### Pfizer BioNTech COVID-19 Booster Dose Recommendations for 16- and 17-Year Old's and Guidance on Pfizer's New Gray Cap Product

December 16, 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: <a href="https://www.michigan.gov/COVIDvaccineprovider">www.michigan.gov/COVIDvaccineprovider</a>

### **Topics Covered**

- Hot off the Press
- Booster Recommendations for 16- and 17-year-olds
- Booster dose recap
- Updated EUA Fact Sheets
- Updated Interim Clinical Considerations
- Pfizer BioNTech COVID-19 Gray Cap Product
- Fact Check
- Resources

### Hot Off the Press

- December 14, 2021-FDA granted an amendment to the Janssen COVID-19 Vaccine EUA Fact Sheets
- Changes to the EUA Fact Sheet for **Healthcare Providers Administering Vaccine** include:
  - Adding a History of Thrombosis with Thrombocytopenia (TTS) following Janssen COVID-19 vaccine
    or any other adenovirus vector vaccine as a contraindication to receipt of Janssen COVID-19 vaccine
  - Adding additional information about TTS to the "Warnings and Precautions" and "Overall Safety" section
- Changes to the EUA Fact Sheet for Recipients and Caregivers include:
  - Revised section on "Who Should Not Get the Janssen COVID-19 Vaccine"
  - Adding blood clots with low level of platelets under the section "What are the Risks of the Janssen COVID-19 Vaccine"

### **Emergency ACIP Meeting Today!**

### Draft - December 15, 2021 MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention Atlanta, Georgia 30329 December 16, 2021

### Thursday, December 16, 2021

12:00 Welcome & Introductions

12:15 Coronavirus Disease 2019 (COVID-19) Vaccines

Introduction

Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)

VaST summary

Updates to the benefit/risk assessment for Janssen COVID-19 vaccines:

Applying the Evidence to Recommendation Framework

Discussion

Adjourn

2:10 Public Comment 2:30 VOTE

2:00

Janssen COVID-19 Vaccine: Updated recommendations for use

Break

Break

COVID-19 vaccine safety surveillance in children 5-11 years of age

Dr. Grace Lee (ACIP Chair)
Dr. Melinda Wharton (ACIP

\*

Dr. Matthew Daley (ACIP, W Dr. Isaac See (CDC/NCEZID) Dr. Keipp Talbot (VaST Chair

Dr. Sara Oliver (CDC/NCIRD

Dr. Sara Oliver (CDC/NCIRD

Dr. John Su (CDC/NCEZID)

**Next ACIP Meeting** 

December 16, 2021, 12:00pm - 4:00pm Eastern

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

Agenda – December 16, 2021 🖪 [1 page]

<u>Webcast Link</u> ☑

Federal Register 🗹

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

**Meeting Agenda** 



### **COVID-19 Vaccine Booster Dose Updates**

- CDC Press Release: Expanding booster doses to everyone (11/19/2021)
- CDC Press Release: Strengthening booster recommendations for 18+ (11-29-21)
- FDA Press Release: Authorizing booster doses for 16- and 17-Year-olds (12-9-21)
- CDC Press Release: Expanding booster recommendations to 16- and 17-year-olds (12-9-21)
- MDHHS Press Release: Pfizer booster doses authorized for ages 16 and 17 (12-10-21)

### **Booster Dose Recommendation**

- All persons aged 18 years and older should receive a booster dose of COVID-19 vaccine, even if they were younger than 18 years of age at the time of their primary series
  - Any COVID-19 vaccine (Pfizer, Moderna, Janssen) can be used for this age group
- Persons who are 16 or 17 years old may receive a booster dose based on individual risks and benefits
  - Only the Pfizer COVID-19 vaccine may be administered for this age group



### Received a Primary Series of Pfizer COVID-19 Vaccine

- Persons 18 years and older should receive a booster dose at least 6 months after completing their primary vaccine series
  - Any COVID-19 vaccine (Pfizer, Moderna, Janssen) can be used
  - Persons who are moderately to severely immunocompromised should receive a booster dose at least 6 months after their additional (3<sup>rd</sup>) dose
- Persons 16 and 17 years of age may receive a booster dose based on individual benefit and risk at least 6 months after completing their primary vaccine series
  - Only the Pfizer vaccine can be used for this dose
  - Persons 16 and 17 years of age who are moderately to severely immunocompromised may receive a booster dose at least 6 months after their additional (3<sup>rd</sup>) dose

### Received a Primary Series of Moderna COVID-19 Vaccine

- Persons 18 years and older should receive a booster dose at least 6 months after completing their primary vaccine series
  - Any COVID-19 vaccine (Pfizer, Moderna, Janssen) can be used
  - Persons who are moderately to severely immunocompromised should receive a booster dose at least 6 months after their additional (3<sup>rd</sup>) dose

### Received a Primary Dose of Janssen COVID-19 Vaccine

- Persons 18 years and older should receive a booster dose at least 2 months after completing their single primary dose
  - Any COVID-19 vaccine (Pfizer, Moderna, Janssen) can be used
  - This booster recommendation includes those who are moderately to severely immunocompromised (remember persons who received Janssen as their primary dose do not receive an additional primary dose, only a booster)



Everyone <u>16</u> years or older is now eligible for a COVID-19 booster!

Immunity decreases naturally over time and cold weather makes viruses even easier to spread. As we gather with friends and family over the holidays, a booster can help keep us protected.

If you got your initial doses of **Pfizer** or **Moderna** at least **6 months ago**, you are now eligible for another dose.

If you got your initial dose of **Johnson & Johnson** at least **2 months ago**, you are eligible for another dose.

Some people may prefer a different vaccine type for their booster; mixing and matching is allowed as long as you are 18+.



For help finding a vaccination site, visit Michigan.gov/COVIDVaccine or call 2-1-1.

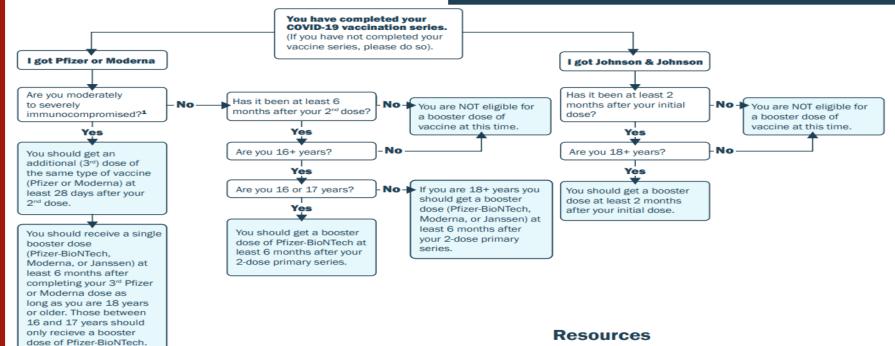
COVID\_Extra\_Dose\_Infographic\_v5\_739226\_7.png (1920×1080) (michigan.gov)

### 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.  $^{\mathbf{2}}$ 

Some people may prefer a different vaccine type for their booster; mixing and matching is allowed as long as you are 18+. If you are 16 or 17 years, the only vaccine you should recieve for your booster is the Pfizer vaccine.



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

**M** DHHS

 Who is moderately to severely immunocompromised? (bit.ly/WholsImmuno)

2. Where can I download my immunization record?

12-10 3rd Dose Flowchart v2 (michigan.gov)



### Pfizer EUA Fact Sheet Information

**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)

> FOR 12 YEARS OF AGE AND OLDER DILUTE BEFORE USE

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 5 years of age and older.

There are 2 formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older:

The formulation supplied in a multiple dose vial with a purple cap MUST BE DILUTED PRIOR TO USE.

The formulation supplied in a multiple dose vial with a gray cap and label with a gray border IS NOT DILUTED PRIOR TO USE.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a purple cap, which is authorized for use in individuals 12 years of age and older and MUST BE DILUTED PRIOR TO USE.

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a purple cap is authorized for use to provide:

- a 2-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;
- a single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine

Healthcare Providers for 12 years of age and older, purple cap (must dilute)

(michigan.gov)

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)

> FOR 12 YEARS OF AGE AND OLDER DO NOT DILUTE

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 5 years of age and older.

There are 2 formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older:

The formulation supplied in a multiple dose vial with a gray cap and label with a gray border IS NOT DILUTED PRIOR TO USE.

The formulation supplied in a multiple dose vial with a purple cap MUST BE DILUTED PRIOR TO USE.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border which is authorized for use in individuals 12 years of age and older and MUST NOT BE DILUTED PRIOR TO USE.

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border is authorized for use to provide:

- . a 2-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:
- a single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY: and
- a single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized

Healthcare Providers for 12 years of age and older, gray cap (no dilution)

(michigan.gov)

**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)

FOR 5 THROUGH 11 YEARS OF AGE DILUTE BEFORE USE

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 5 years of age and older.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border and which is authorized for use to provide a 2-dose primary series to individuals 5 through 11 years of age. The vial labels state: Age 5y to <12y. The carton labels state: For age 5 years to <12 years.

Pfizer-BioNTech COVID-19 Vaccine which is supplied in a multiple dose vial with an orange cap and a label with an orange border, should not be used in individuals 12 years of age and older.<sup>1</sup>

### 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 children, and cases of COVID-19 that result in hospitalization or death following administration of Pitzer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION For reporting requirements.

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

The Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with an orange cap and a label with an orange border, is administered, after

Notwithstanding the age limitations for use of the different formulations and presentations described above, individuals who will turn from 11 years to 12 years of age between their first and

Healthcare Providers for 5-11 years of age, orange cap, (must dilute) (michigan.gov)

There are 3 versions of EUA Fact Sheets for Healthcare Providers and 2 versions for Recipients and Caregivers

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

Ptizer

Moderna

Janssen (Johnson & Johnson)

### **EUA Fact Sheets**

- · EUA Fact Sheet for Healthcare Professionals
  - o 5 Through 11 Years of Age, Orange Cap (must dilute) UPDATED 10/29/21
  - 12 Years of Age and Older, Purple Cap (must dilute) UPDATED 12/9/21
  - 12 Years of Age and Older, Grey Cap (do not dilute) UPDATED 12/9/21
- EUA Fact Sheet for Recipients
  - o 5 Through 11 years of Age UPDATED 10/29/21
    - Spanish UPDATED 10/29/21
  - 12 Years of Age and Older UPDATED 12/9/21
    - Spanish UPDATED 10/29/21
  - Important: Print and provide the above EU recipient/caregiver in Michigan.
  - This version includes the information statem law, patients/parents must be informed about

(VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE

### FOR 12 YEARS OF AGE AND OLDER DO NOT DILUTE

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 5 years of age and older.

There are 2 formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older:

The formulation supplied in a multiple dose vial with a gray cap and label with a gray border IS NOT DILUTED PRIOR TO USE.

The formulation supplied in a multiple dose vial with a purple cap MUST BE DILUTED PRIOR TO USE.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border which is authorized for use in individuals 12 years of age and older and MUST NOT BE DILUTED PRIOR TO USE.

Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with a gray cap and a label with a gray border is authorized for use to provide:

- a 2-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;
- a single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY; and
- a single booster dose to individuals 18 years of age and older who
  have completed primary vaccination with a different authorized
  COVID-19 vaccine. The dosing interval for the heterologous booster
  dose is the same as that authorized for a booster dose of the vaccine

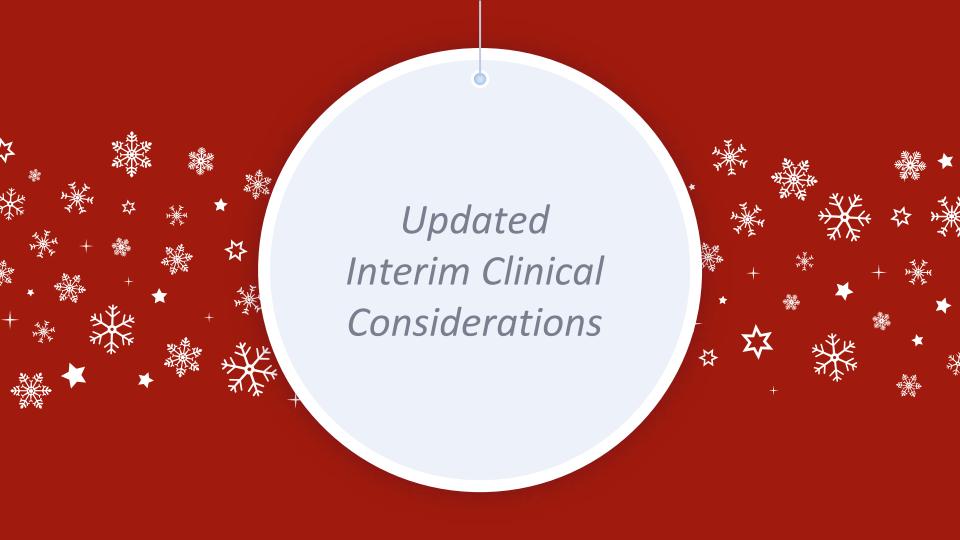
### **Updated EUA Fact Sheets**

www.michigan.gov/covidvaccineprovider

(A) is an FDA-approved COVID-19 that is indicated for active immunization

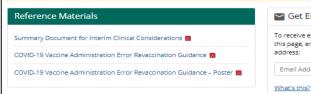
**ENGLISH** 

1



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

CDC expands COVID-19 booster recommendations to 16- and 17-year-olds. Learn more about booster shots.



Get Email Updates To receive email updates about this page, enter your email

Email Address

### Summary of recent changes (last updated December 10, 2021):

. Updated guidance for use of Pfizer-BioNTech COVID-19 vaccine as a booster dose in persons aged 16 years and older

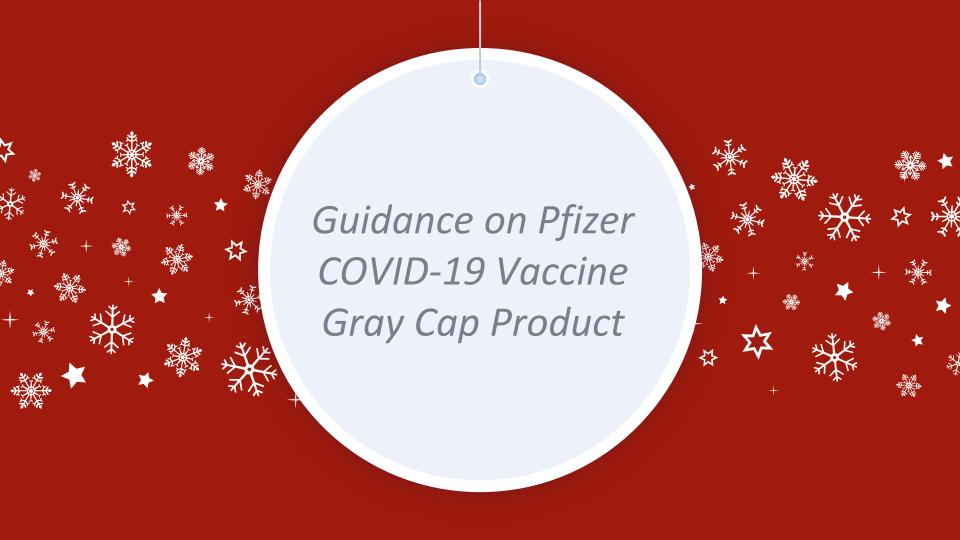
### Key points

- A COVID-19 primary series vaccination is recommended for everyone aged 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- An additional primary mRNA COVID-19 vaccine dose is recommended for moderately or severely immunocompromised people ≥ 12 years of age who received a 2-dose mRNA vaccine primary series.
- A booster dose of COVID-19 vaccine is recommended for all persons aged 18 or older, at least 6 months after completion of a mRNA vaccine (Pfizer-BioNTech or Moderna) primary series, or at least 2 months after single primary dose Janssen vaccine.
- Adolescents aged 16-17 years may receive a single booster dose of Pfizer-BioNTech COVID-19 at least 6 months after completion of the primary series, based on their individual benefits and risks.
- 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.
- The Advisory Committee on Immunization Practices (ACIP) and CDC have issued interim recommendations for the use of three COVID-19 vaccines:
  - Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY
  - Moderna COVID-19 Vaccine

On This Page	
Purpose	Considerations involving pregnancy, lactation, and fertility
COVID-19 vaccines	Vaccination of children and adolescents
Groups recommended for vaccination	Patient counseling
Primary series	
Additional primary dose	Considerations for mRNA COVID-19 vaccines: Pfizer- BioNTech and Moderna
Booster dose	Considerations for Janssen COVID-19 Vaccine
Interchangeability of COVID-19 vaccine products	Contraindications and precautions
Coadministration of COVID-19 vaccines with other vaccines	Reporting of vaccine adverse events
	Laboratory testing
People who received COVID-19 vaccine outside the United States	Appendix A. Vaccine administration errors and deviations
People who received COVID-19 vaccine as part of a clinical trial	Appendix B: Triage of people with a history of allergies or allergic reactions
COVID-19 vaccination and SARS-CoV-2 infection	Appendix C: Ingredients included in COVID-19 vaccines
Vaccinating people with a known COVID-19 exposure or	Appendix a mg. carer a meladed in COVID-15 vaccine.
during COVID-19 outbreaks	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



### Transition to Pfizer 'Gray-Cap'

- A new formulation of Pfizer vaccine for adults/adolescents will be available this December
- Pfizer Tris-Sucrose Adult product (a.k.a. gray cap) ordering will begin on December 23
  - Pfizer 1170 (Purple Cap) will be unavailable for order after 9a.m. on 12/23
  - Gray Cap product won't be available for order until late 12/23 or early 12/24
- All order thresholds thereafter will be for the Pfizer Tris-Sucrose Adult product (Gray Cap)
  in the smallest unit order of 300 doses (current Purple Cap will no longer be available)
- A MIHAN will be going out later today with a holiday shipping reminder and the gray cap ordering update

### Transition to Pfizer 'Gray-Cap' Cont.

- Key Considerations:
  - Providers should maximize use of all remaining Pfizer PBS doses prior to using Tris-Adult
  - Provider sites should carry only one Pfizer adult formulation at a time
  - Provider sites utilizing the Pfizer thermal shipping containers for temporary storage must prepare for use of an ULT freezer or refrigerator moving forward; these shipping containers cannot be utilized to store the Pfizer Tris-Adult formulation

### Pfizer BioNTech COVID-19 Vaccine: Product Characteristics

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older	12 years and older	5 through 11 years
/ial Cap Color and Label with Color Border	PURPLE	GRAY	ORANGE
Dose	30 mcg	30 mcg 30 mcg	
Dose Volume	0.3 mL 0.3 mL		0.2 mL
Amount of Diluent* Needed per Vial	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
<u> </u>		Storage Conditions	
ULT Freezer (-90°C to -60°C)	9 months**	9 months** 6 months*** 6 months*	
Freezer (-25°C to -15°C)	2 weeks	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	1 month	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 6 hours	Discard after 12 hours Discard after 12 hours	

### **Gray Cap Storage Options**



### **Ultra Cold Freezer**

- -90°C to -60°C (-130°F to -76°F)
- Store up to 6 months



### Refrigerator

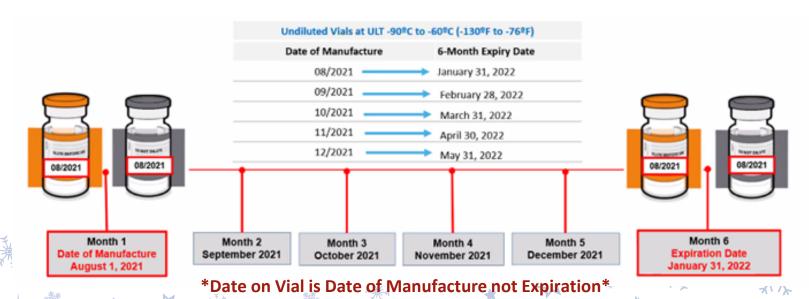
- 2°C to 8°C (35°F to 46°F)
- Store up to 10 weeks

### DO NOT store Gray Cap Vials in Regular Freezer -25°C to -15°C (-13°F to 5°F)

- If vial cartons are delivered at 2°C to 8°C (35°F to 46°F), vaccine needs to stay at 2°C to 8°C (35°F to 46°F)
- One vaccine is thawed, Do Not Refreeze

### Date of Manufacture and Expiration

- Vials can be stored up to 6 months in an Ultra Cold Freezer -90°C to -60°C (-130°F to -76°F)
- Once the vials are thawed and moved to the refrigerator 2°C to 8°C (35°F to 46°F), the vials may be stored for up to 10 weeks
  - The carton should be updated to reflect the 10-week expiration date
- Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons



### **Preparation Instructions**



gray border.

### Dose Verification (individuals 12 years of age and older)

- Verify that the vial has a gray plastic cap and a label with a gray border
- Vaccine intended for persons aged 12 years and older should not be used for persons 5 through 11 years of age



### Thaw vial(s) before use by:

- Allowing vial(s) to thaw in the refrigerator 2°C to 8°C (35°F to 46°F). A carton of 10 vials may take up to 6 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks
- Allowing vial(s) to sit at room temperature up to 25°C (77°F) for 30 minutes
- Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours prior to use

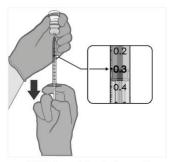
### Preparation Instructions Cont.



Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times
- Do not shake
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles
- Do not use if liquid is discolored or if particles are observed after mixing

### Preparation Instructions Cont.



Withdraw 0.3 mL dose of vaccine.

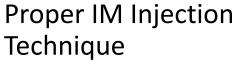


Record the date and time of first puncture. Use within 12 hours after first puncture.

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, preferentially using a low dead-volume syringe and/or needle
- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Administer immediately

- Record the date and time of first vial puncture on the vial label
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 12 hours after first puncture\*

\*Gray cap vial labels and cartons may state that a vial should be discarded 6 hours after first puncture. The information in the EUA fact sheet supersedes what is printed on the labels and cartons



- Deltoid preferred site for 3 years and older
- Administer in thickest, most central part of the muscle
- Use needle length based on patient's age and weight
- Insert the needle into the muscle at a 90° angle





I haven't yet received a shipment of the orange cap vaccine; can I use a vial of the purple or gray cap vaccine to provide a dose to a child 5 through 11 years of age?

- No. The Purple Cap and Gray Cap formulations are NOT AUTHORIZED for use in individuals 5 through 11 years of age.
- The orange cap vaccine is authorized for a 10mcg dose for use in children ages 5 through 11 years.

- At this time, only the Pfizer-BioNTech mRNA COVID-19 vaccine can be used for booster vaccination for those aged 16-17 years, and use should be based on their individual benefits and risks
- Heterologous (mix and match) booster doses can be used in people aged 18 years and older

Can 16- and 17year-olds receive any COVID-19 vaccine for their booster dose?





FORMULATION: 12 Years of Age and Older

### Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine



Diluent Dosage (amount)/ Route Formulation: 12 years of age 1.8 mL of 0.9% sodium chloride (normal saline, 0.3 mL/IM injection and older (purple cap) preservative-free) diluent

### 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).

 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 never received a COVID-19 vaccine. administer 1 dose of Pfizer-BioNTech COVID-19 vaccine.
- 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.
- o 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 or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 2 weeks after completing the primary vaccination series.
- 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 occurs after a dose of an mRNA vaccine, do not administer a subsequent dose of any COVID-19 vaccine. Administration of the subsequent dose of COVID-19 vaccine can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Decisions regarding vaccination should be made in consult with the clinical

team. Considerations can be found at https://www.cdc.gov/ vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html#considerations-pfizer-biontech-moderna

- o 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 care if symptoms of myocarditis or pericarditis develop after vaccination."
- · Additional primary dose for persons who are moderately or severely immune compromised<sup>†</sup>
- For a person aged 12 years and older who received a Pfizer-BioNTech primary mRNA vaccine series: Administer an additional primary dose of Pfizer-BioNTech vaccine at least 28 days after an intial 2-dose Pfizer-BioNTech primary series. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 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 with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Booster doses
- A booster dose, at least 6 calendar months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose or the additional [3rd] dose for moderately or severely immunocompromised persons)
- Should be administered to persons 18 years of age and older (Use of heterologous - mix and match - booster doses is allowed)
- May be administered to persons 16 and 17 years of age based on their individual benefits and risks
- Additional Clinical Considerations
- For persons who received a COVID-19 vaccine:
- » Outside of the United States
- » Not currently authorized/approved in the United States

See clinical guidance, including booster dose recommendations, at https://www.cdc.gov/vaccines/ covid-19/clinical-considerations/covid-19-vaccines-us, html#people-vaccinated-outside-us

### OVID-19 vaccine may be coadministered Precautions: s without regard to timing, including

ATION: 12 Years of Age and Older

g Orders for Administering Vaccine

ons for COVID-19 vaccination and SARS-

idance, including after receiving passive

can be found at: https://www.cdc.

-19/clinical-considerations/covid-19-

inistration.

oV-19-vaccination

ications and Precautions

reaction (e.g., anaphylaxis)

s dose or to a component of the

sed allergy to a component of the

rations/covid-19-vaccines-us.

tps://www.cdc.gov/vaccines/covid-19/

x-C for a list of vaccine components)

r-BioNTech COVID-19 Vaccine

- » Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine
- » Immediate allergic reaction<sup>‡</sup> to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies (excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- » Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Contradiction to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)<sup>5</sup>
- Moderate to severe acute illness

Patient	Needle Gauge	Needle Length	Injection Site <sup>1</sup>
than 130 lbs	22-25	%*"−1"	Deltoid muscle of arm
152 lbs	22-25	1"	Deltoid muscle of arm
	22-25	1-11/2"	Deltoid muscle of arm
	22-25	1-11/2"	Deltoid muscle of arm
	22-25	11/2"	Deltoid muscle of arm
	22-25	11/2"	Deltoid muscle of arm

- and/or parents/legal guardians with a act Sheet for Recipients and Caregivers. r the vaccine. Choose the correct needle , and injection site for persons:
- ngth: 22-25 gauge, 1-inch cle of arm.
- l older: See chart. COVID-19 Vaccine with 0.9% sodium ine, preservative-free) diluent according r's instructions. Follow manufacturer's g/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration
- Document each recipient's vaccine administration information:

ist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation ssessment CDVIDvax Project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html/. Vaccination of these individuals should only be the supervision of a healthcare provider experienced in the management of severe allergic reactions. o mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously cine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.

Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination

DRMULATION: 12 Years of Age and Older

### fizer-BioNTech COVID-19 Vaccine

anding Orders for Administering Vaccine



record: The vaccine and the date it was administered. cturer, lot number, vaccination site and route, nd title of the person administering the vaccine tion record card: Date of vaccination, product nanufacturer, lot number, and name/location of inistering clinic or healthcare professional. Give to ine recipient.

zation information system (IIS): Report the ion to the appropriate state/local IIS.

eparation and administration information is the manufacturer's website at www.cvdvaccine.com. to manage medical emergencies.

n providers should observe patients after n to monitor for the occurrence of immediate actions, including syncope:

utes: persons with a history of: traindication to another type of COVID-19 ne product.

diate (within 4 hours of exposure) non-severe ic reaction to a COVID-19 vaccine. diate allergic reaction of any severity to a non-

0-19 vaccine or injectable therapies hylaxis due to any cause.

utes: All other persons

nay occur in association with injectable vaccines, in among adolescents. Procedures should be in place Illing injuries and manage syncopal reactions. itten protocol to manage medical emergencies vaccination, as well as equipment and medications, at least 3 doses of epinephrine, H1 antihistamine, ssure monitor, and timing device to assess pulse.

- o 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.
- For more information, please see:
- » Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/ info-by-product/pfizer/anaphylaxis-management.html
- » CDC's General Best Practice Guidelines for Immunization. "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/generalrecs/adverse-reactions.html
- » Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catq.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- While this vaccine is under <u>Emergency Use Authorization (EUA)</u>, healthcare professionals are required to report to VAERS:
- » Vaccine administration errors (whether associated
- with an adverse event [AE] or not)
- » Serious AEs (irrespective of attribution to vaccination). » Multisystem inflammatory syndrome (MIS) in
- adults or children » Cases of COVID-19 that result in hospitalization or death
- » Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS:
- » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

e information/quidance, please contact the immunization program at your state or local health department or the te body (e.g., state board of medical/nursing/pharmacy practice).

A +	hor	172	tion	

d procedure shall remain in effect for all patients of the

until rescinded or until

or (or other authorized practitioner)

Educational materials are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.htm

+ For a list of conditions associated with moderate to sewere in: html#considerations-covid19-vax-immunocopromised

12/10/2021 CS2215704

Pfizer-BioNTech COVID-19 Vaccine: 12 Years of Age and Older • Standing Orders for Administering Vaccine (cdc.gov)





### General Information

Vaccine: Pfizer-BioNTech,12 years of age and older (purple cap) Use the correct formulation based on the age of the recipient Diluent: 1.8 mL of 0.9% sodium chloride (normal saline,

preservative-free) Use a new vial every time. Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Prepare the vaccine using a NEW vial of diluent EVERYTIME. Discard the diluent vial and remaining diluent after mixing the vaccine.

### Age Indications

12 years of age and older

### Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature: Refrigerator: Between 2°C and 8°C (36°F and 46°F) Unpunctured vials may be stored in the refrigerator for up to
- Room temperature (for immediate use): Up to 25°C (77°F) Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.

### Prepare the Vaccine

1 month (31 days)

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.\*

Remove vaccine from the storage unit. Check the vial label to ensure it is the correct formulation based on the age of the recipient. The vial for persons 12 years of age and older has a purple cap and purple border on the label. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing.



- · expiration date on the vaccine and diluent
- · any beyond-use dates/times NEVER use expired vaccine or diluent. NEVER use vaccine after the beyond-use date or times.



### Do NOT refreeze thawed vaccine.

- Use vials in the refrigerator before removing vials from ultracold temperature or freezer storage.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

### Schedule for Primary Series and Booster Dose

- 2-dose series separated by 21 days\*
- Moderately and severely immunocompromised people: Administer an additional Pfizer-BioNTech dose at least 28 days after the initial 2-dose primary series."
- A primary series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product.
- A booster dose, at least 6 calendar months after the last dose of a COVID-19 mRNA primary series† (i.e., after the 2nd dose or after the additional [3rd] dose for moderately or severely immunocompromised persons)
- Should be given to persons 18 years of age and older (Use of heterologous- mix and match - booster doses is allowed)
- May be given to persons 16 and 17 years of age based on their individual benefits and risks

### Administration

Intramuscular (IM) injection in the deltoid muscle

With the vaccine at room temperature, gently invert vial 10 times. Do not shake the vial. If the vial is shaken contact the manufacturer The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.



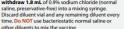
Using a new, sterile alcohol prep pad for each vial. wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, withdraw 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. Do NOT use bacteriostatic normal saline or





mL





\* For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

† Persons vaccinated with Janssen COVID-19 Vaccine: Administer a booster dose at least 2 months (8 weeks) after primary dose 1.

‡ Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves bet



mixed on the vial.

Note the date and time the vaccine was

Keep mixed vaccine between 2°C and 25°C

and avoid exposure to direct sunlight and

ultraviolet light. Administer within 6 hours.

Discard any unused vaccine after 6 hours.

Do not return to freezer storage.

(36°F to 77°F), minimize exposure to room light.

Remove any significant air bubbles with the needle

needle' to withdraw and administer the vaccine.

Bring the dose of vaccine from the designated

preparation area immediately to the patient

treatment area for administration.

still in the vial to avoid loss of vaccine. Use the same

Ensure the prepared syringe is not cold to the touch.











d Administration Summary

e Due	and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
e 1 <sup>‡</sup>	professional, give to the vaccine recipient.
	Immunization information system (IIS) or "registry":

Report the vaccination to the appropriate state/local IIS.

Date of vaccination, product name/manufacturer, lot number,

Personal vaccination record card (shot card):

### Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death Any additional AEs and revised safety reporting requirements

per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA Adverse events should be reported even if the cause is

uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration, Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at www.cvdvaccine.com.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see https://www.cdc.gov/vaccines/covid-19/info-by-product/ clinical-considerations.html#Appendix-A

Then **Next Dose Due** Give dose 1 Give dose 2 at least 21 days after dose today ■ Persons 12-15 years of age: Series complete; no more doses needed Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster Give dose 2 dose 6 months after completion of primary series (or additional primary dose) based on individual benefits and risks Persons 18 years of age and older: Administer booster dose 6 months after completion of primary series (or additional primary dose)§ Give dose 2 at least 21 days after dose 1<sup>‡</sup> Persons 12–15 years of age: Series complete; no more doses needed Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster dose 6 months after completion of primary series (or additional

primary dose) based on individual benefits and risks

primary dose) based on individual benefits and risks

es, including simultaneous administration. When deciding whether to administer COVID-19 vaccines

rson is behind or at risk of becoming behind on recommended vaccines. They should also consider the

ct was received as the first dose. In exceptional situations in which the vaccine product given for the first dose

mmended interval (21 days). It is not necessary to restart the series if the dose is given after the

any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

ninistered before the 4-day grace period (i.e., less than 17 days apart) should be repeated.

Persons 18 years of age and older: Administer booster dose 6 months

after completion of primary series (or additional primary dose)

Persons 12–15 years of age: Series complete; no more doses needed

Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster

Persons 18 years of age and older: Administer booster dose 6 months

dose 6 months after completion of primary series (or additional

after completion of primary series (or additional primary dose) 1

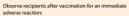


Ø.



coverings for vaccine recipients older than 2 years of age (if tolerated).

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.



- . 30 minutes: Persons with a history of:
- A contraindication to another type of COVID-19 vaccine product
- Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine
- Immediate allergic reaction of any severity to a non-
- COVID-19 vaccine or injectable therapies
- Anaphylaxis due to any cause
- 15 minutes: All other persons



a previous e vaccine endix-C for a

at this time<sup>5</sup>

outbreak) and the reactogenicity profile of the vaccines.

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine. Immediate allergic reaction<sup>®</sup> to any non-COVID-19 or injectable

therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) This includes non-COVID-19 vaccines and therapies with

- multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe. allergic reaction to a previous dose of the COVID-19 vaccine

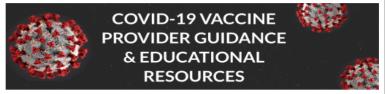
ient can safely receive vaccination. Healthcare providers and health departments nt COVIDvax Project (https://www.cdc.gov/vaccinesafety/ensuringsafety/ in an appropriate setting under the supervision of a healthcare provider

known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People least 28 days to receive Janssen COVID-19 Vaccine. a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

2/13/2021 CS321570-F

Pfizer-BioNTech COVID-19 Vaccine: 12 Years of Age and Older • Preparation and Administration Summary (cdc.gov)

### 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: December 16, 2021

**Education Corner - Email Archive** 

**Enrollment** 

Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information, EUAs & EUIs







# MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider









## Thank You Happy Holidays!

Next "Noontime Knowledge" Update: TBD Find us at checcimms@michigan.gov

