MASSACHUSETTS COVID-19 VACCINE PROGRAM

COVID-19 Vaccine Guidance for Vaccine Providers

Updated June 17, 2021

This guidance provides information on:

- Becoming a COVID-19 vaccine provider
- Information about COVID-19 vaccine products
- Requesting vaccine and reporting to the Massachusetts Immunization Information System (MIIS)
- Storage and handling
- Clinical considerations
- Resources

This guidance is current as of the date above. Carefully review the weekly Massachusetts COVID-19 Program (MCVP) Bulletin for the most up-to-date information on priority groups currently eligible for COVID-19 vaccination, vaccine supply, process for requesting vaccine, and updated clinical considerations regarding COVID-19 vaccination.

The weekly Bulletin is emailed to the vaccine coordinators identified on the MCVP Provider Agreement, and are posted here. Confirm that the contact information in the MIIS for your site's primary and back-up coordinator is correct to ensure that your site receives all relevant communications regarding COVID vaccine ordering, storage and handling, administration, and reporting.

Your strong recommendation to get a COVID-19 vaccine is critical for vaccine acceptance (New 6/17/21)

- Patients consistently rank healthcare providers as their most trusted source of vaccine information.
- Make it clear to your patients that you recommend COVID-19 vaccination for them.
- Tell your patients how important COVID-19 vaccines are to protect their health, as well as the health of their family and friends.
- COVID-19 vaccines are new, and it's understandable that your patients may have questions. Your answers can help them make an informed decision about getting vaccinated.
- Make it clear that you understand they may have questions, and you want to answer them, so they feel confident in choosing to get vaccinated.
- How to talk to your patients about COVID-19 vaccination.

Becoming a COVID-19 vaccine provider (Updated 6/17/21)

All providers participating in the Massachusetts COVID-19 Vaccine Program (MCVP) are required to sign an MCVP Agreement to receive delivery of COVID-19 vaccine.

- Providers must be registered with the Massachusetts Immunization Information System (MIIS) and complete the onboarding process with the MIIS User Support Team to ensure that

immunization data are being sent to the MIIS registry. Contact the MIIS Unit for more information: miishelpdesk@mass.gov.

- Providers registered with the MIIS all received the MCVP Agreement. New sites that register with the MIIS will receive the Agreement automatically. If you have not received the Agreement, contact the DPH Vaccine Unit at DPH-Vaccine-Management@massmail.state.ma.us. The MCVP Agreement must be completed in order to receive vaccine.
- Download frequently asked questions about the MCVP Provider Agreement: Massachusetts COVID-19 Vaccine Program (MCVP) Agreement FAQ PDF | Doc, updated
- Request, sign, and electronically submit the MCVP Agreement Form. Contact the DPH Vaccine Unit for more information: dph-vaccine-management@massmail.state.ma.us.

Importance of trained healthcare professionals

Healthcare professionals are essential to ensuring the American population is vaccinated safely as soon as possible. You play a critical role in proper vaccine storage, handling, preparation, and administration, and they must be prepared to respond to vaccine recipients' questions and concerns. It is important that all healthcare professionals receive the training needed to effectively meet the demands of their roles. Training must be ongoing as new COVID-19 vaccines become available and as vaccine recommendations evolve. CDC COVID-19 Vaccination Training and Education can be found at: https://www.cdc.gov/vaccines/covid-19/training.html.

Emergency Use Authorization of COVID-19 vaccines

There are currently three COVID-19 vaccines that have received emergency use authorization (EUA) from the FDA and are recommended by the Advisory Committee on Immunization Practices (ACIP). The ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

- The FDA-issued EUA and Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The EUA fact sheets are updated regularly. Please check the website to make sure you are using the most up-to-date fact sheets.
- EUA fact sheets for vaccine recipients are available for each product in multiple languages. The EUA fact for vaccine recipients must be provided for to each recipient or their caregiver prior to administration of each dose.
- EUA fact sheets for both providers and vaccine recipients can be found at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Summary of information for each COVID-19 vaccine product

	Pfizer	Moderna	Janssen
Age group	≥ 12 y/o	≥ 18 y/o	≥ 18 y/o
Dose schedule	2 doses, 3 weeks apart	2 doses, 4 weeks apart	Single dose
Dose/route	0.3 mL/intramuscular	0.5 mL/ intramuscular	0.5 mL/ intramuscular
Reconstitution	Reconstitute with 1.8 mL of sterile Sodium Chloride Injection, USP. Use within 6 hours of dilution.	No	No
Standing orders	https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf
Storage/handling summary	https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf
Vaccine preparation and administration summary	https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Prep-and-Admin-Summary.pdf
Expiration date	On vials	Scan the QR code on the vial or carton or go to http://www.modernatx.com/covid19vaccine-eua	Scan QR code on outer carton or call 1-800-565-4008 or go to www.vaxcheck.jnj
Return shipping contain information	https://www.cvdvaccine-us.com/images/pdf/Return%20Instructions.pdf	Use the mailing label on the inside of a flap on the box.	Do not return shipping containers.
Website for more information	www.cvdvaccine.com	https://www.modernatx.com/covid19vaccine-eua/providers/	https://www.janssencovid19vaccine.com/

For all COVID-19 vaccines

- Both doses of a 2-dose schedule should be the same COVID-19 vaccine product.
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- Do not shake vials of COVID-19 vaccine.
- Monitor COVID-19 vaccine expiration and beyond use dates.
    - Rotate stock so that the oldest vaccine is used first
    - Use the Vaccine Expiration Date Tracking Tool
    - Use Beyond-use Date in Vial or Syringe for COVID-19 Vaccines
    - Arrange to transfer vaccine that you will not be able to use for before the expiration date. Use these resources to manage COVID vaccine transfers:
        - MDPH Redistribution Guidance for COVID-19 Vaccines
        - USP Transporting COVID-19 Vaccines Off-Site
        - MIIS Transferring Vaccine through MIIS Video
        - MIIS How to Use the Inventory Decrementing Tool Video
- Ancillary supplies, including syringes, needles, vaccination record cards, and personal protective equipment to support COVID-19 vaccinations, are supplied by the US Government. The ancillary kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities. For problems regarding the ancillary kits, contact McKesson Customer Service at 833-272-6634 or email SNSSupport@McKesson.com.

Special Considerations for Specific Vaccine Products (New 6/17/21)

- **Pfizer:** Maximizing Doses of Pfizer-BioNTech COVID-19 Vaccine – maximum 6-dose vial. Open the Pfizer-BioNTech guide | Watch the Pfizer-BioNTech video
- **Moderna:** Maximizing Doses of Moderna COVID-19 Vaccine - maximum 15-dose vial. Open the Moderna guide.
- **Janssen:** Thrombosis with thrombocytopenia syndrome (TTS), a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin, has been reported following administration of Janssen COVID-19 vaccine. See the CDC Interim Clinical Considerations for more information.
    - Women aged <50 years can receive any FDA-authorized COVID-19 vaccine. However, they should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines).
    - Persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.

Ordering COVID-19 vaccine (New 6/17/21)

Providers can order vaccine directly from the MIIS as needed, within certain limits. This direct ordering process will allow providers more flexibility in identifying their vaccine needs and in planning their order timing. Review the COVID-19 Vaccine Ordering Guidance for Providers.

Receipt of vaccine shipments

When a shipment arrives, open vaccine packages **immediately**, check the temperature monitor reading, inspect the vaccine boxes, compare the vaccine received with the vaccine products that show on the packing list, and store at the appropriate temperature. If you believe that a vaccine shipment has been compromised, temperature monitors are out-of-range, or a warm indicator is not activated, **contact the distributor/manufacturer immediately**. Contact information is included in the shipment boxes.

- Inspect ancillary kits for damage and check the package against the packing list. If the product is damaged or does not match the packing list, **contact McKesson immediately.**
- Calls about vaccine viability, damage, or packing slip discrepancies must reach McKesson (for Moderna and Janssen vaccine) or Pfizer (for Pfizer vaccine) the same day the shipment arrived at the office as documented by the carrier.
    - McKesson: 833-343-2703 or COVIDVaccineSupport@McKesson.com
    - Pfizer: 800-666-7248 or cvgovernment@pfizer.com

Storage and handling

- The CDC Vaccine Storage and Handling Toolkit has been updated to reflect specific information for COVID vaccine, including transport information.
- The USP COVID-19 Vaccine Handling Toolkit provides specific information on transporting vials and predrawn syringes.
- Use the COVID-19 Vaccine Management Standard Operating Procedure (SOP) Template to ensure the vaccine cold chain is maintained for optimum potency. All staff handling vaccines must read, sign, and adhere to the protocols described in this document.

Vaccine wastage

Providers should make every effort to reduce lost or expired COVID-19 vaccine. If vaccine is lost/expired, report the wastage in the Vaccines Module of the MIIS. Review the MIIS Storage/Handling Issue Mini Guide for instructions. Failure to properly report vaccine wastage causes inaccurate inventories leading to less vaccine being allocated to you in future orders.

Vaccine redistribution

It is critical to document all vaccine transfers in the MIIS; failure to do so will cause inaccurate inventories leading to less vaccine being allocated to you in future orders. You should only transfer COVID-19 vaccine to providers that have completed the MCVP agreement. Providers receiving COVID-19 vaccine should confirm what has been physically received is what has been transferred before completing the transfer. Please review:

- Transferring vaccine from one site to another 6-minute video instruction video

- How to Login and Navigate the MIIS
- How to Complete a Transfer Mini Guide
- Quick Start – Complete a Transfer

Transporting COVID-19 vaccines

CDC guidance on transport of mRNA COVID-19 vaccines allows for the transport of punctured vials, as long as the cold chain is maintained. Transporting vaccine in prefilled syringes is discouraged but, when necessary, may be done with strict adherence to the guidance in the USP COVID-19 Vaccine Handling Toolkit.

Clinical considerations for the administration of COVID-19 vaccines (Updated 6/17/21)

- **Use product-specific standing orders** (see table above) to administer COVID-19 vaccine.
- **Screen patients for vaccine contraindications and precautions** using the CDC COVID-19 Prevaccination Checklist. For information on contraindications and precautions, refer to the product-specific standing orders (see table above) and the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.
- **See** CDC Interim Clinical Considerations for Use of COVID-19 Vaccines for information on:
    - Administration of 2nd doses
    - Interchangeability of COVID-19 vaccine products
    - Vaccination of persons with SARS-CoV-19 infection or exposure
    - Vaccination of pregnant people and those with certain medical conditions
    - Patient counseling
    - Contraindications and Precautions
    - Vaccine administration errors and deviation
- **People vaccinated outside the United States**
    - COVID-19 vaccines not authorized by FDA but listed for emergency use by the World Health Organization (WHO)
        - People who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
        - People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by WHO may be offered a complete FDA-authorized COVID-19 vaccine series.
    - COVID-19 vaccines neither authorized by FDA nor listed for emergency use by WHO
        - People who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by WHO may be offered a complete FDA-authorized COVID-19 vaccine series.
- **COVID-19 vaccines and other vaccines may be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days. When deciding whether to co-administer another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease

(e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

- **COVID vaccination of children and adolescents**
    - Mass.gov: COVID vaccination of people younger than age 18, including consent form
    - CDC.gov: Covid vaccination of children and adolescents

Avoid vaccine administration errors (New 6/17/21)

Interim recommendations for COVID-19 vaccine administration errors differ from ACIP's general best practice guidelines. Review vaccine administration errors and deviations for COVID-19 vaccines to learn about the interim recommendation for each type of error. For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS) unless otherwise indicated in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

Routine observation periods following COVID-19 vaccination (Updated 6/17/21)

Use CDC COVID-19 Prevaccination Checklist to identify histories of allergic reactions. CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes:
    - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
    - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination).
    - History of anaphylaxis due to any cause
- 15 minutes: All other people

Note: Persons may be observed for longer, based on clinical concern. For example, if a person develops itching and swelling confined to the injection site during their post-vaccination observation period, this period may be extended to assess for development of any hypersensitivity signs or symptoms consistent with anaphylaxis.

Managing severe allergic reactions following COVID-19 vaccination (Updated 6/17/21)

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following vaccination with COVID-19 vaccines. See CDC: Interim considerations: preparing for the management of anaphylaxis after COVID-19 vaccination.

- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times. Vaccination sites should plan adequate staffing and supplies (including at least 3 doses of epinephrine) for the assessment and management of anaphylaxis.
- See Medical Management of Vaccine Reactions in Adults in a Community Setting and Medical Management of Vaccine Reactions in Children and Teens, which include standing orders for management of anaphylactic reactions in a community setting.
- Patients should be screened prior to receipt of each vaccine dose, and persons with a contraindication (including history of a severe or immediate reaction following the first dose of mRNA COVID-19 vaccine) should not be vaccinated.
- People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

Reporting adverse events and administration errors to the Vaccine Adverse Event Reporting System (VAERS)

Healthcare providers are **required** to report to VAERS (https://vaers.hhs.gov/) the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
    - Death;
    - A life-threatening AE;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

Adverse events should also be reported to the specific vaccine manufacturer following the instructions in the EUA fact sheets for providers.

V-safe After Vaccination Health Tracker

Providers should give all vaccine recipients information and encourage them to enroll in **v-safe**, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. Through **v-safe**, vaccine recipients report side effects to CDC and receive reminders about their second COVID-19 vaccine dose if they need one. For more information and fact sheets for vaccine recipients, go to https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

Report doses administered to the Massachusetts Immunization Information System (MIIS)

Provider sites must comply with the MIIS Reporting Order for COVID Vaccine to report vaccine administration data to the MIIS within **24 hours**. Doses administered information in the MIIS and the number of doses available to Massachusetts are used to determine your allocations. If report doses administered are not reported to the MIIS, it will appear that the provider has more inventory than they may actually have on hand. **This will reduce their next allocation.**

- Providers must comply with the reporting requirements as outlined in 105 CMR 222.1000(D) including demographic information.
- For providers without the capacity to automatically report doses administered via an electronic health record, the Clinic Roster functionality allows for easy reporting of a single lot number of vaccine that was administered by the same clinician to multiple patients, as in the case of a large vaccine clinic. This MIIS mini-guide describes how to create, search for, and submit a clinic roster to the MIIS.
- Answers to most questions about using the MIIS can be found at www.miisresourcecenter.com.

Use MIIS reports to monitor COVID-19 vaccination coverage in your practice (New 6/17/21)

- MIIS Coverage Reports allow providers to evaluate the immunization coverage for its practice. Check the "Include patient listing tables" box to ensure the output includes patient information. Use the Custom Coverage report to research COVID-19 coverage rates.
- MIIS Reminder/Recall Reports provide a list of patients that are due or overdue for a specific vaccine, based on criteria specified by the user. Reminders are created for patients that will soon be due for a particular immunization and Recalls are created for patients that are currently overdue for a particular immunization

Where to go when you have questions about COVID-19 vaccines (Updated 6/17/21)

General information about COVID-19 vaccine products for clinicians and healthcare professionals can be found on the COVID-19 Vaccination webpage.

Clinical information including FAQs, Contraindications and Precautions as well as Administration resources can be found for each vaccine on their own product webpage. Scrolling to the bottom of each vaccine specific webpage will bring you to a list of Storage and Handling Resources.

- Pfizer-BioNTech COVID-19 Vaccine
- Moderna COVID-19 Vaccine
- Janssen/J&J COVID-19 Vaccine

CDC is constantly adding information and developing new content on our websites. Content syndication ensures that your website content automatically reflects any changes that CDC makes.

Please contact CDC INFO with any questions you may have. You can call 800-CDC-INFO (800-232-4636).

See also Mass.gov Guidance for COVID-19 Vaccine Providers.

Save time by contacting the correct source to answer questions and resolve issues. Please check the following list when deciding whom to contact for assistance.

Important: Calls about vaccine viability, damage, or packing slip discrepancies must reach McKesson (for Moderna and Janssen vaccine) or Pfizer (for Pfizer vaccine) the same day the shipment arrived at the office as documented by the carrier.

- **Pfizer vaccine shipment has a problem:**
  - Pfizer Customer Service: 800-666-7248, Email: cvgovernment@pfizer.com
- **Moderna or Janssen vaccine shipment has a problem:**
  - Phone: 833 272-6635 Monday-Friday, 8 a.m.- 8 p.m. ET
  - Email (only send after hours): COVIDVaccineSupport@McKesson.com
- **Ancillary kit accompanying any vaccine product has a problem:**
  - McKesson Customer Service: 833-272-6634, Email: SNSSupport@McKesson.com

For temperature excursions that occur after shipment is received, contact the manufacturer

- **Moderna:** 1-866-663-3762 or email excursions@modernatx.com
- **Pfizer:** (800) 666-7248 or email cvgovernment@pfizer.com
- **Janssen:** 800-565-4008 (or) 908-455-9922, or email JSCCOVIDTEMPEXCURSION@its.jnj.com

For questions regarding general MCVP questions

- **Vaccine Unit** (dph-vaccine-management@massmail.state.ma.us)
  - Enrollment into MCVP
  - Vaccine storage and handling and transfer
  - Vaccine shipments, inventory, and number of doses allocated
  - Vaccine wastage/expiration
- **MIIS** (miishelpdesk@mass.gov) Due to the volume of inquiries, it is taking 2-3 business days for the Help Desk to respond. Answers to most questions can be found at the MIIS Resource Center.
  - MIIS registration/onboarding
  - How to log in to the MIIS and report vaccines to the MIIS
  - Running reports in the MIIS
  - Adding users/sites to the MIIS
- **COVID-19 email box** (COVID-19-Vaccine-Plan-MA@mass.gov)
  - Where and how to get vaccinated

For clinical questions regarding COVID-19 vaccine, contact CDC at https://www.cdc.gov/cdc-info or call 1-800-232-4636 or email using the CDC-Info web form.