptoms such as fever, chills, and myalgia after the 1st dose.

[6] Janssen vaccine: most systemic post-vaccination symptoms are mild in severity, resolve within 1-2 days after vaccination, and are more frequent in younger vs older people (≥60yrs).

[7] 2nd dose should be administered as close to the recommended interval as possible. 2nd doses inadvertently administered earlier than the recommended dosing interval (earlier than the 4-day grace period) do not need to be repeated. If 2nd dose is not administered within 42 days of the 1st dose, the series does not need to be restarted (only limited data available on efficacy beyond this window).

[8] Providers should observe patients for the occurrence of immediate adverse reactions for at least 15mins after vaccinations and for 30mins for those with the following precautions: history of any immediate allergic reaction to any other vaccines or injectable therapy, contraindication to mRNA COVID-19 vaccine who receive Janssen vaccine and vice versa, or history of anaphylaxis due to any cause.

[9] For temporary storage only. Dry ice must be replenished within 24hrs of delivery and every 5 days. Remaining doses must be transferred to refrigerator.

[10] Vials stored in freezer may be returned one time to ultra-cold freezer at which time the 2-week time frame is suspended.

[11] Recombinant, replication-incompetent Ad26 vector, encoding stabilized variant of the SARS-CoV-2 Spike (S) protein.

[12] Sequencing of cases showed 94.5% prevalence of the B.1.351 variant.

[13] Sequencing of cases showed 69.4% prevalence of the P.2 variant.

[14] Engineered portion of viral spike (S) glycoprotein from SARS-CoV-2, combined with adjuvant (saponin-based Matrix-M).

[15] Longer inter-dose interval of 12 weeks or more have been evaluated in clinical trials with increased efficacy reported.

[16] Results from the South Africa Phase 2b trial showed a 55.4% efficacy for the prevention of mild, moderate and severe COVID-19 disease in the HIV-negative trial participants.

[17] Based on data from controlled clinical trials as presented in the EUA Fact Sheet for Healthcare Providers.

[18] In participants with or without evidence of prior SARS-CoV-2 infection.

[19] Against predominantly circulating Variants of Concern and Variants of Interest. For variants "not considered Variants of Concern/Interest", efficacy is 100%.

[20] High-risk populations include patients aged >65yrs, age <65yrs with certain comorbidities or having life circumstances with frequent COVID-19 exposure.

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(Rev. 7/2021)