

COVID-19 vaccine candidate side-by-side comparison

Updated: November 4, 2021



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Summary of changes since last publication (update: November 4, 2021)

- Added information on a booster dose in non-immunocompromised individuals.
- Added information on heterologous (mix and match) boosters.
- Added information on approval of BioNTech/Pfizer vaccine for pediatric patients aged 5-11 years, including descriptive 2-month efficacy analysis.
- Added information on orange cap (pediatric) BioNTech/Pfizer vaccine formulation (10 mcg/0.2 mL).
- Updated the number of myocarditis/pericarditis cases reported to VAERS in association with mRNA vaccine and included crude incidence rates from Ontario, Canada, and Israel.
- Added information from VAERS on crude incidence rates of GBS with Janssen vaccine.
- Added 6-month efficacy data for Moderna vaccine.
- Updated VE data for Moderna, BioNTech/Pfizer, and Janssen vaccine against Delta variant (Kaiser and VA studies).
- Added CPT codes for booster doses and pediatric BioNTech/Pfizer formulation first and second doses.
- Removed AstraZeneca vaccine information.
- Removed expanded vaccine summary.

Expanded vaccine summary is available upon request by emailing pharmacyquestions@vizientinc.com.

COVID-19 vaccine candidate side-by-side comparison

| Vaccine candidates | | | | |
|------------------------------------|---|--|---|---|
| | mRNA vaccines | | Replication-defective vectored vaccines | Protein subunit vaccines |
| | mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| Manufacturer | Moderna/NIAID | Pfizer/BioNTech SE | Janssen | Novavax |
| FDA-approved indications | | | | |
| | N/A | Active immunization to prevent COVID-19 disease in individuals ≥ 16 y. | N/A | Investigational |
| EUA-approved indications | | | | |
| | <ul style="list-style-type: none"> Active immunization to prevent COVID-19 disease in individuals ≥ 18 y. Third primary series dose to individuals ≥ 18 y who have been determined to have certain kinds of immunocompromise. Single booster dose in: ≥ 65 y; 18-64 y at high risk of severe COVID-19; 18-64 y with institutional or occupational exposure. Heterologous booster dose in eligible individuals following completion of primary vaccination with a different vaccine. | <ul style="list-style-type: none"> Two-dose primary series to individuals ≥ 5 y to <16 y. Third primary series dose to individuals ≥ 12 y who have been determined to have certain kinds of immunocompromise. A single booster dose in: ≥ 65 y; 18-64 y at high risk of severe COVID-19; 18-64 y with institutional or occupational exposure. Heterologous booster dose in eligible individuals following completion of primary vaccination with a different vaccine. | <ul style="list-style-type: none"> Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥ 18 y. Single booster dose in ≥ 18 y. Heterologous booster dose in eligible individuals following completion of primary vaccination with a different vaccine. | Investigational – EUA expected to be submitted in Q4 2021. |
| Vaccine platform technology | LNP-encapsulated, nucleoside-modified RNA | | Recombinant, replication-defective adenovirus type 26 vector leveraging AdVac technology | Recombinant nanoparticle vaccine technology, leveraging Sf9/BV insect cell platform and Matrix-M™ adjuvant technology |

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| Targeted SARS-CoV-2 antigen | Full-length, prefusion stabilized SARS-CoV-2 spike protein | | | |
| Pharmacology | <ul style="list-style-type: none"> mRNA encoding for the SARS-CoV-2 spike glycoprotein is delivered to cells in a lipid capsule. Using mRNA, cells manufacture the spike protein (antigen). Spike protein stimulates the body's immune response and production of antibodies against SARS-CoV-2. | DNA sequence for SARS-CoV-2 spike glycoprotein (antigen) is encoded into a human or non-human adenovirus. Upon delivery to the host cell, host cells manufacture the spike protein (antigen), which stimulates the body's immune response. JNJ-78436735 uses a human adenovirus with a low prevalence in humans. Due to genetic alterations, adenovirus vectors are unable to replicate once in the host cell. | | <ul style="list-style-type: none"> Genetic sequence encoding spike protein is cloned into baculovirus and inserted into Sf9 insect cells, where spike protein is produced and isolated/extracted. Matrix-M adjuvant boosts immune response; stimulates entry of antigen-presenting cells into the injection site and enhancing B- and T-cell responses. |
| Immunology | | | | |
| Humoral | Development of binding and neutralizing antibodies against SARS-CoV-2 spike protein | | | |
| Cellular (CD4+) | Th1-biased | Th1-biased | Th1-biased | Th1-biased |
| Cellular (CD8+) | √ | √ | √ (varies by age and dose) | √ |
| Manufacturing | Genetically engineered | | | |
| How supplied | | | | |
| Multidose vial | <ul style="list-style-type: none"> 10 to 11 doses/5.5 mL vial 13 to 15 doses/7.5 mL vial Does not contain latex | Purple cap (≥ 12 y) <ul style="list-style-type: none"> 6 doses/vial Does not contain latex Orange cap (5-<12 y) <ul style="list-style-type: none"> 10 doses/vial Does not contain latex | <ul style="list-style-type: none"> 5 doses/vial Does not contain latex | 10 doses/vial |

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| Vial storage prior to use | | | | |
| Ultra-low or Frozen | Store frozen between -50° C to -15° C | <p>Purple cap (≥ 12 y)</p> <ul style="list-style-type: none"> • ULT freezer (-90° C to -60° C): Those with an expiry date of July 2021 through February 2022 may remain in use for 3 mos beyond the printed date. • Freezer (-25° C to -15° C): 2 wks. May be returned a single time to the recommended storage condition of -90° C to -60° C. • Thermal container may be used as temporary storage when consistently re-filled to top of container with dry ice. <p>Orange cap (5-<12 y)</p> <ul style="list-style-type: none"> • ULT freezer (-90° C to -60° C): 6 mos • Freezer (-25° C to -15° C): N/A | <ul style="list-style-type: none"> • Stored frozen prior to shipment but should not be stored frozen at vaccination site. • If vaccine is frozen upon receipt, thaw at 2° C to 8° C or if needed immediately, thaw at room temperature (4 h to thaw carton of 10 vials, 1 h to thaw individual vial). | N/A |
| Refrigeration (2° to 8° C) | 30 d | <p>Purple cap</p> <ul style="list-style-type: none"> • Undiluted vial: 30 d <p>Orange cap</p> <ul style="list-style-type: none"> • Undiluted vial: 10 wk | <ul style="list-style-type: none"> • Stable for 6 mo • Prior to discarding doses, validate the expiration date through the Expiry Checker (based on lot numbers). | Stable until date printed on label |

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| Room temperature | 24 h | Purple cap (≥ 12 y) <ul style="list-style-type: none"> 6 h, stored between 2°C to 25°C Orange cap (5-<12 y) <ul style="list-style-type: none"> Undiluted vial: 12 h | 12 h | NR |
| BU after vial entry | <ul style="list-style-type: none"> 12 h, stored between 2°C to 25°C Discard after 20 punctures | Purple cap (≥ 12 y) <ul style="list-style-type: none"> 6 h, stored between 2°C to 25°C Orange cap (5-<12 y) <ul style="list-style-type: none"> 12 h, stored between 2°C to 25°C Vial may state 6 h expiration, but EUA information supersedes | <ul style="list-style-type: none"> 6 h, stored between 2°C to 8°C OR 2 h, stored at room temperature, up to 25°C | NR |
| Vaccination schedule | | | | |
| Dose | <ul style="list-style-type: none"> Primary dose: 100 mcg/0.5 mL Booster dose: 50 mcg/0.25 mL | <ul style="list-style-type: none"> Primary dose ≥ 12 y: 30 mcg/0.3 mL (Purple cap) Booster dose ≥ 18 y: 30 mcg/0.3 mL (Purple cap) Primary dose 5 to <12 y: 10 mcg/0.2 mL (Orange cap) | Primary and booster dose: 5×10 ¹⁰ vp /0.5 mL | 5 mcg protein antigen + 50 mcg Matrix-M adjuvant |
| Primary series | 2-dose series (28 d between doses) for non-immunocompromised. | 2-dose series (21 d between doses) for non-immunocompromised. | 1 dose primary series regardless of immune status | 2-dose series (21 d between doses) |
| | <ul style="list-style-type: none"> 3-dose series for immunocompromised individuals ≥ 18 y. | <ul style="list-style-type: none"> 3-dose series for immunocompromised individuals ≥ 12 y. | | |

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| | <ul style="list-style-type: none"> Third dose (100 mcg) is given at least 28 d following the second dose and should be with the same mRNA vaccine. | <ul style="list-style-type: none"> Third dose (30 mcg) is given at least 28 d following the second dose and should be with the same mRNA vaccine. | | |
| Booster dose | <ul style="list-style-type: none"> ≥ 6 mo following the primary 2 or 3-dose series Heterologous doses (mix and match) are allowed for boosters. Eligibility: <ul style="list-style-type: none"> ≥ 65 y ≥ 18 y who live in long-term care settings. ≥ 18 y who have underlying medical conditions. ≥ 18 y who work or live-in high-risk settings. | | <ul style="list-style-type: none"> ≥ 2 mo following a single-dose primary regimen Heterologous doses (mix and match) are allowed for boosters. Eligibility: ≥ 18 y | N/A |
| Interchangeability of vaccines | <p>Primary series and additional primary doses should be with the same mRNA vaccine product. Heterologous doses (mix and match) are allowed for booster doses.</p> <ul style="list-style-type: none"> Pre-print results^a for heterologous SARS-CoV-2 booster vaccinations are available (NCT04889209). 458 adults who received a primary vaccination series with mRNA-1273, Ad26.CoV2.S, BNT162b2 were randomized into 9 groups (n = 50/group) and received a homologous or heterologous booster at least 12 wks after primary vaccination. Analysis of immunogenicity and safety endpoints is descriptive only. Study was designed to identify only serious ADEs with incidence at least 10%. Most ADRs were of grade 2 severity and the most common were injection site, malaise, myalgias, and headache. bAb titers were assessed at day 15. The geometric mean fold rises in bAb titers ranged from 4.6 to 56 and were greatest for those who received a mRNA booster after an Ad26.CO2.S primary vaccine. All groups with the exception of homologous Ad26.CoV2.S prime boost group achieved post-boost neutralizing geometric mean IU 50/mL levels >100, which in a previous study correlated with 90.7% vaccine effectiveness. | | | A trial was initiated in the UK in June to evaluate a booster dose in patients who have received 2 doses of another authorized vaccine. ^b |

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| Preparation and administration | | | | |
| Dilution required | No | Yes (Purple and Orange cap) | No | No |
| Preparation | <ul style="list-style-type: none"> Frozen vials must be thawed prior to administration – either under refrigeration (2 h and 30 min) or at room temperature ($\leq 25^{\circ}\text{C}$ for 1 h). After thawing, do not refreeze. Swirl vial gently after thawing and between each withdrawal. Record date and time of first use on vial label. | <ul style="list-style-type: none"> Frozen vials must be thawed to room temperature prior to dilution – either under refrigeration or at room temperature. Dilute in original vial with 1.8 mL (purple cap) or 1.3 mL (orange cap) of sterile 0.9% Sodium Chloride Injection, USP (Do not use bacteriostatic 0.9% Sodium Chloride Injection). Record the date and time of dilution on the vaccine vial label. | <ul style="list-style-type: none"> Before withdrawing each dose, carefully mix the contents of the vial by swirling gently in an upright position for 10 sec. Record data and time of first use on vial label. | N/A |
| Administration | Intramuscular | Intramuscular | Intramuscular | Intramuscular |
| Co-administration with other vaccines | <ul style="list-style-type: none"> COVID-19 vaccines may be administered without regard to timing of other vaccines. Administer each injection in a different site. | | | N/A |
| Considerations for use in specific populations | | | | |
| Current or prior history of SARS-CoV-2 infection | <ul style="list-style-type: none"> Current infection - vaccination should be deferred until the person has recovered from acute illness and criteria have been met for isolation discontinuation. Prior infection – vaccination can be given to people with prior SARS-CoV-2 infection. | | | N/A |
| History of passive antibody therapy for COVID-19 | Defer vaccination for at least 90 d after receipt of monoclonal antibodies or convalescent plasma. | | | N/A |

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| Myocarditis/pericarditis history | <ul style="list-style-type: none"> • Occurrence after first dose of an mRNA (males \leq 30 y after dose 2 appear to be at greatest risk) – For the majority, defer second dose, but in certain circumstances, a second dose may be considered. • History of myocarditis or pericarditis unrelated to mRNA – May be vaccinated after episode has completely resolved. | | | N/A |
| GBS history | <ul style="list-style-type: none"> • May receive any of the authorized or approved COVID-19 vaccines. • Janssen vaccine may be associated with an increased risk of GBS (males \geq 50 y appear to be at greatest risk); therefore, discuss mRNA vaccines as an alternative. | | | N/A |
| Moderate to severe immune compromise | Consider an additional primary dose (same mRNA vaccine product) at least 28 d after the second dose, followed by a single booster dose at least 6 mo later (any authorized vaccine). | | 1-dose primary series; eligible for booster at \geq 2 mos after initial dose (any authorized vaccine). | N/A |
| History of HIT | Should be offered an mRNA vaccine if it has been \leq 90 d since illness has resolved. After 90 d, patients may be vaccinated with any COVID-19 vaccine. | | | N/A |
| Persons receiving HCT and CAR-T-cell therapy | If doses received prior to HCT or CAR-T cell therapy, revaccinate with a primary series at least 3 mos after transplant or CAR-T-cell therapy. | | | |
| Pregnancy or lactation | <ul style="list-style-type: none"> • Experts do not believe that any of the COVID-19 vaccines pose a risk because the vaccines are non-replicating and cannot cause infection in the mother or fetus. However, the safety of COVID-19 vaccines has not been evaluated in clinical trials. There is no recommendation for routine pregnancy testing prior to vaccination. In general, non-live vaccines do not pose a risk to mothers or breast-feeding infants. • V-safe data as of Feb. 28, 2021: 35,691 pregnancies self-reported at time of vaccination (n = 16,439 (Moderna) and n = 19,252 (Pfizer))^c • V-safe pregnancy registry as of Feb. 28, 2021: 3,958 pregnancies enrolled with 827 completed pregnancies, including 712 live births. No safety signals detected with vaccine (pregnancy outcome, pregnancy complications, neonatal outcomes).^c No outcomes reported in those vaccinated early in pregnancy; report describes mostly neonatal outcomes from third trimester exposure. • In a V-safe pregnancy cohort of 2,456 participants who received mRNA vaccine at $<$20 wk of gestation and who were pregnant at \geq6 wk of gestation, there were 165 SABs reported, 253 | | | N/A |

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| | | participants lost to follow-up, and 2,020 known to be pregnant at 20 wks. Cumulative risk of SAB from 6-19 wks' gestation was 14.1% (95% CI, 12.1-16.1%) in the vaccine cohort (vs. 12.8% (95% CI, 10.8-14.8% for age-standardized cumulative risk of SAB). ^d | | |
| -- | | Phase 2/3 study (NCT04754594) to evaluate safety and immunogenicity of vaccine in pregnancy. | Phase 2/3 study (NCT04754594) to evaluate safety and immunogenicity of vaccine in pregnancy. | -- |
| Pediatric patients | <p>12 to <18 y</p> <ul style="list-style-type: none"> Phase 2/3 trial (NCT04649151) in 12 to <18 y (TeenCOVE) data published. EUA filled June 10, 2021; delayed to further investigate myocarditis, review may not be completed until 2022. <p>6 mo to <12 y</p> <ul style="list-style-type: none"> Phase 2/3 trial (NCT04796896) in 6 mo to <12 y (KidCOVE) enrolled. Dose, 2-12 y: 50 or 100 mcg. Top-line results released for 50 mcg. Filing will be delayed. Dose, <2 y: 25, 50, or 100 mcg. | <p>12 to 15 y</p> <ul style="list-style-type: none"> Approved for EUA; recommended for use. Phase 3 (NCT04368728) results published. <p>5 to 11 y</p> <ul style="list-style-type: none"> Phase 1/2/3 trial (NCT04816643) in 6 mo to <12 y began in March. Approved for EUA; recommended for use. <p><11 y</p> <ul style="list-style-type: none"> EUA submissions anticipated for children 2 y to <5 y and 6 mo to <2 y as soon as 4th quarter 2021 Dose: 3 mcg | <p>12 to <18 y</p> <ul style="list-style-type: none"> Phase 2 trial (NCT04535453) J&J plans to conduct additional trials in pediatrics 2-11 y, <2 y, and in immunocompromised pediatrics 1-17 y. | <p>12 to <18 y</p> <ul style="list-style-type: none"> Phase 3 trial (PREVENT-19) in 12 to <18 y. |

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| Safety | | | |
| Contraindications | <ul style="list-style-type: none"> Severe allergic reaction (e.g. anaphylaxis) after a previous dose of or to a component of the vaccine. Immediate (within 4 h of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. | | N/A |
| Precautions | <ul style="list-style-type: none"> Appropriate treatment to manage immediate allergic reactions must be available. Reports suggest increased risks of myocarditis and pericarditis, particularly within 7 d following the second dose. Syncope may occur in association with administration of injectable vaccines. Immunocompromised persons may have a diminished response to vaccination. Vaccine may not protect all vaccine recipients. | <ul style="list-style-type: none"> Appropriate treatment to manage immediate allergic reactions must be available. Reports suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites combined with thrombocytopenia. Most cases occur within 14 d and in females 18-49 y. Increased risk of thrombosis of the cerebral venous sinuses and other sites combined with thrombocytopenia. Most cases occur within 14 d and in females 18-49 y. | N/A |
| Observation period | <ul style="list-style-type: none"> 30 mins for persons with history of an immediate allergic reaction of any severity to a vaccine or injectable therapy; history of anaphylaxis due to any cause; contraindication to a different CV19 vaccine. 15 mins: all others. | | N/A |

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| Solicited local ADEs | <ul style="list-style-type: none"> Most common is injection site pain, comparable incidence after dose 1 and 2 (83.7% and 88.4%, respectively). Most local ADEs were grade 1 or 2; grade 3 events were more common after dose 2, and the most common grade 3 was injection site pain (4.1% after dose 2). | <ul style="list-style-type: none"> 5-11 y: Pain (84.3%), redness (26.4%), and swelling (20.4%) at injection site. 12-15 y: Pain (90.5%), swelling (10.5%), and redness (8.6%) at injection site. 16-55 y: Pain (88.6%) and swelling (10.6%) at injection site. ≥ 56 y: Pain (78.2%), swelling (11.8%), and redness (10.4%) at injection site. | <ul style="list-style-type: none"> Most common is injection site pain (48.6%). Most events are of grade 1 or 2 severity; <0.5% incidence of grade 3 events. | <ul style="list-style-type: none"> Most common is injection site pain after first (53.3%) and second dose (76.4%). Most events grade 1 or 2 severity and of short duration (2.3 d after first dose and 2.8 d after second dose). |
| Solicited systemic ADEs | <ul style="list-style-type: none"> Most common are fatigue and headache, incidence and severity increased after dose 2 (fatigue: 37.2% (dose 1), 65.2% (dose 2); headache: 32.7% (dose 1) and 58.6% (dose 2)). Most common grade 3 ADEs after dose 2 were fatigue (9.7%), myalgia (8.8%), headache (4.5%), and arthralgia (5.2%). | <ul style="list-style-type: none"> 5-11 y: Fatigue (51.7%), headache (38.2%), muscle pain (17.5%), and chills (12.4%). 12-15 y: Fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%) and joint pain (20.2%). 16-55 y: Fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), and fever (17.8%). | <ul style="list-style-type: none"> Most common are headache (38.9%), fatigue (38.2%), and myalgia (33.2%). Most events grade 1 or 2 severity. Numeric imbalances, with more events in vaccine vs. placebo group were observed for: TE events; seizures; tinnitus; and non-serious urticaria. | <ul style="list-style-type: none"> Most common are headache, muscle pain, and fatigue after both dose 1 (24.5%, 21.4%, and 19.4%) and dose 2 (40%, 40.3%, and 40.3%). Most events grade 1 or 2 severity with < 2 d duration. Grade 4 events reported in 3 vaccine recipients. |

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| | | | <ul style="list-style-type: none"> 16-55 y: Fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), and fever (17.8%). | | |
| Post-marketing safety issues | <p>Myocarditis</p> <ul style="list-style-type: none"> Most common in males \leq 29 y after dose 2. Crude reporting rates (per million doses) of myopericarditis in males \leq 29 y, after dose 2 (VAERS, 10/6): <ul style="list-style-type: none"> Age 12-15: 39.9 (Pfizer) Age 16-17: 69.1 (Pfizer) Age 18-24: 36.8 (Pfizer and Moderna) Age 25-29: 10.8 (Pfizer and Moderna) Crude reporting rates (per million doses) of myopericarditis in males \leq 29 y, after dose 2 (Ontario, 10/24):^e <ul style="list-style-type: none"> Age 12-17: 123.8 (Pfizer and Moderna) Age 18-24: 171 (Pfizer and Moderna) Reporting rate for myocarditis in males 16-19 y in Israel after dose 2: 1 case per 6,637 doses (Pfizer).^f Reporting rate for myocarditis in males aged 18-29 y in Nordic countries after dose 2: 1 case per 4,800 (Moderna). Several countries have suspended use of mRNA-1273 in younger patients due to myocarditis concerns including: Ontario, Canada (male, 18-24 y), Finland (male, \leq 30 y), Sweden (all, year of birth 1991 or later), Denmark (all, \leq 18 y), Norway (male, \leq 30 y). <p>EMA is evaluating risk of erythema multiforme, nephrotic syndrome, and glomerulonephritis in association with mRNA vaccines.</p> | <p>TTS (as of 8/25):</p> <ul style="list-style-type: none"> 44 cases out of 14.2 million doses Females aged < 50 y should be aware of the rare, but increased risk <p>GBS (VAERS, Feb – July 2021)^g</p> <ul style="list-style-type: none"> 130 presumptive reports; 59.7% males Median age: 56 y (IQR, 45-62 y) Median time to onset: 13 d (IQR, 10-18 d) Crude reporting rate: 1 case per 100,000 doses Observed to expected rate ratio elevated in all groups except for those aged 18-29 y | 1 case of myocarditis reported in vaccine recipient in phase 3 trial (the safety data board ruled it a viral myocarditis) | | |

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| Phase 3 trials – efficacy results | | | | |
| Symptomatic COVID-19 (without previous SARS-CoV-2 infection) | COVE (NCT04470427) <ul style="list-style-type: none"> Primary endpoint, measured ≥ 14 d to 5.3 mo after dose 2 744 cases in placebo group vs. 55 cases in vaccine group VE: 93.2% (95% CI, 91-94.8) | ≥ 12 y cohort (NCT04368728) <ul style="list-style-type: none"> Primary endpoint, measured from 7 d to 6 mo after dose 2 850 cases in placebo group vs. 77 cases in vaccine group VE: 91.3% (95% CI, 89.0-93.2) | ENSEMBLE 1 (NCT04505722) <ul style="list-style-type: none"> Secondary endpoint, measured 14 d and 28 d after vaccine 14 d: 351 cases in placebo group vs. 117 cases in vaccine group; VE of 66.9% (95% CI, 59.1-73.4) 28 d: 195 cases in placebo group vs. 66 cases in vaccine group; VE of 66.5% (95% CI, 55.5-75.1). | Primary endpoint, measured ≥ 7 d to 3 mos (UK trial) or 2 mos (PREVENT-19) after dose 2 UK trial <ul style="list-style-type: none"> 96 cases in placebo group vs. 10 cases in vaccine group Overall VE: 89.7% (95% CI, 80.2-94.6) VE against Wuhan strain: 96.4% (95% CI, 73.8-99.4) |
| | TeenCOVE (NCT04649151) <ul style="list-style-type: none"> Secondary endpoint (median follow-up after dose 2 was 53 d) 4 cases in placebo group vs. 0 cases in vaccine group VE: 100% (VE 93% for CDC COVID-19 definition) | 12-15 y cohort (NCT04368728) <ul style="list-style-type: none"> Descriptive, measured ≥ 7 d after dose 2 (58% had follow-up of at least 56 d) 16 cases in placebo group vs. 0 cases in vaccine group VE: 100% (95% CI, 75.3-100) | | PREVENT-19 (NCT04611802) <ul style="list-style-type: none"> 63 cases in placebo group vs. 14 in vaccine group VE: 90.4% (95% CI, 82.9-94.6) VE, non VOC/VOI: 100% (95% CI, 80.8-100) VE, against any VOC/VOI: 92.6% (95% CI, 83.6-96.7) |
| | 5-11 y old cohort <ul style="list-style-type: none"> Descriptive, measured ≥ 7 d after dose 2 (mean follow-up for 56 d) 16 cases in placebo group vs. 3 cases in vaccine group VE: 90.7% (95% CI, 67.7-98.3) | | | |

| | Vaccine candidates | | | |
|-----------------------------|--|--|--|--|
| | mRNA vaccines | | Replication-defective vectored vaccines | Protein subunit vaccines |
| | mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| Moderate or severe COVID-19 | <p>COVE</p> <ul style="list-style-type: none"> Secondary endpoint, prevention of severe COVID-19 up to 5.3 mo 106 cases in placebo group vs. 2 cases in vaccine group VE: 98.2% (95% CI, 92.8-99.6) <p>TeenCOVE</p> <ul style="list-style-type: none"> No severe cases | <p>≥ 12 y old cohort</p> <ul style="list-style-type: none"> Secondary endpoint, prevention of severe COVID-19 up to 6 mo after dose 1 30 cases in placebo group vs. 1 case in vaccine group VE: 96.7% (95% CI, 80.3-99.9) <p>12-15 y old cohort</p> <ul style="list-style-type: none"> No severe cases <p>5-11 y old cohort</p> <ul style="list-style-type: none"> No severe cases | <ul style="list-style-type: none"> Primary endpoint, (moderate to severe/critical), measured 14 d and 28 d after vaccine 14 d: 348 cases in placebo group vs. 116 cases in vaccine group; VE of 66.9% (95% CI, 59-73.4). 28 d: 193 cases in placebo group vs. 66 cases in vaccine group; VE of 66.1% (95% CI, 55-74.8). U.S. only: VE of 72% (95% CI, 58.2-81.7) | <p>UK trial</p> <ul style="list-style-type: none"> Secondary endpoint, prevention of severe cases 5 cases in placebo group vs. 0 cases in vaccine group VE (non alpha strain): 96.4% (95% CI, 73.8-99.5) <p>PREVENT-19</p> <ul style="list-style-type: none"> Secondary endpoint, prevention of moderate to severe cases 14 cases in placebo group vs. 0 cases in vaccine group VE: 100% (95% CI, 87-100) |
| | | | <ul style="list-style-type: none"> Planned analysis (severe/critical) measured 14 d and 28 d after vaccine 14 d: 60 cases in placebo group vs. 14 cases in vaccine group; VE of 76.7% (95% CI, 54.6-89.1) 28 d: 34 cases in placebo group vs. 5 cases in vaccine group; VE of 85.4% (95% CI, 54.2-96.9) | |

| Vaccine candidates | | | | |
|-------------------------|--|--|---|---|
| mRNA vaccines | | | Replication-defective vectored vaccines | Protein subunit vaccines |
| mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| COVID-19 related deaths | COVE (5.3 mo follow-up) <ul style="list-style-type: none"> 3 in placebo group 1 in vaccine group | ≥ 12 y old cohort (6 mo follow-up) <ul style="list-style-type: none"> COVID-19 or COVID-19 pneumonia 3 in placebo group 1 in vaccine group | ENSEMBLE 1 <ul style="list-style-type: none"> 5 in placebo group 0 in vaccine group | UK trial <ul style="list-style-type: none"> 1 in placebo group 1 in vaccine group PREVENT-19 <ul style="list-style-type: none"> 0 deaths |
| Variants of Concern | | | | |
| Definition | Evidence of an increase in transmissibility, more severe disease, significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. | | | |
| B.1.617.2 (Delta) | Front-line workers in US (Delta prominent weeks)^h <ul style="list-style-type: none"> Adjusted VE against symptomatic disease: 66% (95% CI, 26-84) | England^{k,l} Adjusted VE against symptomatic infection <ul style="list-style-type: none"> ≥21 d after dose 1: 35.6% (95% CI, 22.7-46.4) ≥14 d after dose 2: 88.0% (95% CI, 85.3-90.1) VE for hospitalization after second dose^q: 96% (95% CI, 86-99) vs. 96% for alpha. | VA (Feb. 1 – Aug. 13)^j VE (95% CI) against infection: <ul style="list-style-type: none"> March: 88% (87-89) August: 3% (-7-12) | NR |
| | Mayo Clinic (Jan. – July 2021)ⁱ <ul style="list-style-type: none"> VE against symptomatic infection in July: 76% (95% CI, 58-87). VE against hospitalization in July: 81% (95% CI, 33-96.3). | Mayo Clinic (Jan. – July 2021)ⁱ <ul style="list-style-type: none"> VE against symptomatic infection in July: 42% (95% CI, 13-32%). VE against hospitalization in July: 75% (95% CI, 24-93.9%). | | |
| | Ontario (Dec. 2020 – May 2021)^m <ul style="list-style-type: none"> VE against symptomatic infection ≥ 14 d after dose 1: 70%; 95% CI, 64-76 (vs. 82% for alpha). VE against hospitalization or death ≥ 14 d after dose 1: 90% (95% CI, 82-94). | Qatar (Dec. 2020 – July 2021)ⁿ | | |

| Vaccine candidates | | | |
|---|---|---|--------------------------|
| mRNA vaccines | | Replication-defective vectored vaccines | Protein subunit vaccines |
| mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| <p>VE against asymptomatic or symptomatic infection</p> <ul style="list-style-type: none"> • ≥ 14 d after dose 1: 79% (95% CI, 58.9-90.1). • ≥ 14 d after dose 2: 84.8% (95% CI, 75.9-90.8). • VE against severe, critical, or fatal CV19 disease ≥ 14 d after dose 2: 100% (95% CI, 41.2-100). <p>VA (Feb. 1 – Aug. 13)ⁱ VE against infection</p> <ul style="list-style-type: none"> • March: 92% (95% CI, 92-93) • August: 64% (95% CI, 62-66) | <p>Ontario (Dec. 2020 – May 2021)^m VE against symptomatic disease:</p> <ul style="list-style-type: none"> • ≥ 14 d after dose 1: 57%; 95% CI, 53-61% (vs. 67% for alpha). • ≥ 7 d after dose 2: 92%; 95% CI, 90-94%. • VE against hospitalization or death ≥ 14 d after dose 1: 81%; 95% CI, 76-86. <p>Qatar (Dec. 2020 – July 2021)ⁿ VE against asymptomatic or symptomatic infection:</p> <ul style="list-style-type: none"> • ≥ 14 d after dose 1: 64.2% (95% CI, 38.1-80.1%). • ≥ 14 d after dose 2: 53.5% (95% CI, 43.9-61.4%). • VE against severe, critical or fatal COVID-19 disease ≥ 14 d after dose 2: 89.7% (95% CI, 61-98.1%). <p>Scotland^o VE for RT-PCR confirmed infection 14 d after second dose: 79% (95% CI, 75-82) vs. 92% for alpha.</p> <p>Israel (June – July 2021)^p VE and lower/upper CIs:</p> | | |

| Vaccine candidates | | | |
|---------------------|---|---|--------------------------|
| mRNA vaccines | | Replication-defective vectored vaccines | Protein subunit vaccines |
| mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| | <ul style="list-style-type: none"> SARS-CoV-2 cases: 39.0% (9.0-59.0) Symptomatic COVID-19: 40.5% (8.7-61.2) COVID-19 hospitalization: 88.0% (78.9-93.2) Severe-COVID-19: 91.4% (82.5-95.7) <p>Kaiser (Dec. 2021 – August 2021)^a VE (95% CI) against:</p> <ul style="list-style-type: none"> SARS-CoV-2 infection: 73% (72-74). Hospital admission: 90% (89-92). SARS-CoV-2 infection declined from 88% during first full mo after vaccination to 47% (43-51) after 5 mos. Delta infection declined from 93% during first full mo after vaccination to 53% (39-65) after 4 mos. Delta hospitalizations: 93% (84-96) up to 6 mos <p>VA (Feb. 1 – Aug. 13)ⁱ VE (95% CI) against infection:</p> <ul style="list-style-type: none"> in March: 91% (91-92) in August: 50% (47-52) | | |

| | Vaccine candidates | | | |
|-----------|---|--|---|--|
| | mRNA vaccines | | Replication-defective vectored vaccines | Protein subunit vaccines |
| | mRNA-1273 (Moderna) | Comirnaty, mRNA-BNT162b2 (BioNTech/Pfizer) | Ad26.COVS.2.S (J&J) | NVX-CoV2373 (Novavax) |
| CPT codes | <ul style="list-style-type: none"> 91301 (\$0.010) 0011A – first dose (\$40.00) 0012A – second dose (\$40.00) 0013A – third dose (\$40.00) 0064A - booster | <p>Purple cap</p> <ul style="list-style-type: none"> 91300 (\$0.010) 0001A – first dose (\$40.00) 0002A – second dose (\$40.00) 0003A – third dose (\$40.00) 0004A – booster <p>Orange cap</p> <ul style="list-style-type: none"> 91307 (\$0.010) 0071A – first dose 0072A – second dose | <ul style="list-style-type: none"> 91303 (\$0.010) 0031A – single dose (\$40.00) 0034A - booster | <ul style="list-style-type: none"> 91304 0041A – first dose 0042A – second dose |

Abbreviations: ADE = adverse drug event; bAb = binding antibodies; BU = beyond use; CPT = current procedural terminology; CVST = cerebral venous sinus thrombosis; EMA = European Medicines Agency; EUA = emergency use authorization; GBS = Guillain-Barre syndrome; HIT = heparin induced thrombocytopenia; LNP = lipid nanoparticle; mRNA = messenger ribonucleic acid; SAB = spontaneous abortion; TTS = thrombotic thrombocytopenia syndrome; ULT = ultra-low temperature; VE = vaccine efficacy; VTE = venous thromboembolism; VP = viral particle

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