What Massachusetts COVID-19 Vaccine Providers Need to Know

Week of 9/15/21

Latest Numbers

- As of 9/15, 4,565,377 people in Massachusetts have been fully vaccinated.

Who to Vaccinate this Week

- Anyone age 12 and older who lives, works, or studies in Massachusetts is eligible for a vaccine. Health care providers can also vaccinate their patient panels regardless of place of residency.
- Effective 8/13/21, CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.

What to Know this Week

New Vaccines for Kids FDA Statement, 9/10/2021: FDA press statement from Dr. Woodcock and Dr. Marks: [FDA Will Follow The Science On COVID-19 Vaccines For Young Children](#).

On 8/30/2021 ACIP unanimously recommended use of the FDA approved Pfizer-BioNTech COVID-19 Vaccine, which will now be marketed as Comirnaty, for people aged 16 years and older.

- The Pfizer-BioNTech COVID-19 vaccine also remains recommended under an Emergency Use Authorization (EUA) as:
  - a 2-dose primary series for adolescents 12 through 15 years old; and
  - an additional (third) dose for people 12 years of age and older who are moderately to severely immunocompromised.
- This decision doesn’t affect how the Pfizer-BioNTech COVID-19 Vaccine is given, but it reinforces the safety and effectiveness of the vaccine shown in clinical studies and by the millions who have already received the vaccine.
- This decision does not affect CDC’s recommendations for using the Moderna and Johnson & Johnson’s Janssen COVID-19 vaccines for people 18 years and older.
- Comirnaty is in the identical formulation and presentation as the Pfizer-BioNTech COVID-19 Vaccine already authorized under the EUA. Therefore, clinicians may use currently available inventory as licensed or authorized. The updated FDA [Vaccine Information Fact Sheet for Recipients and Caregivers](#) should continue to be given to all approved age groups before vaccination. CDC is not releasing a Vaccine Information Statement (VIS) for Comirnaty at this time.
• We are in an interim phase, where Pfizer is available both by EUA and approval/licensure. Rather than the traditional Vaccine Information Statements (VIS), we now see an interim combined EUA/VIS.
  o For Recipients it is called: VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)
  o For Healthcare Providers it is called: FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) / EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

• Booster doses of COVID-19 vaccine for immunocompetent people who have completed a primary series:
  o Not yet authorized or recommended.
  o COVID-19 vaccines continue to maintain a high level of protection against severe disease, hospitalization, and death
  o ACIP will continue to evaluate the ability of booster doses to improve protection, the impact of variants on vaccine effectiveness, and available safety data.
  o ACIP anticipates reconvening in mid-September to consider additional data on safety and effectiveness of a booster dose for immunocompetent people in preparation for a future vote.
  o After FDA regulatory action on booster doses, ACIP will meet to make recommendations on the use of a booster dose, after thoroughly reviewing the evidence.
  o CDC has a new COVID-19 Vaccine Booster Shot webpage

New J&J/Janssen Vaccine: Available for Ordering. To best utilize this vaccine in the field, please order this product for use in populations in which it is most needed.

There are currently no allocations or order caps for this vaccine. Please be good stewards of this important public health resource and follow these guidelines for managing your inventory:
• Use what you currently have on hand, re-order only what you need based on your current administration data, use what you order, and reorder small quantities when you need more.

Reminder CDC released materials to help parents or other caregivers of people with intellectual and developmental disabilities (IDD) navigate important conversations about COVID-19. CDC’s COVID-19 Materials for People with Intellectual and Developmental Disabilities and Care Providers includes:
  • Posters to download, print, and hang in your health facility
  • Fact sheets in multiple languages
  • Web pages with answers to common questions
  • Social stories, videos, and interactive activities

Reminder CDC has launched the SmartFind COVID-19 Vaccine ChatBot, a new resource to quickly connect healthcare providers and others to clear, consistent, and credible information about COVID-19 vaccines. The automated ChatBot features include:
• Answers to common questions and answers about COVID-19 vaccines that are authorized and recommended, or undergoing large-scale (Phase 3) clinical trials in the United States
• 24-7 access to COVID-19 vaccine information on web-based devices, including mobile phones and tablets
• Links to additional resources, such as where to find a COVID-19 vaccination location
Remind on August 25, CDC updated the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States to include information on people vaccinated for COVID-19 as part of a clinical trial in the United States. Some people in the United States have completed a COVID-19 vaccination series as part of a U.S.-based clinical trial involving a vaccine that is not currently authorized by FDA. There is information regarding:

- People who received the full series of an active COVID-19 vaccine as part of a U.S.-based clinical trial that is not authorized by FDA but is listed for emergency use by WHO
- People who received the full series of an active COVID-19 vaccine candidate as part of a U.S.-based clinical trial that is neither authorized by FDA nor listed for emergency use by WHO
- Specific recommendations for people who received the AstraZeneca COVID-19 vaccine and the Novavax COVID-19 vaccine during a clinical trial

Reminder The Pfizer tray of 1170 ordering cadence has changed from a 1-day to a 3-day window once the order is approved and submitted to CDC. Supplemental dry ice will no longer be supplied by Pfizer or CDC. Sites are required to secure dry ice if the shipper is used to store the Pfizer vaccines.

- The Pfizer box of 450 is no longer available to order from the CDC.
- Order request less than 1170 will be fulfilled by transfer from another provider site.
  - Vaccines are transferred in the refrigerated temperature range.
  - Upon delivery, vaccines must be placed in the refrigerator for 30 days.

Reminder Updated Standing Orders, Prep & Admin Summaries, Prevaccination Screening Form, Fact Sheets

- Prevaccination Screening Form
- Pfizer Standing Orders
- Pfizer Prep and Admin Summary
- Moderna Standing Orders
- Moderna Prep and Admin Summary
- Pfizer EUA/Vaccine Information fact sheets for providers and recipients
- Moderna EUA fact sheets for providers and recipients

Reminder Adherence to MCVP Agreement: As a reminder, providers are responsible for adhering to all requirements outlined in the MCVP. Specifically, providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices, and FDA. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as “off-label use”) is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.
Resources & Learning Opportunities

Reminder COVID-19 vaccine flyers and EUA factsheets are available in 26 different languages.

Reminder CDC’s primary publication for disseminating the science it produces is the Morbidity and Mortality Weekly Report, better known as MMWR. The staff at MMWR have launched a new landing page to help people find the latest information on COVID-19 vaccine effectiveness and safety.

New CDC MMWRs

September 10, 2021 (Early Release)
- Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021
- Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1–August 6, 2021

September 10, 2021
- Long-Term Symptoms Among Adults Tested for SARS-CoV-2 — United States, January 2020–April 2021
- SARS-CoV-2 Transmission to Masked and Unmasked Close Contacts of University Students with COVID-19 — St. Louis, Missouri, January–May 2021

Reminder MDPH Immunization Division is pleased to present free accredited COVID-19 Vaccine content. These training sessions are designed for health care providers, vaccine coordinators, and all health care personnel who handle and/or administer COVID-19 vaccines.