This past year, three COVID-19 vaccines produced by Pfizer-BioNTech, Moderna, and Janssen Biotech, Inc. were granted Emergency Use Authorization (EUA) by FDA. On Aug. 23, FDA fully licensed the Pfizer-BioNTech product, marketed as Comirnaty, for persons aged 16 years and older. A comparison of key details for each vaccine can be found below, which has evolved over time. This list is not exhaustive. For further details, please see the FDA documents for Pfizer-BioNTech, Moderna, and Janssen (J&J).

New Updates
On Sept. 22, 2021, following recommendations from the Vaccines and Related Biological Products Advisory Committee, FDA amended the emergency use authorization for the Comirnaty COVID-19 vaccine to allow for a single booster dose to be administered at least six months after completion of the primary series for specific populations. On Sept. 23, CDC endorsed the Advisory Committee on Immunization Practices’ (ACIP) recommendations for a booster shot of the Comirnaty COVID-19 vaccine for certain populations and recommended a booster dose for those in high-risk occupational and institutional settings.

Key Updates
Coadministration of Vaccine
Following an emergency ACIP meeting on May 12, 2021, CDC revised vaccine administration guidance indicating that COVID-19 vaccines can be co-administered with other vaccines without regard to timing. Coadministration information is summarized in CDC’s Interim Clinical Considerations guidance.

Variants
In December 2020, the B.1.617.2 variant, or Delta variant, was first identified in India, and quickly became the dominant variant in over 98 countries, including the United States. COVID-19 vaccines remain effective against the Delta variant. However, studies have shown that vaccine efficacy rates are lower against the Delta variant compared to the original strain.

In late July 2021, CDC published a report evaluating outbreaks of SARS-CoV-2 associated with large public gatherings in Barnstable County, Massachusetts and found 74% of reported COVID-19 cases were breakthrough infections – with 90% of infections caused by the Delta variant – that occurred in people who were fully vaccinated with two doses of Pfizer-BioNTech or Moderna, or one dose of the J&J vaccine. This information prompted CDC to recommend the use of masks in indoor public spaces, regardless of vaccination status, in areas where COVID-19 transmission is high.

In addition to the Delta variant, CDC and WHO continue to monitor other variants of interest, including the B.1.621 variant, or Mu variant. Pfizer is currently conducting Mu variant vaccine effectiveness studies.

Side Effects
Since April 2021, FDA has investigated uncommon but severe side effects associated with the COVID-19 vaccines. The mRNA vaccines (Pfizer-BioNTech and Moderna) were found to have a suggested increased risk of myocarditis and pericarditis. The J&J vaccine was found to have a suggested increased risk of thrombosis with
thrombocytopenia syndrome and Guillain-Barré Syndrome. All events were found to be uncommon, and the vaccines’ benefits continue to outweigh the risks found.

**Pregnant and Lactating People**

Preliminary data from FDA and CDC safety systems have not identified any safety concerns among pregnant or lactating people. Additionally, completed data from animal studies show no issues. Pregnant and lactating people should discuss the risks and benefits with their provider. Additionally, the American College of Obstetricians and Gynecologist, the Society for Maternal-Fetal Medicine, and CDC now recommend that all pregnant and lactating people should be vaccinated against COVID-19 in response to growing evidence of safe and effective use of COVID-19 vaccines during pregnancy and breastfeeding.

**Immunocompromised Individuals**

On Aug. 12, FDA authorized the use of an additional vaccine dose for mRNA vaccines’ Pfizer-BioNTech and Moderna for certain immunocompromised individuals. ACIP met on Aug. 13 to discuss further clinical recommendations for moderately to severely immunocompromised individuals. You can find more information on CDC’s recommendations for who should receive an additional dose on its website.

<table>
<thead>
<tr>
<th>Comirnaty (Pfizer-BioNTech) Vaccine</th>
<th>Moderna Vaccine</th>
<th>J&amp;J Vaccine</th>
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</table>
| **Target Population** | • Full BLA license approved for people aged 16 and older.  
• EUA authorized for people aged 12 and older.  
• **Update:** EUA authorized for single booster dose, which can be administered at least six months after completion of the primary series in certain populations:  
  o Individuals 65 years of age and older.  
  o Individuals 18-64 years of age at high risk of severe COVID-19.  
  o Individuals 18-64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications from COVID-19. | • EUA authorized for people aged 18 and older. | • EUA authorized for people aged 18 and older. |
| **Vaccine Efficacy** | • Clinical trial data demonstrated vaccine efficacy was 95.0% against symptomatic, laboratory- | • Clinical trial data demonstrated vaccine efficacy was 94.1% against symptomatic, | • Clinical trial data demonstrated vaccine efficacy was 66.3% at least 14 days after |
**Disclaimer:**
Vaccine effectiveness data is emerging. Much of this information is from clinical trials and may be outdated. CDC is currently conducting studies on vaccine effectiveness, which can be found [here](#).

<table>
<thead>
<tr>
<th>Vaccine Administration</th>
<th>Comirnaty (Pfizer-BioNTech) Vaccine</th>
<th>Moderna Vaccine</th>
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<tbody>
<tr>
<td><strong>Confirmed COVID-19</strong></td>
<td>confirmed COVID-19 in people ages 16 years and older without evidence of previous SARS-CoV-2 infection following receipt of two doses of Pfizer-BioNTech COVID-19 vaccine. In adolescents ages 12–15 years, efficacy was 100% in the clinical trial.</td>
<td>laboratory-confirmed COVID-19 following receipt of two doses of Moderna COVID-19 vaccine.</td>
<td>vaccination against symptomatic, laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection; 93.1% for the prevention of COVID-19-associated hospitalization; and 75% against all-cause death.</td>
</tr>
<tr>
<td><strong>Vaccine Administration Factsheet and Package Insert</strong></td>
<td>• Two shots are required, three weeks apart. Each dose contains 0.3mL of vaccine. • The vaccine must be diluted with saline before it is injected. • After dilution, one vial contains six doses. Vial labels and cartons may state that after dilution, a vial contains five doses. The information found in the updated EUA factsheet supersedes the number of doses.</td>
<td>• Two shots are required, one month apart. Each dose 0.5mL of vaccine. • The vaccine is ready to administer. • The vaccine is supplied in two multiple-dose vial presentations. A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each) and a multiple-dose vial containing a maximum of 15 doses: range 13-15</td>
<td>• One shot is required. Each dose contains 0.5 mL of vaccine. • The vaccine is ready to administer. No dilution required. • There are five doses per vial. Once punctured, vials can be stored in a refrigerator (36 °F to 46 °F) for up to six hours or up to two hours at room temperature (77 °F).</td>
</tr>
<tr>
<td><strong>Moderna Administration Factsheet</strong></td>
<td>• Two shots are required, one month apart. Each dose 0.5mL of vaccine. • The vaccine is ready to administer. • The vaccine is supplied in two multiple-dose vial presentations. A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each) and a multiple-dose vial containing a maximum of 15 doses: range 13-15</td>
<td>• Two shots are required, one month apart. Each dose 0.5mL of vaccine. • The vaccine is ready to administer. • The vaccine is supplied in two multiple-dose vial presentations. A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each) and a multiple-dose vial containing a maximum of 15 doses: range 13-15</td>
<td>• One shot is required. Each dose contains 0.5 mL of vaccine. • The vaccine is ready to administer. No dilution required. • There are five doses per vial. Once punctured, vials can be stored in a refrigerator (36 °F to 46 °F) for up to six hours or up to two hours at room temperature (77 °F).</td>
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| doses stated on vial labels and cartons. Undiluted vials can be stored in a refrigerator for up to one month (30 days). Once it is thawed, it must be used within two hours. Diluted vials can be stored between 35°F to 77°F for up to six hours.  
• Certain moderately to severely immunocompromised persons can receive an additional (or third) dose of the vaccine at least 28 days after the initial primary two-dose series of the same vaccine.  
• **Update:** A single booster dose of 0.3 mL can be given at least six months after completion of primary vaccination series. | doses (0.5 mL each). It can be stored in a refrigerator (36°F to 46°F) for 30 days and at room temperature (46°F to 77°F) for 24 hours. After the first dose has been withdrawn, the filter should be held at 36°F to 77°F and discarded within 12 hours)  
• Certain moderately to severely immunocompromised persons can receive an additional (or third) dose of the vaccine at least 28 days after the initial primary two-dose series of the same vaccine. |  |
| **Possible Side Effects**  
• The benefits of vaccine outweigh the risks; however, side effects have been reported. Common side effects include pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever.  
• Other side effects include severe allergic reactions, non-severe allergic reactions, myocarditis, pericarditis, injection site swelling, injection site redness, nausea, feeling unwell, swollen lymph nodes, diarrhea, vomiting, and arm pain.  
• **Update:** Reported side effects for the booster dose are similar to the |  
• The benefits of vaccine outweigh the risks; however, side effects have been reported. Common side effects include pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, swollen lymph nodes in the same arm as the injection, nausea and vomiting, and fever  
• **Side effects** that have been reported post authorization include severe allergic reactions, myocarditis, and pericarditis. |  
|  |  |  
• The benefits of vaccine outweigh the risks; however, side effects have been reported. Common side effects include pain at the injection site, headache, fatigue, muscle aches, and nausea.  
• Other side effects include severe allergic reactions, blood clots with low level of platelets, and Guillain Barre Syndrome. |  |  
|  |  |  |

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<td>primary series doses. However, mild to moderate lymphadenopathy was reported at a higher rate compared to the primary series doses.</td>
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**Safety for Pregnant/Lactating People**

- **Preliminary data** from FDA and CDC safety systems have not identified any safety concerns. Additionally, completed data from animal studies show no issues.
- **Pregnant/lactating** people should discuss the risks and benefits with their provider.

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