MDHHS
Michigan Department of Health & Human Services

Recent Updates to CDC's Recommendations for COVID-19 Boosters

October 29, 2021

Housekeeping

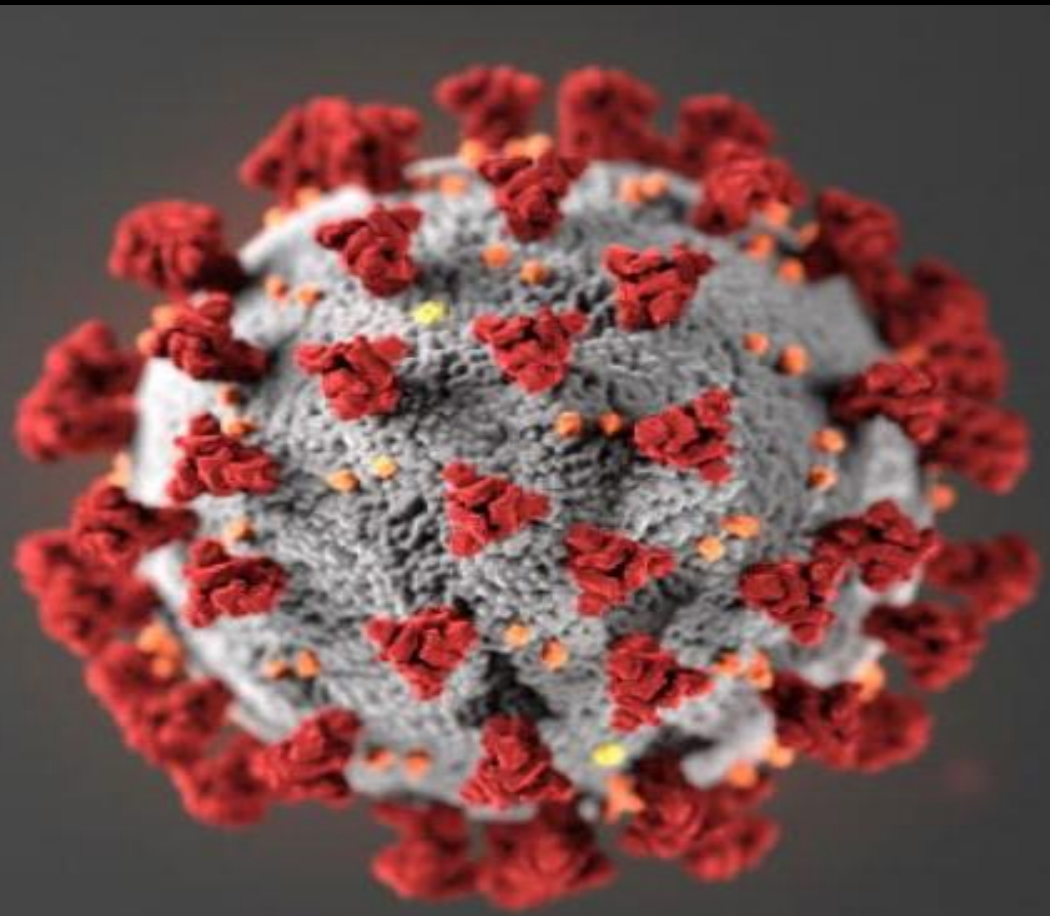
- **How to Ask Questions**
  - Click on the 

 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions
- **Slides & Recording**
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccineprovider

Topics Covered

- COVID-19 Vaccine Booster Dose Recommendations
- Moderately to Severely Immunocompromised People
- Clinical Consideration Updates
- EUA
- Fact Check
- Resources

COVID-19 Vaccine Booster Dose Recommendations



COVID-19 Vaccine Booster Dose in Persons who Completed an mRNA Primary Series

Persons who SHOULD receive a COVID-19 booster dose

- 65 years and older
- 18 years and older residing in long-term care setting
- 50 through 64 years with certain underlying medical conditions

Persons who MAY receive a COVID-19 booster dose, based on individual benefits and risks

- 18 through 49 years with certain underlying medical conditions (includes pregnant people)
- 18 through 64 years at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

- Booster dose administered at least 6 months after completion of mRNA primary series
- Any FDA-approved or authorized COVID-19 vaccine (Pfizer-BioNTech, Moderna, or Janssen) can be used for booster dose, regardless of vaccine received for primary series

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Individual Risk-Benefit Assessment for People who "May Receive" mRNA Booster Dose

- Individual risk factors for COVID-19 infection
  - Risk of exposure (occupational and institutional settings)
  - Risk for infection (time since completion of primary series)
- Potential impact of COVID-19 infection
  - Risk for severe infection (underlying conditions)
  - Risk associated with a person's circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)
- Potential benefits of booster
  - Reduced risk of infection, including severe infection
- Potential risks of booster
  - Common risks of transient local and systemic symptoms
  - Rare risks of serious adverse events

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

COVID-19 Vaccine Booster Dose in Persons who Received a Dose of Janssen Vaccine

- Persons aged 18 years and older who received primary vaccination with Janssen COVID-19 vaccine should receive a single COVID-19 vaccine booster dose at least 2 months later
- Any FDA-approved or authorized COVID-19 vaccine (Pfizer-BioNTech, Moderna, or Janssen) can be used as the booster dose, at an interval of at least 2 months since the primary Janssen vaccine dose

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Heterologous (mix-and-match) Booster Dose

- Heterologous dosing may be considered for the **booster dose only**
  - Primary series doses and additional dose should utilize the same vaccine product with limited exceptions
    - Additional dose only indicated for moderately to severely immunocompromised people who received 2 doses of mRNA vaccine
- Interval from the primary series should follow the interval recommended by the primary series
  - People who received a single dose Janssen primary series can receive a mRNA COVID-19 booster dose at least 2 months after completing primary series
- Individual risk-benefit assessment may inform which booster product to use
  - Availability of booster product
  - Risk profile of vaccine boosters, including rare events

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Potential Risks of COVID-19 Vaccine Booster Doses, Based on Rare Events Observed After Primary Vaccination

- Janssen:
  - Thrombosis with thrombocytopenia syndrome (TTS): highest risk in women aged 18-49 years
  - Guillain-Barré Syndrome (GBS): highest risk in men aged 50-64 years

- mRNA:
  - Myocarditis and pericarditis: highest risk in males aged 12-30 years

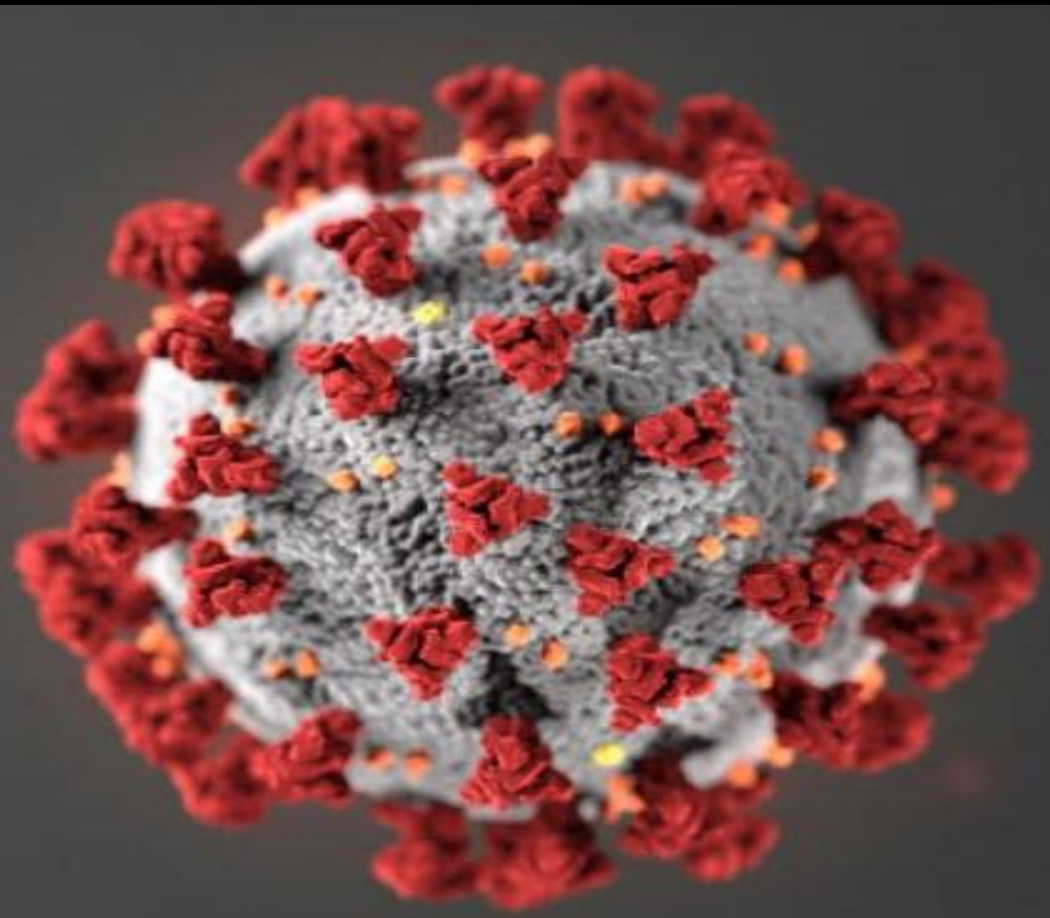
Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

FDA-Authorized or Approved COVID-19 Vaccines for Primary or Booster Vaccination

Vaccine	Primary series/dose				Booster dose	
	Dose (volume)	No. doses (interval)	Age (yrs)	Interval from primary to booster dose	Dose (volume)	Age (yrs)
Pfizer-BioNTech	30 µg (0.3 ml)	2 (21 days)	≥12	≥6 months	30 µg (0.3 ml)	≥18
Moderna	100 µg (0.5 ml)	2 (28 days)	≥18	≥6 months	**50 µg (0.25 ml)**	≥18
Janssen	5×10^{10} VP (0.5 ml)	1 (N/A)	≥18	≥2 months	5×10^{10} VP (0.5 ml)	≥18

- Any of the COVID-19 vaccines (Pfizer-BioNTech, Moderna, Janssen) can be used for booster vaccination, regardless of the vaccine product used for primary vaccination
  - When a heterologous (mix-and-match) booster dose is administered, the booster dose eligibility criteria and interval for receiving a booster dose are those of the vaccine used for primary vaccination

Moderately to Severely Immunocompromised People



Additional dose of mRNA COVID-19 Vaccine in Immunocompromised Persons

- Moderately-to-severely immunocompromised persons aged 12 years and older (PfizerBioNTech) or 18 years and older (Moderna) who completed an mRNA COVID-19 vaccine primary series should receive an additional mRNA vaccine dose at least 28 days after their second dose
- Recommendation does not apply to immunocompromised recipients of Janssen COVID-19 vaccine; these persons should follow the booster dose recommendations

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Recommendation for Moderately to Severely Immunocompromised People

- If received mRNA primary series
  - Administer mRNA **additional dose** at least 28 days after second dose
    - If received Moderna primary, Moderna additional dose is 0.5mL
  - Administer any COVID-19 vaccine **booster dose** 6 months or more after the additional dose (after third mRNA vaccine dose)
    - If Moderna booster dose is used, dose is 0.25mL
    - Pfizer-BioNTech dose is the same for primary series, additional and booster dose
- If received Janssen primary dose – Administer any COVID-19 vaccine booster dose at least 2 months after the initial Janssen dose
  - If Moderna booster dose is used, dose is 0.25mL

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Moderately to Severely Immunocompromised People

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

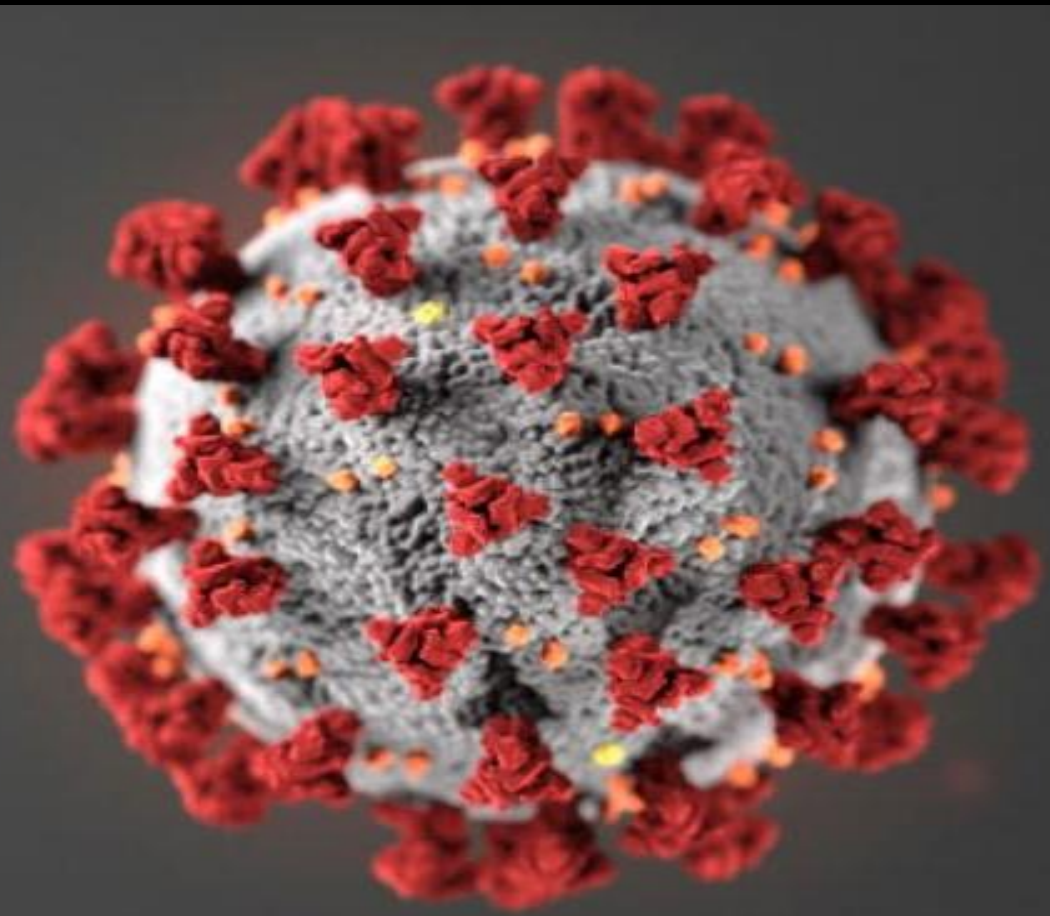
Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Key Clinical Considerations Regarding Booster Doses

- Indication for and timing of booster dose depends on which primary series was administered
- Booster product can be the same as or different than the primary series product
  - Any FDA-approved or authorized COVID-19 vaccine can be used for booster dose, regardless of vaccine received for primary series
- Moderna booster dose is half (0.25mL) of the primary series dose (0.5mL)
- Special considerations for moderately and severely immunocompromised people

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Updated CDC Interim Clinical Considerations



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

CDC now recommends that certain people are now eligible to receive a COVID-19 booster shot, including those who received Moderna and Johnson & Johnson/Janssen COVID-19 vaccines. Get more information and read CDC's media statement.

Reference Materials

- Summary Document for Interim Clinical Considerations
- Summary Document for Interim Clinical Considerations poster
- COVID-19 Vaccine Administration Errors and Deviations
- COVID-19 Vaccine Administration Errors and Deviations Poster
- Presentation: Clinical Care Consideration Slides for Healthcare Providers

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Summary of recent changes (last updated October 25, 2021):

- Updated guidance in section on Considerations for use of a COVID-19 booster dose
- New section added on Overview of COVID-19 vaccines recommendations
- Updated guidance in section on COVID-19 vaccine dosage and schedule
- Updated guidance in section on People vaccinated for prevention of COVID-19 outside the United States
- Updated guidance in section on COVID-19 vaccination and SARS-CoV-2 infection for People with prior or current SARS-CoV-2 infection; People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A); People who received passive antibody products; and Vaccinated people who subsequently develop COVID-19
- New guidance on Considerations for COVID-19 revaccination in the section on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people
- Updated Table in Appendix A: Vaccine administration errors and deviations

Key points

- COVID-19 vaccination is recommended for everyone aged 12 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- COVID-19 vaccines currently approved or authorized by FDA are effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.

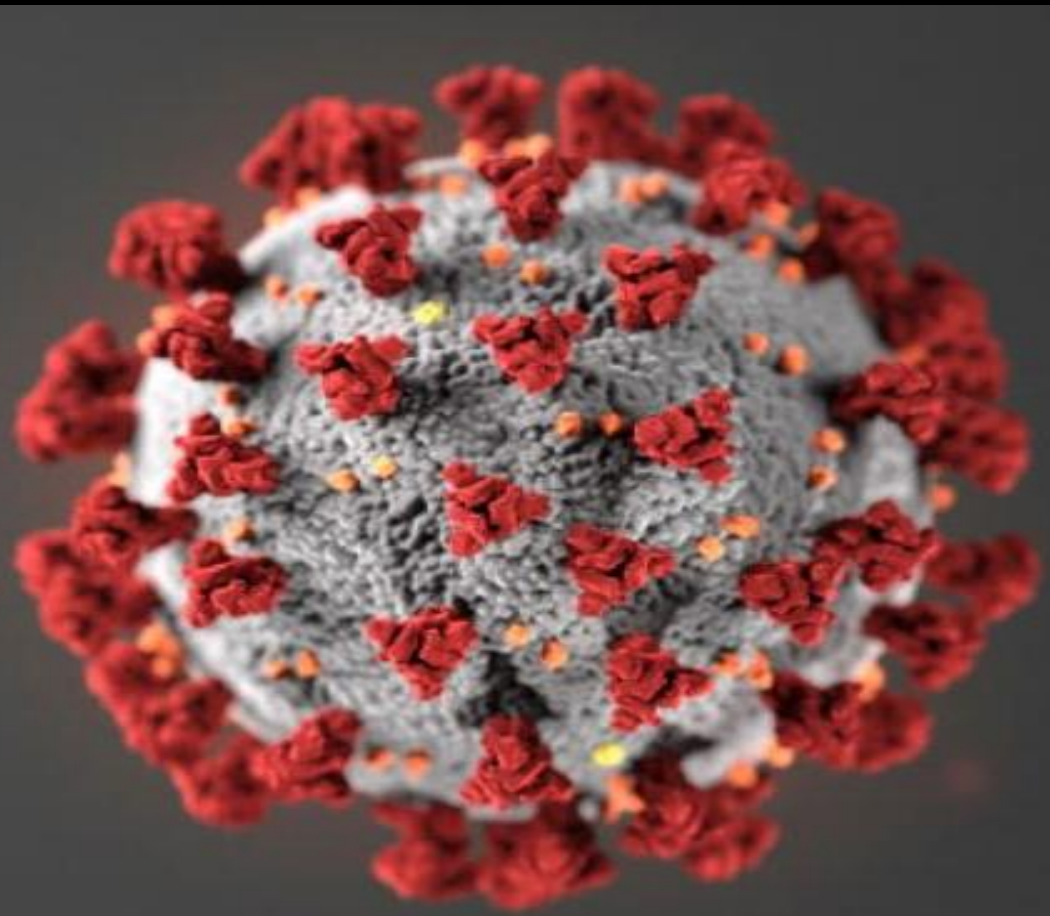
On This Page

- Purpose
- Overview of COVID-19 vaccine recommendations
- COVID-19 vaccine dosing and schedule
- Interchangeability of COVID-19 vaccine products
- People vaccinated for prevention of COVID-19 outside the United States
- People vaccinated for prevention of COVID-19 as part of a clinical trial in the United States
- Coadministration of COVID-19 vaccines with other vaccines
- COVID-19 vaccination and SARS-CoV-2 infection
- Antiviral therapy and COVID-19 vaccination
- Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks
- Vaccinating people receiving medical care unrelated to COVID-19
- Vaccinating people undergoing SARS-CoV-2 screening
- Considerations for vaccination of people with certain underlying medical conditions
- Considerations for use of the Janssen COVID-19 vaccine in certain populations
- Considerations involving pregnancy, lactation, and fertility
- Vaccination of children and adolescents
- Patient counseling
- Contraindications and precautions
- Reporting of vaccine adverse events
- Laboratory testing
- Appendix A. Vaccine administration errors and deviations
- Appendix B: Triage of people with a history of allergies or allergic reactions
- Appendix C: Ingredients included in COVID-19 vaccines
- Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Updated EUA’s



CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

- Upcoming Noontime Knowledge: October 1, 2021 at 12:00 p.m. EST

Education Corner

Enrollment

Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

- Pfizer
- Moderna
- Janssen (Johnson & Johnson)

EUA Fact Sheets

- EUA Fact Sheet for Healthcare Professionals - *UPDATED 10/20/21*
- EUA Fact Sheet for Recipients - *UPDATED 10/20/21*
  - Important: Print and provide the above EUA Fact Sheet to each COVID-19 vaccine recipient/caregiver in Michigan.
  - This version includes the information statement about the MCIR (as indicated in Michigan VISs). Per state law, patients/parents must be informed about MCIR.
  - Translations
    - Arabic Updated 6/25/21
    - Cherokee Updated 6/25/21
    - Chinese-Simplified Updated 9/22/21
    - Chinese-Traditional
    - Chuukese
    - French
    - German
    - Haitian-Creole
    - Hmong
    - Italian
    - Japanese
    - Korean - Updated 9/22/21
    - Marshallese
    - Polish
    - Somali
    - Spanish - Updated 9/22/21
    - Tagalog - Updated 9/22/21

ENGLISH

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)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide:

- **a two-dose primary series to individuals 12 years of age and older;**
- **a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2**
- **a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.**

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide:

- **a two-dose primary series to individuals 12 through 15 years;**
- **a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
  - **65 years of age and older**

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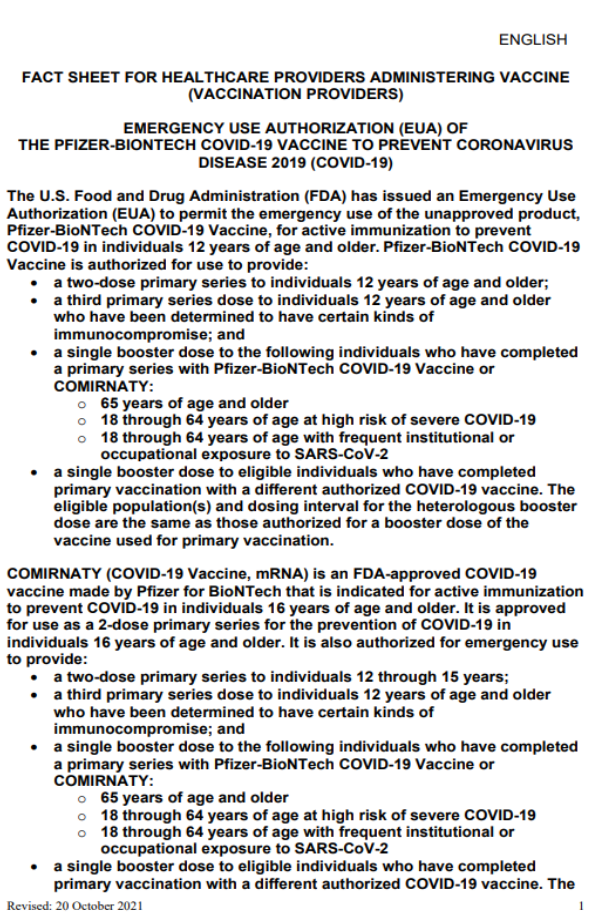
Updated EUA Fact Sheets

www.michigan.gov/covidvaccineprovider

All EUA Fact Sheets Updated October 20, 2021



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- **a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2**
- **a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.**

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- **a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
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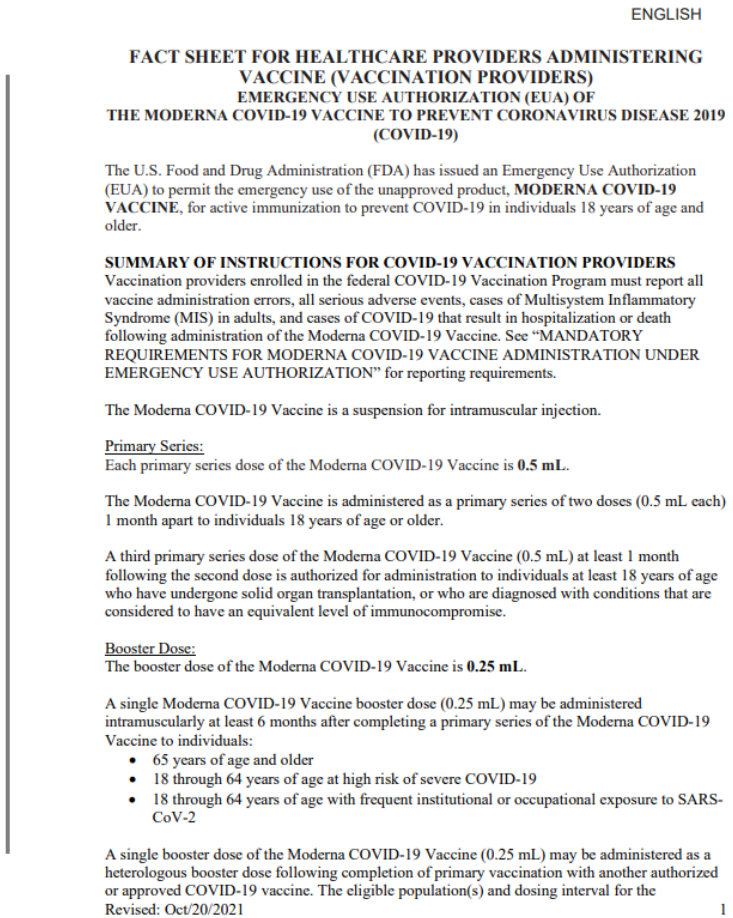
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2**
- **a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The**

Revised: 20 October 2021 1

Pfizer



ENGLISH

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection.

Primary Series:
Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:
The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

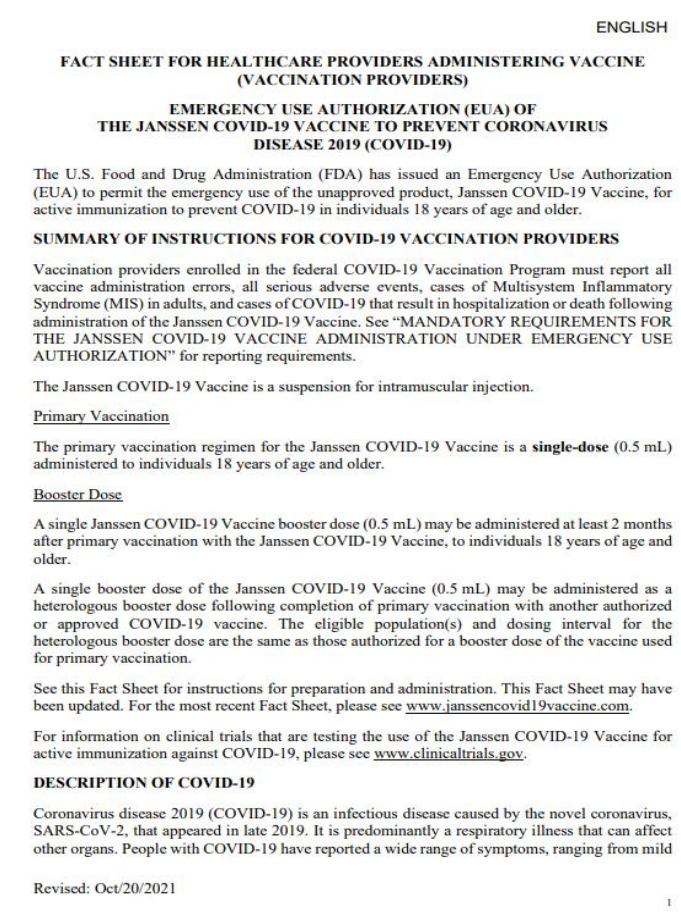
A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the

Revised: Oct/20/2021 1

Moderna



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The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection.

Primary Vaccination

The primary vaccination regimen for the Janssen COVID-19 Vaccine is a **single-dose** (0.5 mL) administered to individuals 18 years of age and older.

Booster Dose

A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older.

A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.janssencovid19vaccine.com.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

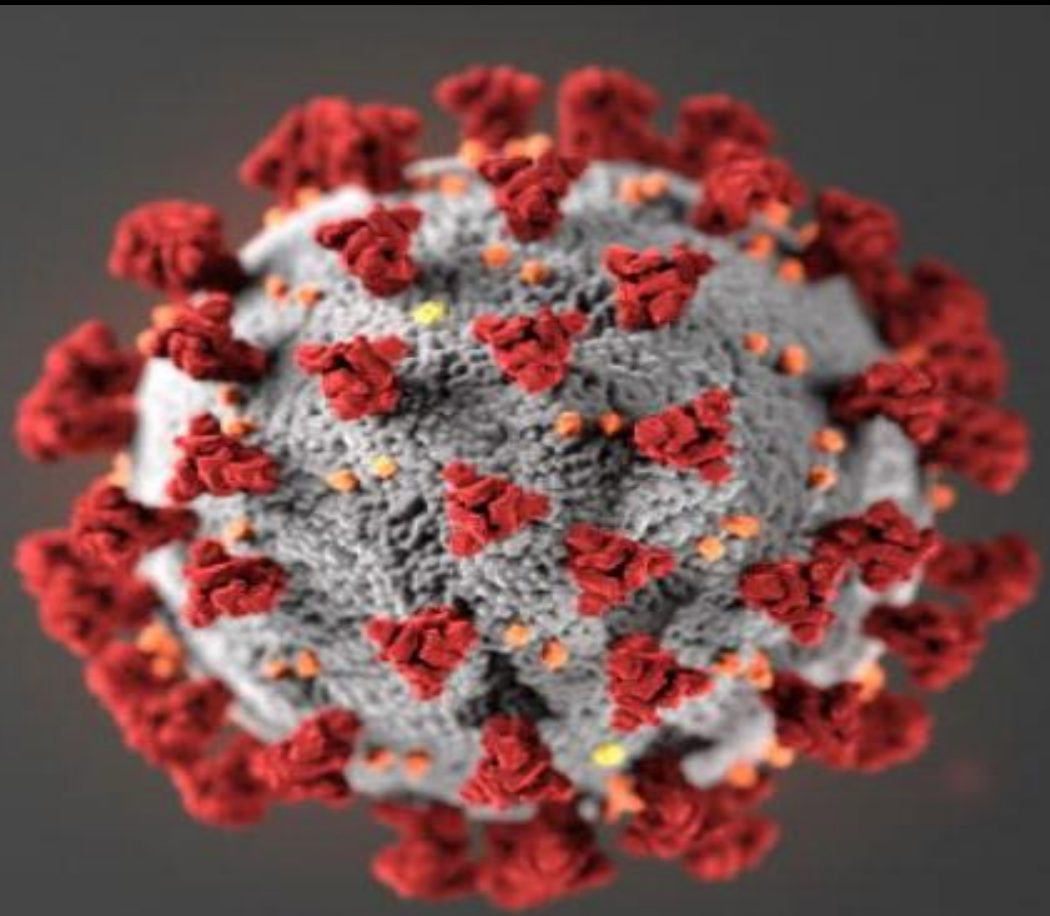
DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild

Revised: Oct/20/2021 1

Janssen (J & J)

Fact Check!



Should pregnant people get a COVID-19 booster dose?

- Pregnant and recently pregnant people (for at least 42 days following end of pregnancy) are more likely to get severely ill from COVID-19 compared with non-pregnant people
- CDC recommends that people aged 18-49 years with certain medical conditions, including pregnancy, **may** receive an mRNA COVID-19 booster dose based on their individual benefits and risks

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
People with Certain Medical Conditions | CDC

Is a moderately to severely immunocompromised patient who received a 3rd (additional) dose 28 days after their primary series, also recommended to receive a booster dose 6 months later?

- Moderately and severely immunocompromised people aged 18 years and older who completed an mRNA COVID-19 vaccine primary series and received an additional mRNA vaccine dose **may** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing their third mRNA vaccine dose (if Moderna vaccine booster is used, administer 0.25mL)
- In such situations, people who are moderately and severely immunocompromised may receive a total of four COVID-19 vaccine doses

Can my patient who received Janssen (J & J) receive a booster dose using Moderna and if yes, how much do I administer?

- People aged 18 years and older who received a single dose Janssen primary series **should** receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna or Janssen) at least 2 months (8 weeks) after completing their Janssen primary series
- Moderna Booster Dose: 0.25 mL. **This is half the amount used for the primary series and additional dose**

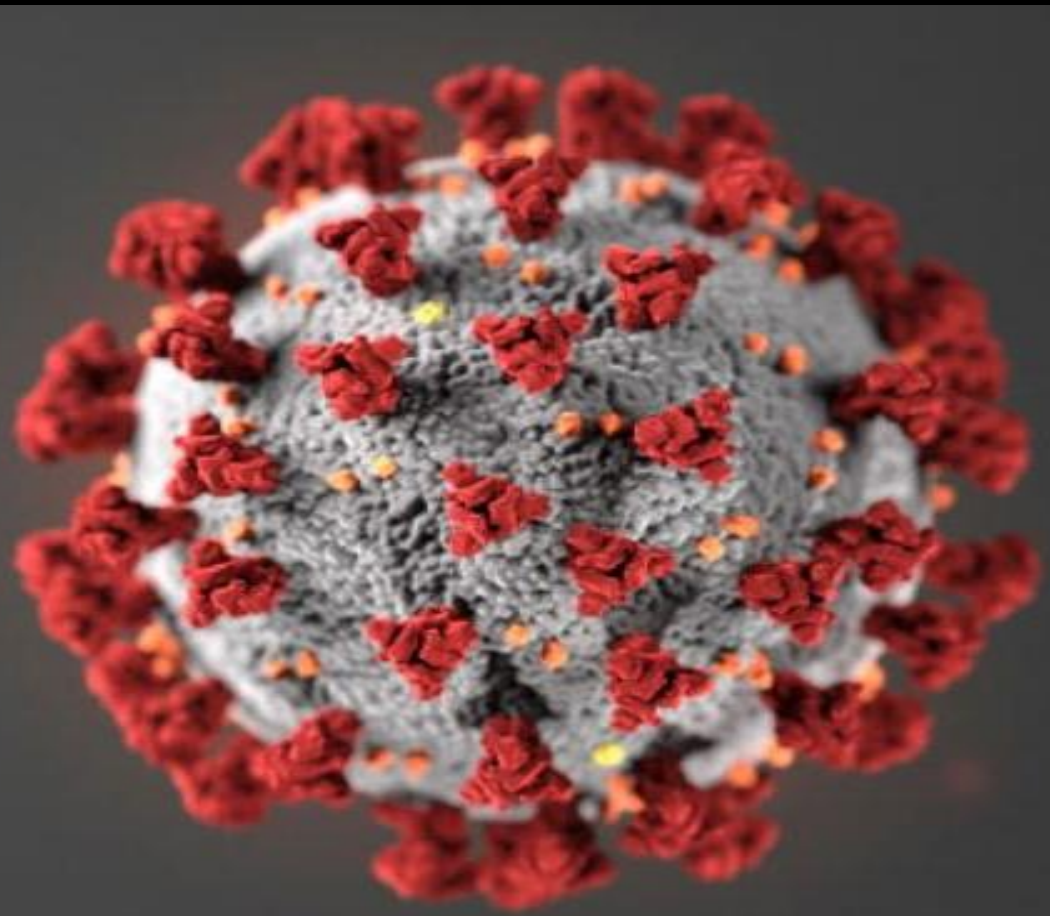
What are the risks to getting a booster dose?

- So far, reactions reported were similar to that of the primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the primary series, serious side effects are rare, but may occur
- Educate on what to expect after vaccination: Possible Side Effects After Getting a COVID-19 Vaccine | CDC
- Provide information and encourage enrollment in v-safe after COVID-19 vaccination
- Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:
    - Vaccine administration errors
    - Serious adverse events
    - Cases of Multisystem Inflammatory Syndrome
    - Cases of COVID-19 that result in hospitalization or death

Is an additional dose or booster dose needed to be considered fully vaccinated?

- A person is considered fully vaccinated against COVID-19 2 weeks or more after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or 2 weeks or more after receipt of the single dose of the Janssen vaccine
- Administration of an additional dose or a booster dose is not required to be considered fully vaccinated for public health purposes at this time

Resources



Coming Soon!

Dear Immunization Partners,

The Michigan Department of Health and Human Services (MDHHS), based on the CDC Interim Clinical Considerations, would like to provide clarification on the recommendations for COVID-19 vaccine booster doses and heterologous COVID-19 vaccine booster doses.

On October 25, 2021, the Centers for Disease Control and Prevention (CDC) released the updated *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*. For individuals who received a Pfizer-BioNTech or Moderna mRNA COVID-19 vaccine.

The following groups are eligible for a booster shot at 6 months or more after their initial series:

- 65 years and older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings
- People aged 18 years and older who received the Johnson & Johnson (J&J) COVID-19 vaccine primary series should also receive a single COVID-19 vaccine booster dose two or more months after their J&J primary dose.

There are now ***booster*** recommendations for all three available COVID-19 vaccines in the United States and a heterologous (mix and match) booster dose may be considered. Eligible individuals may choose which vaccine they receive as a ***booster*** dose. Some people may prefer the vaccine type that they originally received, and others may prefer to get a different vaccine product for their ***booster***.

Key points regarding mix and match booster dose:

- CDC's recommendations now allow for a mix and match dosing approach for booster doses. **Mixing and matching of COVID-19 vaccines only applies to the booster dose.**
- If a mix-match approach is used for the booster dose, the interval should follow the interval recommended for the primary series.

EXAMPLES:

For those that received an mRNA primary vaccination series and are now receiving J & J as a booster dose, you would follow an interval of 6 months or more.	For those that received J & J as their primary vaccination series and are now receiving an mRNA vaccine as a booster dose, you would follow an interval of 2 months or more since their initial dose.

- Any COVID-19 vaccine (Pfizer, Moderna, J&J) can be used for booster vaccination regardless of the vaccine product used for primary vaccination
- If the booster dose is given earlier than the recommended interval, the booster dose does **not** need to be repeated.

Vaccine Manufacturer	Booster Volume
Pfizer-BioNTech	0.3 mL
Moderna	0.25 mL * This is half the amount used for the primary series and additional dose.
Janssen	0.5 mL

DRAFT

...e a COVID-19 vaccine booster dose and will benefit from additional protection. It is also important to ensure that unvaccinated people take the first step and get an initial COVID-19 vaccine primary series. Encourage those still needing protection to get vaccinated.

Thank you for all your hard work to protect Michiganders from vaccine-preventable diseases!

The Immunization Nurse Education Team,
Andrea, Dianne, Heidi, Sarah, and Terri

Recommendations for Immunocompromised People

Primary series doses and additional doses should utilize the same product.

This additional (3rd) dose guidance only applies to those ... immunocompromised and received the initial 2-dose mRNA COVID-19 prim... series. (Pf...-BioNTech or Moderna).

- Immunocompromised individuals are ...led to ... additional (3rd) dose of an mRNA (Pfizer or Moder... vaccine 28 d... their 2nd dose in the 2-... prima... series.
- Immunocompromised individuals w... received their 2-dose mRNA primary series and the additional (3rd) mRNA vaccine are recommended to receive ANY COVID-19 vaccine booster (Pfizer, Moderna, J&J) dose 6 months or more after the additional (3rd) mRNA vaccine dose.
- Immunocompromised individuals who received J&J are not recommended for an additional (3rd) dose. They are recommended to receive a booster dose. Give any COVID-19 vaccine (Pfizer, Moderna, J&J) booster dose 2 or more months after the initial J&J dose.

DRAFT

Resources:

Clinical consideration for use of a COVID-19 vaccine booster dose.

Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A.

Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).

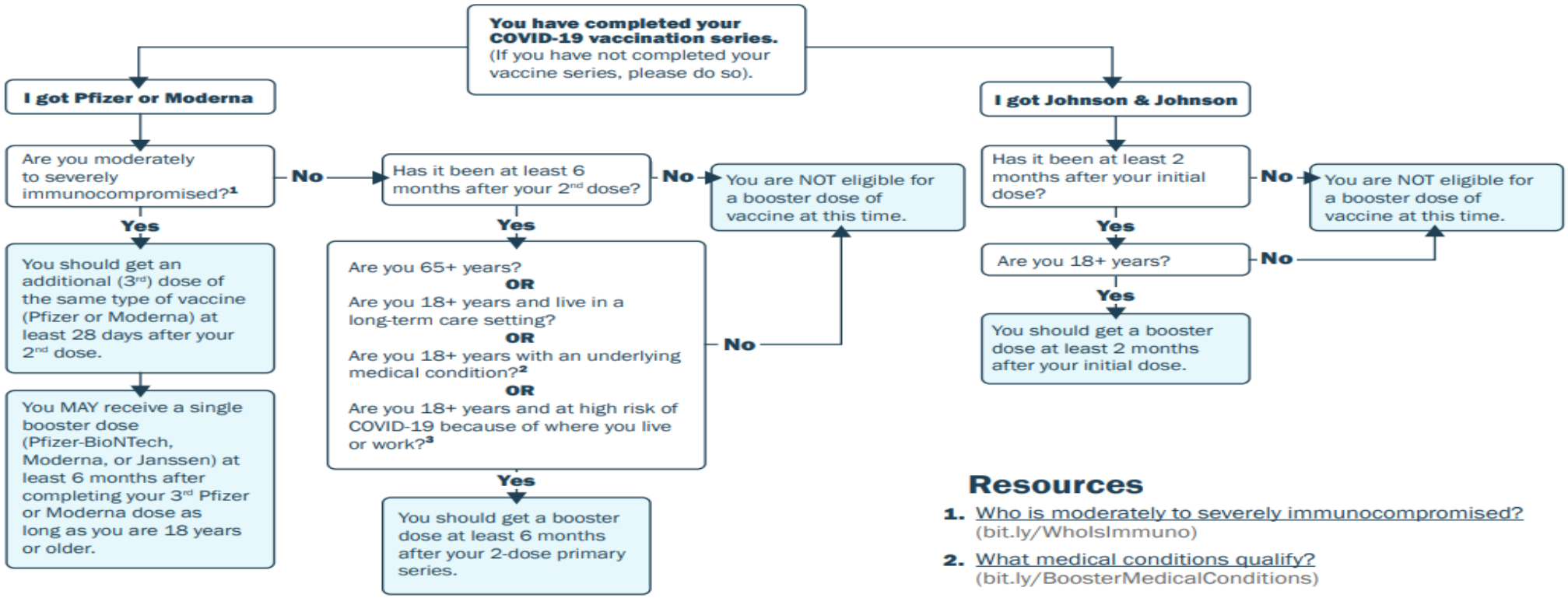
www.michigan.gov/covidvaccineprovider

Who is eligible for an extra dose of COVID-19 vaccine?

Reminder!

Bring a copy of your COVID-19 vaccination record card with you to your appointment.[4]

Some people may prefer a different vaccine type for their booster; mixing and matching is allowed.



MDHHS
Michigan Department of Health & Human Services

Learn More: Michigan.gov/COVIDvaccine
Find a Vaccine: VaccineFinder.org

Resources

1. Who is moderately to severely immunocompromised? (bit.ly/WhoIsImmuno)
2. What medical conditions qualify? (bit.ly/BoosterMedicalConditions)
3. Who is at high risk due to work or institutional setting? (bit.ly/EligibleForBooster)
4. Where can I download my immunization record? (Michigan.gov/MIIMMSportal)

10-27 3rd Dose Flowchart DRAFT v4 (michigan.gov)

Who is eligible for an extra dose of COVID-19 vaccine?

Remember to bring a copy of your COVID-19 vaccine record with you to your appointment.

Some people may prefer a different vaccine type for their booster; mixing and matching is allowed.

MDHHS
Michigan Department of Health & Human Services

If you are **immunocompromised** and have had your initial 2 doses of Pfizer or Moderna, get a 3rd dose at least **28 days** after dose 2.

You MAY receive a single booster dose (Pfizer-BioNTech, Moderna, or Janssen) at least 6 months after completing your 3rd Pfizer or Moderna dose as long as you are 18 years or older.

If your initial 2 doses were **Pfizer** or **Moderna**, you qualify for a booster dose at least **6 months** after dose 2 if:

- You are 65+ years.
- You are 18+ years and live in a long-term care setting.

OR

- You are 18+ years with an underlying medical condition.
- You are 18+ years and at high risk of COVID-19 because of where you live or work.

Talk to your doctor about your individual benefits and risks.

If your initial dose was **Johnson & Johnson** and you are 18+ years, you qualify for a booster dose at least **2 months** after your initial dose.

COVID_Extra_Dose_Infographic_v5_739226_7.png (1920×1080) (michigan.gov)

COVID-19 Vaccine Booster Shots

Updated Oct. 27, 2021 Languages Print

Some COVID–19 Vaccine Recipients Can Get Booster Shots

- People 65 years and older, 50–64 years with underlying medical conditions, or 18 years and older who live in long-term care settings should receive a booster shot.
- People 18 years and older should receive a booster shot at least 2 months after receiving their Johnson & Johnson/Janssen COVID-19 vaccine.

IF YOU RECEIVED
Pfizer-BioNTech or Moderna

You are eligible for a booster if you are:

- 65 years or older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

When to get a booster:
At least 6 months after your second shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States

IF YOU RECEIVED
Johnson & Johnson's Janssen

You are eligible for a booster if you are:
18 years or older

When to get a booster:
At least 2 months after your second shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

COVID-19 Vaccination

- Product Info by U.S. Vaccine
  - Pfizer-BioNTech Vaccine
  - Moderna Vaccine
  - Janssen/J&J Vaccine
  - EUA
  - FAQs for Healthcare Professionals
- Clinical Care
- Provider Requirements and Support
- Training and Education
- Vaccine Recipient Education
- Health Departments
- Planning & Partnerships
- Vaccine Effectiveness Rese

U.S. COVID-19 Vaccine Product Information

Español

Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.

Pfizer-BioNTech | Moderna | Janssen/J&J

Prevaccination Screening Form

Download a prevaccination checklist in multiple languages.

Arabic | English | French | Haitian Creole | Korean | Portuguese | Simplified Chinese | Spanish | Vietnamese

Requirements, Trainings, and Resources

Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage

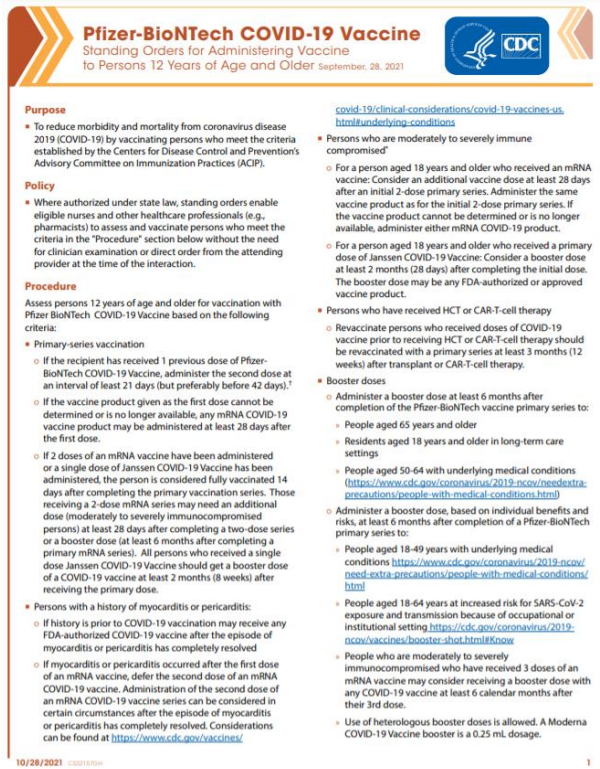
Vaccine Storage and Handling Toolkit

FAQs for Healthcare Professionals

COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

[Pfizer-BioNTech Standing Order]



Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine
to Persons 12 Years of Age and Older September, 28, 2021

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

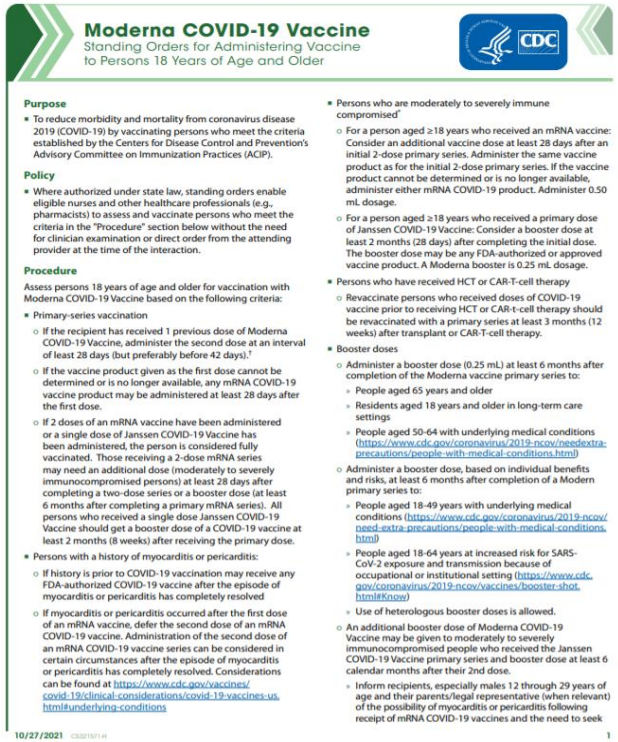
Procedure

Assess persons 12 years of age and older for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days (but preferably before 42 days).†
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
  - If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 14 days after completing the primary vaccination series. Those receiving a 2-dose mRNA series may need an additional dose (moderately to severely immunocompromised persons) at least 28 days after completing a two-dose series or a booster dose (at least 6 months after completing a primary mRNA series). All persons who received a single dose Janssen COVID-19 Vaccine should get a booster dose of a COVID-19 vaccine at least 2 months (8 weeks) after receiving the primary dose.
- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
- Persons who are moderately to severely immune compromised*
  - For a person aged 18 years and older who received an mRNA vaccine: Consider an additional vaccine dose at least 28 days after an initial 2-dose primary series. Administer the same vaccine product as for the initial 2-dose primary series. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product.
  - For a person aged 18 years and older who received a primary dose of Janssen COVID-19 Vaccine: Consider a booster dose at least 2 months (28 days) after completing the initial dose. The booster dose may be any FDA-authorized or approved vaccine product.
- Persons who have received HCT or CAR-T-cell therapy
  - Revaccinate persons who received doses of COVID-19 vaccine prior to receiving 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.
- Booster doses
  - Administer a booster dose at least 6 months after completion of the Pfizer-BioNTech vaccine primary series to:
    - People aged 65 years and older
    - Residents aged 18 years and older in long-term care settings
    - People aged 50-64 with underlying medical conditions (https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medical-conditions.html)
  - Administer a booster dose, based on individual benefits and risks, at least 6 months after completion of a Pfizer-BioNTech primary series to:
    - People aged 18-49 years with underlying medical conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions/html
    - People aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting https://cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#Know
    - People who are moderately to severely immunocompromised who have received 3 doses of an mRNA vaccine may consider receiving a booster dose with any COVID-19 vaccine at least 6 calendar months after their 3rd dose.
    - Use of heterologous booster doses is allowed. A Moderna COVID-19 Vaccine booster is a 0.25 mL dosage.

10/28/2021

[Moderna Standing Orders]



Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, administer the second dose at an interval of least 28 days (but preferably before 42 days).†
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
  - If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated. Those receiving a 2-dose mRNA series may need an additional dose (moderately to severely immunocompromised persons) at least 28 days after completing a two-dose series or a booster dose (at least 6 months after completing a primary mRNA series). All persons who received a single dose Janssen COVID-19 Vaccine should get a booster dose of a COVID-19 vaccine at least 2 months (8 weeks) after receiving the primary dose.
- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
- Persons who are moderately to severely immune compromised*
  - For a person aged ≥18 years who received an mRNA vaccine: Consider an additional vaccine dose at least 28 days after an initial 2-dose primary series. Administer the same vaccine product as for the initial 2-dose primary series. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product. Administer 0.50 mL dosage.
  - For a person aged ≥18 years who received a primary dose of Janssen COVID-19 Vaccine: Consider a booster dose at least 2 months (28 days) after completing the initial dose. The booster dose may be any FDA-authorized or approved vaccine product. A Moderna booster is 0.25 mL dosage.
- Persons who have received HCT or CAR-T-cell therapy
  - Revaccinate persons who received doses of COVID-19 vaccine prior to receiving 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.
- Booster doses
  - Administer a booster dose (0.25 mL) at least 6 months after completion of the Moderna vaccine primary series to:
    - People aged 65 years and older
    - Residents aged 18 years and older in long-term care settings
    - People aged 50-64 with underlying medical conditions (https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medical-conditions.html)
  - Administer a booster dose, based on individual benefits and risks, at least 6 months after completion of a Modern primary series to:
    - People aged 18-49 years with underlying medical conditions (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html)
    - People aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#Know)
    - Use of heterologous booster doses is allowed.
  - An additional booster dose of Moderna COVID-19 Vaccine may be given to moderately to severely immunocompromised people who received the Janssen COVID-19 Vaccine primary series and booster dose at least 6 calendar months after their 2nd dose.
    - Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek

10/27/2021

[Janssen Standing Orders]

Janssen COVID-19 Vaccine (Johnson & Johnson)
Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- If the recipient has received 1 dose of a Janssen COVID-19 Vaccine, no additional primary-series doses are needed. A booster dose is recommended 2 months (8 weeks) after the primary dose; any FDA-authorized or approved COVID-19 vaccine may be given.
- If the recipient has received 1 dose of an mRNA vaccine, the same brand should be administered for the second dose of the primary series.
- In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine, (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. See footnote for further information on administering Janssen COVID-19 Vaccine to persons with a contraindication to mRNA COVID-19 vaccines. §
- A person is considered fully vaccinated ≥ 14 days after a single dose of Janssen COVID-19 Vaccine has been administered or after completing a 2-dose series of an mRNA vaccine. All persons who received a single dose Janssen COVID-19 Vaccine should get a booster dose of a COVID-19 vaccine at least 2 months (8 weeks) after receiving the primary dose. Those vaccinated with a 2-dose mRNA vaccine series should receive a 3rd dose if moderately to severely immunocompromised at least 28 days after completing a two-dose series. A booster dose (at least 6 months after completing a primary mRNA series or after an additional dose) is recommended for different age and risk groups. See CDC clinical considerations for more information (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html).
- Thrombocytopenia syndrome (TTS) and thrombocytopenia:
  - Inform women aged 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group after Janssen COVID-19 vaccination and about the availability of other authorized vaccines (i.e., mRNA vaccines).
  - Offer another FDA-authorized or approved vaccine (i.e., mRNA vaccine) to persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized or approved COVID-19 vaccine.

NOTE: Persons at risk or with a history of other thrombosis not associated with thrombocytopenia can receive an FDA-authorized or approved vaccine

- People with a history of Guillain-Barré Syndrome (GBS):
  - Can receive any FDA-authorized or approved COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, discuss with these patients the availability of mRNA COVID-19 vaccines that offer protection against COVID-19.

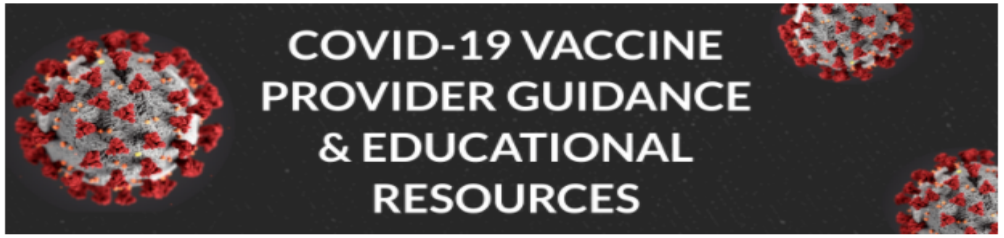
Booster doses:
- Administer a booster (2nd) dose at least 2 months (8 weeks) after completion of the Janssen COVID-19 Vaccine primary dose to:
  - All persons who received the Janssen COVID-19 Vaccine
  - Use of heterologous booster doses is allowed. A Moderna COVID-19 Vaccine booster is a 0.25 mL dosage.
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Janssen COVID-19 Vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.*
- Defer vaccination with Janssen COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

10/27/2021

Updated Resources

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

COVID-19 Vaccine Provider Guidance and Educational Resources



This webpage will house materials to support COVID-19 Vaccine Providers in successful implementation of the COVID-19 Vaccination Program. Be sure to "bookmark" this page and check back frequently for updates!

GENERAL COVID-19 VACCINE RESOURCES

Clinical Guidance for Michigan Providers Regarding Additional Dose of an mRNA COVID-19 Vaccine

Increasing Access to Vaccine Opportunities: Recommendations for Health Care Providers - *Updated 6/18/21*

COVID-19 Vaccines During Hospital Stays and Medical Appointments - *Updated 6/14/21*

COVID-19 Vaccination Clinic Preparation Checklist & Resource Toolkit - *Updated 5/28/21*

ACIP Recommendations for COVID-19 Vaccine

Interim Clinical Considerations for COVID-19 Vaccine

CDC COVID-19 Vaccine Resources for Healthcare Professionals

- Vaccine administration, storage and handing, reporting, and patient education for each specific vaccine

COVID-19 Vaccine Training Module

- Self-paced module with certificate of completion (no CE)
- **MDHHS strongly recommends that all COVID-19 Vaccine Providers complete this training.**

CDC HCP Vaccine Administration Resource Library

CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

- **Upcoming Noontime Knowledge: October 1, 2021 at 12:00 p.m. EST**

Education Corner

Enrollment

Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

ACIP Meeting Webpage

- Meeting Agendas
- Meeting Minutes
- Live Meetings
- Presentation Slides

Next ACIP Meeting

November 2-3, 2021 from 10am-5pm Eastern

This meeting is virtual. No registration is required to watch the webcasts.

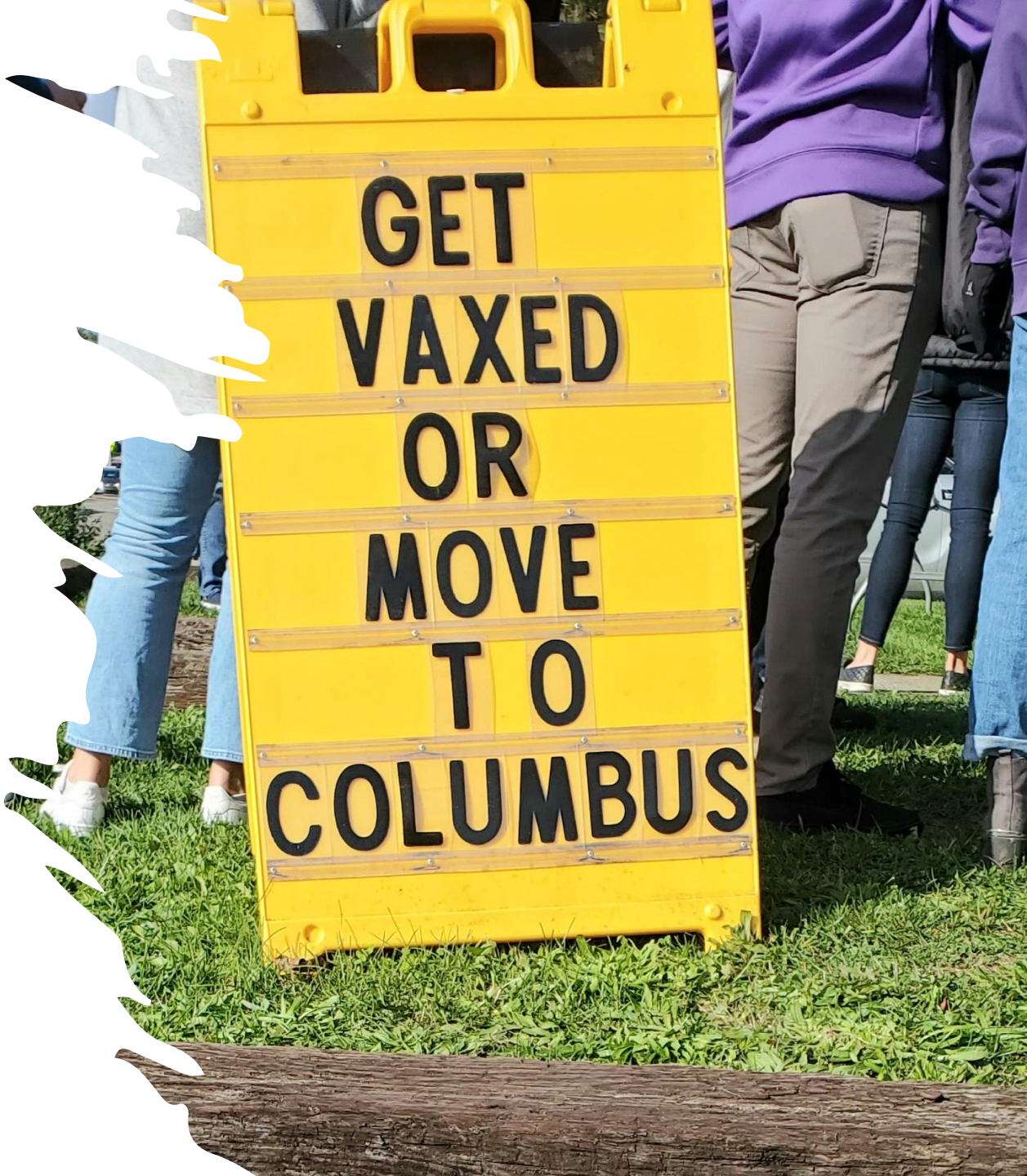
Draft Agenda – November 2-3, 2021

Webcast Link

Federal Register

https://www.cdc.gov/vaccines/acip/meetings/index.html

Regardless if you say “GO BLUE” or “GO GREEN” we all can agree on this….

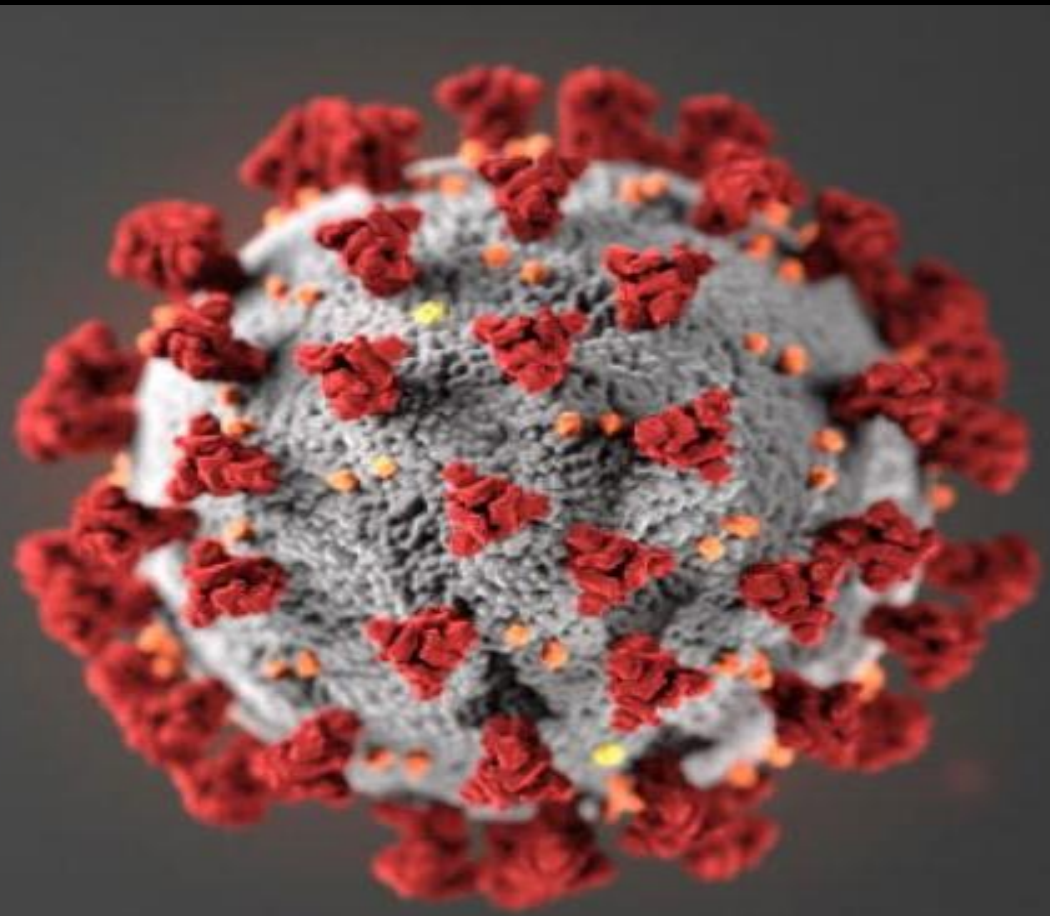


Thank You!

Next “Noontime Knowledge” Update: TBD

Please watch your email for a date, link, and topic!

Questions Email: checcimms@michigan.gov



www.michigan.gov/COVIDvaccineprovider