# Summary Document for Interim Clinical Considerations
for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

## Category
- Pfizer-BioNTech
- Moderna
- Janssen

## Vaccine types
- mRNA
- Replication-incompetent adenovirus type 26 vector

## Age groups
- 12 through 15 years of age (authorized)
- ≥ 16 years (approved COMIRNATY)
- ≥18 years

## Dose
- Pfizer-BioNTech: 30 µg
  - 100 µg (primary series and additional dose)
  - 50 µg (booster dose)
- Moderna: 100 µg
  - 0.5 mL (primary series and additional dose)
  - 0.25 mL (booster dose)
- Janssen: 5 × 10¹⁰ viral particles

## Dose volume
- Pfizer-BioNTech: 0.3 mL
  - 0.5 mL (primary series and additional dose)
  - 0.25 mL (booster dose)
- Moderna: 0.5 mL
- Janssen: 0.5 mL

## Number of doses in primary series
- Pfizer-BioNTech: 2
  - 2
  - N/A
- Moderna: 2
- Janssen: 1

## Interval between primary series doses
- Pfizer-BioNTech: 3 weeks (21 days)
  - 1 month (28 days)
- Moderna: 1 month (28 days)
- Janssen: N/A

## Additional dose for moderately or severely immunocompromised persons
- Pfizer-BioNTech: Recommended at least 28 days after the 2nd dose or a primary series for moderately and severely immunocompromised people 12 years of age and older
  - Use the same vaccine product as the primary series
- Moderna: Recommended at least 28 days after the 2nd dose of a primary series for moderately and severely immunocompromised people 18 years of age and older
  - Use the same vaccine product as the primary series
- Janssen: Not authorized as an additional dose. See booster dose guidance

## Booster dose
- Pfizer-BioNTech: A single booster dose **should** be administered to:
  - People 65 years and older
  - People 18 years and older in long-term care settings
  - People aged 50-64 years with underlying medical conditions
  - People aged 18-49 years with underlying medical conditions
  - People aged 18-64 years at increased risk of SARS-CoV-2 exposure and transmission because of occupational and institutional setting

- Moderna: A single booster dose **should** be administered to:
  - People 65 years and older
  - People 18 years and older in long-term care settings
  - People aged 50-64 years with underlying medical conditions
  - People aged 18-49 years with underlying medical conditions
  - People aged 18-64 years at increased risk of SARS-CoV-2 exposure and transmission because of occupational and institutional setting

- Janssen: A single booster dose should be administered to all people 18 years and older who received a primary single-dose Janssen COVID-19 Vaccine*

## Interval between primary and booster doses
- Pfizer-BioNTech: At least 6 calendar months after completing the primary series
- Moderna: At least 6 calendar months after receiving the primary series
- Janssen: At least 2 months (8 weeks) after completing the primary dose
All currently authorized or approved COVID-19 vaccines

### Interchangeability of vaccines
- Primary series and additional primary doses (for moderately and severely compromised people) should be with the same mRNA vaccine product. In exceptional situations, such as a contraindication to a second dose of mRNA vaccine or when a previous dose product cannot be determined or is not available, another FDA-approved or -authorized COVID-19 vaccine may be used. Heterologous doses (mixing and matching) are allowed for booster doses. [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Interchangeability](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Interchangeability).†

### Coadministration with other vaccines
- COVID-19 vaccine and other vaccines may be administered on the same day, as well as any interval without respect to timing. When deciding whether to administer COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable diseases (e.g., during an outbreak), and the reactogenicity profile of the vaccines.

### Persons with prior or current COVID-19
- COVID-19 vaccines can be given safely to people with prior SARS-CoV-2 infection
- Defer vaccination until person has recovered from the acute illness and [criteria](https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html) have been met for them to discontinue isolation

### Women aged <50 years
- Risk of Thrombosis with Thrombocytopenia syndrome (TTS)
- Can receive any FDA-authorized or approved vaccine but should be informed of risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of Janssen (Johnson & Johnson) COVID-19 Vaccine and the availability of other COVID-19 vaccine options*

### Persons who received monoclonal antibodies or convalescent plasma for COVID-19 treatment
- Defer vaccination for at least 90 days

### Persons with a known SARS-CoV-2 exposure
- People in community or outpatient setting should defer vaccination until [quarantine period](https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html) has ended
- Residents or patients in congregate settings may be vaccinated if they do not have [symptoms consistent with COVID-19](https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)

### History of heparin-induced thrombocytopenia (HIT)
- If within 90 days of illness, offer an mRNA vaccine, after 90 days vaccinate with any FDA-authorized or approved COVID-19 vaccine

### Persons with underlying conditions
- May receive COVID-19 vaccine

### Persons with moderate and severe immune compromise
- Can receive any FDA-authorized or approved COVID-19 vaccine
  - Following 2-dose mRNA primary series, immunocompromised people ≥ 12 years should receive an additional dose (same mRNA vaccine product) at least 28 days after the second dose, followed at least 6 months later by a single booster dose (any FDA-authorized or -approved vaccine product)
  - Following 1 primary dose of Janssen, immunocompromised people ≥ 18 years should receive a single booster dose (any FDA-authorized or -approved vaccine product) at least 2 months (8 weeks) after the initial Janssen dose. Currently there is no recommendation for those who received the Janssen primary series to receive an additional primary series dose.

### Persons receiving HCT and CAR-T-cell therapy
- If received doses of COVID-19 vaccine prior to receiving an HCT or CAR-T cell therapy, should be revaccinated with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy
<table>
<thead>
<tr>
<th>All currently authorized or approved COVID-19 vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons with a history of myocarditis or pericarditis</strong></td>
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<tr>
<td>- If myocarditis or pericarditis occurred after a dose of an mRNA COVID-19 vaccine, should defer receiving a subsequent dose</td>
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<tr>
<td>- A subsequent dose can be considered in certain circumstances including personal risk of severe COVID-19 and level of community transmission.</td>
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<tr>
<td>- If a history of myocarditis or pericarditis unrelated to an mRNA COVID-19 vaccination, may receive COVID-19 vaccine after the episode has completely resolved.</td>
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<tr>
<td><strong>Persons with a history of Guillain-Barré Syndrome (GBS)</strong></td>
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<tr>
<td>- Can receive any FDA-authorized or approved COVID-19 vaccine; however, discuss the availability of mRNA vaccines to because of possible association between GBS and Janssen COVID-19 vaccination.</td>
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<tr>
<td><strong>Pregnant or breastfeeding people or people trying to get pregnant</strong></td>
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<tr>
<td>- Are recommended to receive a COVID-19 vaccine primary series, additional dose (if indicated) and booster dose, inform of risk of TTS after receipt of Janssen (Johnson &amp; Johnson) COVID-19 Vaccine and the availability of other options</td>
</tr>
<tr>
<td><strong>Adolescents</strong></td>
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<tr>
<td>- Adolescents aged 12-17 are ONLY eligible for Pfizer-BioNTech COVID-19 Vaccine</td>
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<tr>
<td>- Adolescents and adults aged 18 years and older are eligible for all COVID-19 vaccines</td>
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<tr>
<td><strong>Persons vaccinated outside the United States</strong></td>
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<tr>
<td>- Received all recommended doses of an FDA-authorized or approved COVID-19 vaccine, do not need primary series doses; if only one dose of a two-dose vaccine has been received provide the second dose as close to the recommended time as possible.</td>
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<tr>
<td>- Received a non FDA-authorized or approved vaccine</td>
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<tr>
<td>- If vaccine is listed for emergency use by the World Health Organization (WHO) and received all recommended doses, do not need any additional primary series doses with an FDA-authorized or approved vaccine</td>
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<tr>
<td>- If vaccine is listed for emergency use by WHO, but has not received all recommended doses, may be offered a complete FDA-authorized or -approved series</td>
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<tr>
<td>- If vaccine is not listed for emergency use by WHO, may be offered a complete FDA-authorized or approved COVID-19 vaccine series</td>
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<tr>
<td>- If received a mixed dose regimen of FDA-authorized, FDA-authorized, or WHO-emergency use listed COVID-19 vaccine for primary series, do not need any primary series doses.</td>
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<tr>
<td><strong>Contraindications</strong></td>
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<tr>
<td>- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine</td>
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<tr>
<td>- Immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine</td>
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<tr>
<td><strong>Precaution</strong></td>
</tr>
<tr>
<td>- Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])</td>
</tr>
<tr>
<td><strong>Post-vaccination observation periods</strong></td>
</tr>
<tr>
<td>- <strong>30 minutes:</strong> persons with a precaution to vaccination (i.e., history of an immediate allergic reaction of any severity to a vaccine or injectable therapy) and persons with a history of anaphylaxis due to any cause</td>
</tr>
<tr>
<td>- <strong>15 minutes:</strong> all other persons</td>
</tr>
<tr>
<td><strong>SARS-CoV-2 antibody testing</strong></td>
</tr>
<tr>
<td>- Antibody testing not recommended for vaccine decision-making or to assess immunity following vaccination</td>
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</tbody>
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*Any person who develops TTS after a Janssen primary dose should NOT get a Janssen booster.† Although CDC provides considerations for a mixed series in exceptional circumstances for a primary or additional dose ([https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Interchangeability](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Interchangeability)), this is still considered an administration error that requires VAERS reporting. Heterologous booster doses are allowed and are not considered a vaccine error.*