## Interim Clinical Considerations for COVID-19 Vaccine in Children Ages 5–11 Years

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cdc.gov/coronavirus

#### **Outline of Presentation**

- The Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years
  - Formulation and dosing
- Vaccine recipients
  - Underlying medical conditions
  - Prior SARS-CoV-2 infection
  - Children with a history of MIS-C
- Patient and parent/guardian counseling
- Vaccine administration
  - Coadministration
  - Administration errors

# Pfizer-BioNTech COVID-19 Vaccine Formulation and Dosing in Children Ages 5–11 years



#### Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

\*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS) Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf

#### Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)		
Storage conditions				
Ultralow temperature freezer (-90°C to -60°C)	9 months	6 months		
Freezer (-25°C to -15°C)	2 weeks	N/A		
Refrigerator (2°C to 8°C)	1 month	10 weeks		

Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf

#### Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)		
Number of doses	2 2			
Interval	3 weeks (21 days)	3 weeks (21 days)		
Additional primary dose	Moderate and severe immunocompromise	Not recommended		
	Not recommended 12–17 years			
Booster dose	Recommended for certain groups ≥18 years*	Not recommended		

\*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underying medical conditions, or who work or live in highrisk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021

#### Vaccine Dosage

- Children should receive the age-appropriate vaccine formulation regardless of their size or weight.
  - As opposed to many medications, vaccine dosages are based on age and not size or weight.
- The dosage should be based on the child's age on the day of vaccination.
  - If a child turns from 11 to 12 years of age in between their first and second dose and receives 5–11 years 10 µg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error per the EUA.

## Vaccine Recipients



### **Underlying Medical Conditions**

- Children with underlying medical conditions may be at increased risk for severe illness from COVID-19<sup>1</sup>, however, severe COVID-19 can occur in children with and without underlying medical conditions.
- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, regardless of underlying medical conditions.

<sup>1</sup>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#ChildrenAndTeens <sup>2</sup>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

#### **Current or Prior SARS-CoV-2 Infection**

- People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) AND they have met criteria to discontinue isolation<sup>1</sup>.
  - Isolation and precautions can typically be discontinued 10 days after positive test if asymptomatic or 10 days after symptom onset and after resolution of fever for at least 24 hours)
- Serologic testing to assess for prior infection is **not** recommended for the purpose of vaccine decision-making<sup>2</sup>.

<sup>1</sup> https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html <sup>2</sup> https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

#### **Prior SARS-CoV-2 Infection**

- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity.
- >7 million adolescents ages 12–15 years have been fully vaccinated with Pfizer-BioNTech COVID-19 Vaccine in the United States<sup>1</sup> and in the general population there has been no safety concerns associated with vaccination of those who had prior infection.

## **Prior SARS-CoV-2 Infection**



Data from clinical trials in children ages 5–11 years indicate that the Pfizer-BioNTech COVID-19 Vaccine **can be given safely** to those with evidence of a prior SARS-CoV-2 infection.



Current evidence suggests that protection from reinfection is high after initial infection but decreases with time due to **waning immunity**.



Substantial **heterogeneity** exists in individual immune response to infection, and in adults, asymptomatic infection leads to **lower antibody levels**.



Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection **increases protection** from subsequent infection, including in the setting of more infectious variants.

Dan 2021, <u>Science: https://doi.org/10.1126/science.abf4063</u>; Cavanaugh 2021, <u>MMWR</u>; 70(32):1081-3. Lumley 2021; <u>Clin Infect Dis</u>; doi: 10.1093/cid/ciab608. Gazit 2021, <u>medRxiv</u>; <u>https://doi.org/10.1101/2021.08.24.21262415</u>. Shenai 2021, <u>medRxiv</u>; <u>https://doi.org/10.1101/2021.09.12.21263461</u>.

## **Limitations of Antibody Testing**

- Antibody tests cannot determine when a person was infected.
- Antibody tests greatly vary in their sensitivity, particularly >3 months after infection.
- People can test positive on commercial antibody tests even after other markers of immunological response, such as neutralizing antibodies, have waned.
- At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.

### Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- The benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C are likely to outweigh a theoretical risk of an MIS-like illness or the known risks of COVID-19 vaccination for people who meet all of the following criteria:
  - 1) Clinical recovery has been achieved, including return to normal cardiac function;
  - 2) It has been  $\geq$ 90 days since their diagnosis of MIS-C;
  - 3) They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission;
  - 4) Onset of MIS-C occurred before any COVID-19 vaccination.

### Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- COVID-19 vaccination may also be considered for children with a history of MIS-C who do not meet all the prior criteria.
- Experts view clinical recovery, including return to normal cardiac function, an important factor when considering COVID-19 vaccination.
- Additional factors when considering individual benefits and risks may include:

An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)
 Timing of immunomodulatory therapies

#### Children Diagnosed with MIS-C after COVID-19 Vaccination

- In the rare instance a person develops MIS-C or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist should be considered.
- Because MIS-C is a condition known to occur with SARS-CoV-2 infection, these individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection.

Any cases should be reported to Vaccine Adverse Event Reporting System (VAERS) <u>https://vaers.hhs.gov/reportevent.html</u>

Consultation from Clinical Immunization Safety Assessment Project is available <u>http://www.cdc.gov/vaccinesafety/Activities/CISA.html</u>

## Counseling



#### **Counseling: Expected Side Effects from Pfizer-BioNTech COVID-19 Vaccine**

- Children may experience **fewer side effects** than adolescents or young adults<sup>1</sup>.
- Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection<sup>1</sup>.
- Expected side effects include
  - Local: pain, swelling, erythema at the injection site
  - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy
- Routine antipyretic or analgesic medications can be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate.
  - In general, Aspirin is **not** recommended for use in children and adolescents ≤18 years due to risk of Reye's syndrome.

#### **Counseling: Possible Risk of Myocarditis**

- Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose.
- The observed risk is highest in males 12–29 years of age<sup>1</sup>.
- The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is **lower** than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults<sup>2</sup>.

<sup>1</sup>Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep 2021;70:977–982.

DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7027e2</u>

<sup>2</sup>Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7035e5</u>

#### **Counseling: Possible Risk of Myocarditis**

- No cases of myocarditis or pericarditis were reported in clinical trial for children ages 5–11 years (n=3,082), although the study was not powered to assess the risk of myocarditis<sup>1</sup>.
- The baseline risk of myocarditis is much higher in adolescents ages 12–17 years compared to children ages 5–11 years.

### **Counseling: Possible Risk of Myocarditis**

- FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine in children ages 5–11 years based on the determination that the benefits of COVID-19 vaccination outweigh risks in this population.
- People receiving mRNA COVID-19 vaccines, especially males ages <30 years, should be made aware of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines.
  - Seek care for symptoms of
    - Chest pain
    - Shortness of breath
    - Feelings of having a fast-beating, fluttering, or pounding heart

Any cases should be reported to VAERS

https://vaers.hhs.gov/reportevent.html

## Administration



### Coadministration

- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age<sup>1</sup>.
  - Separate injection sites by 1 inch or more.
  - For older children ( $\geq$ 11 years), the deltoid muscle can be used.
  - For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

### **Administration Errors**

- Formulations of the Pfizer-BioNTech COVID-19 Vaccines are NOT interchangeable.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their first dose, they should receive a single age-appropriate 10 µg dose for their second dose 21 days later and should be considered as having a completed primary series.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their second dose, they should be considered has having a completed primary series.

### **Administration Errors**

- If an individual aged ≥12 years inadvertently receives a 10 µg dose, the dose should be repeated with the age appropriate 30 µg dose immediately.
  - Exception for children who turned from 11 to 12 years in between their first and second dose and receive a second 10 μg dose to complete their series.
- Due to the rare risk of myocarditis, males aged <30 years may consider waiting 21 days (the recommended interval) after the erroneous dose to repeat the dose.

### **Administration Errors**

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

> COVID-19 Vaccine Administration Errors and Deviations



A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This table provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, it includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors.

#### For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the <u>state immunization program</u> and/or <u>immunization information system (IIS)</u> to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.

Interim recommendations for COVID-19 vaccine administration errors and deviations

Ade	ditional	Clin	ical				Pfizer-BioNTech Vaccine Preparation	COVID	-19 Va		
Res	sources		2		Pfize	er-BioNTech COVID-19 Vac e Preparation and Administration Summ	ccine	die length b for adults 19 nd prepare the uent and a NEN edie and syrin	ased on the 9 years of a 9 injection. W vial of vacc 1 ge EVERY TH	erecipient's age. ge and older. Ince EVERY TIME. WE	
		Prettor	vaccination Checklis COVID-19 Vaccines	Pfizer-BioNTech Dondrg Orden for Adm to Pensons 12 Years of Ag t	COVID-19 V https://www. ge and Older	Vaccine Contraction of the second sec	d on their individual benefits and risk for: 19 1-49 years with underlying medical conditions much <i>qool</i> contransitues 2019. now/need-extu- resongle with medical conditions in thm0 19 18-64 years at increased risk for SARS-GoV- d transmission because of occupational or settings on Mi injection in the deficid muscle <b>zen Vaccine</b> emust be thwed before using.	ed for mixing supply kit. saline,	Don't	Do <b>NOT</b> use needles and syringes designated for administration to mix vaccine and diluent. Do <b>NOT</b> use bacteriostatic normal saline or other diluents.	
		For vaccine r The following question are should not get the the areq question, it do vectored, it just me question is not cheer, p	ecipients: is soli haj as delettos Pilera is any reson cOSO 31 accient toby. If yes annes' yes' en ont recessarily man yes should to be an addited gestime may to acient if a mean add acient gestime may to acient if a mean ad you'resthcare provide to estant it.	Name Age	Ten No Statt	are to a comparent of an exhibit COVID-19 variation doma or Plana Berlinkshi midlim adapted berlinkshi midlim adapted berlinkshi midlim adapted berlinkshi adapted and and and the anit shappassed adapted to a comparent of the variation loss of a the the described berlinkshi and a state of a state to an when hane a contamented basis that a state to an exhibit COVID-19 berlinkshi and a state basis berlinkshi and a state to a state of the state basis berlinkshi and the state to a state of the state basis berlinkshi and the state to a state of the state basis berlinkshi and the state to a state of the state basis berlinkshi and the state of the state of the state of the state of the state of the COVID-199 basis of the state of the state of the state of the covid-199 basis of the state of t	In the refrigerator or at room temperature: w: Between 2°C and 8°C (36°F and 46°F) ed vials may be stored in the refrigerator for up to days). <b>perature (for immediate use):</b> Up to 25°C (77°F) ed vials cannot be kept at noom temperature for thorus (including thaw time). he needed to thaw vaccine varies based on	re and after		Do NOT shake the vial. Do NOT shake the vial. Do NOT use or save any remaining diluent to mix with additional vials of vaccine of roo other uses.	
Summary Document for Interim Clinical Considerations Tor Use of COVID-19 Vaccines Currently Authorized or Approved in the United States				a d'hourdeas with themicographics photoine     a d'hourdeas with themicographics photoine     to de avoid and a set with themicographics can receive any     to de avoid the themicographics can receive any     form     proprior intervented to have a personalises to a	The formation of visits, ize that was vaccine. erefrigerator before removing vials from ultra- ture or freezer storage. rond-use date labels for this vaccine to track it refrigerated and frozen temperatures.	"Ubing a 21 gauge on narrown reade he vial					
Vaccine type	Pfizer-BioNTech	Moderna	Janssen Replacitor-incompetere	spreading of before the associate supremu down, to be provide the second magnetic second seco	000	ory of a international allergic traction <sup>14</sup> of any intershy to other society on specialize tracting Lin, international mension, or subconferences vaccines or therapies) to include persons with a interfaint for a society or pechalist tracting that i interfaint multiple components, one fieldshi to polyethylane glycal (150) or another vaccine imposents, toth welcan K and unknown which components	cine at room temperature, gently times. Do not shake the vial. If ken, contact the manufacture swhite to off-white in color and opaque particles. Do not use if blored.		Don't	Do <b>NOT</b> use the same insertion point every time. This may cause vaccine to leak from the vial.	
Age groups	12 through 15 years of age (authorized) a 16 years (approved COMIRNATY)	≥18 years	218 years	COVID: 19 wecover		Include the investigated allergic reaction, give with a contraundiciption to, lancount COVID 119 Vaccime is a precaution to both with veccimes (see factorized) <sup>1</sup> feedes to servere acute threes	sterile alcohol prep pad for each vial, toppers of the diluent and vaccine 21-gauge (or narrower) needle, i mL of 0.9% sodium chloride	ubbles,	2	Do <b>NOT</b> remove air bubbles with the needle outside of the vial as vaccine can be easily lost in the process.	
Dose volume	0.3 ml	0.5 ml	0.5 ml	ill analysis is failed a that to see by a second size of the		in it to a definition of each of the CP to the first the data. We will have not each data the instantial to the data transformation of the data transformat	rd diluent vial and any remaining time. Do NOT use bacteriostatic or other diluents to mix the vaccine.	nount of ose, ine.	<b>%</b>	Do <b>NOT</b> combine remaining vaccine from multiple vials to obtain a full dose.	
Interval between doses All currently authorized or approv	worker work feature ends to certain people?     3 weeks (21 days)  ved COV/ID-19 vaccines      Vaccines are not interchangeable. However, is succetional	1 month (28 days)	N/A	e injectable filmagy such as filma	pat, annas,	editionative relative for parties to detect a or of our Processing Interface on construction, Page 1 and Page 2 and Pa	pproved or Authorized in the United States at stially infectious body fluids or has open lesions on the 1			1	
Interchangeability of vaccines Interval between COVID-19 and other (non-COVID-19) vaccines	previous doue product cannot be determined or is not avail by product (linear considerations.html) COVID-19 vaccine and other vaccines may be administered whether to administer COVID-19 vaccine and other vaccine on recommended vaccines, their risk of vaccine-preventable	able, interchangeability may be allow on the same day, as well as any interv i, providers should consider whether e diseases (e.g., during an outbreak), i	ed (http://www.cdc.gou/vaccines/could-193/nfo- al without respect to timing. When deciding the patient is behind or at risk of becoming behind and the reactogenicity profile of the vaccines.	nuelve unt anun KS-A) after a COVID-19 infection		And Analysis of the State of					
Persons with prior or current COVID-19	COVID-19 vaccines can be given safely to people with prior     Defer vaccination until perion has recovered from the acute     generation with 2219 non-the dispetition in here patie	SARS-CoV-2 infection illness and <u>criticia</u> have been met fo <u>oris html</u>	r them to discontinue isolation <u>Crites //www.cd</u> c.			https:/	//www.cdc.go	v/va	acci	nes/covid-19/c	linical-
Women aged <50 years Persons who received monocional antibodies or convalescent plasma for COVID-19 treatment	Can receive any FDA-authorized or approved vaccine but th receipt of Jamsen Uebrison & Johnson's COVID-19 Vaccine a     Defer vaccination for at least 90 days	ould be informed of risk of thrombos nd the availability of other COVID-19	is with thrombocytopenia syndrome (TTS) after vaccine options	Bearing the second seco		<u>CO</u>	nsiderations/c	ovid	<b>I-19</b>	-vaccines-us.ht	tml
Persons with a known SARS-CoV-2 exposure	Persons in community or outpatient setting should defer va convil-sour are sick/sourcestanchtm3     Residents or patients in compregate settings may be vaccha consultions.2019.ncov/ymptoms.testing/sumptons.htm3	ccination until <u>quatantine period</u> has ned if they do not have <u>symptoms co</u>	ended Ottas://www.cdc.gov/coronastrus/2019. nsistent with COVO-19 Ottas://www.cdc.gov/				https://www.cdc.go	ov/vaco	cines/	Updates wil covid-19/info-by-produ	l be posted

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For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



## **Back up slides**



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### **Administration Sites**

Age	Needle length	Injection site		
	<sup>5</sup> / <sub>8</sub> -1" <sup>1</sup>	Deltoid muscle of arm (preferred)		
3-10 years	1-1¼"	Vastus lateralis muscle of anterolateral thigh (alternative)		
	⁵⁄₅−1"¹	Deltoid muscle of arm (preferred)		
11-18 years	1-1½"	Vastus lateralis muscle of anterolateral thigh (alternative)		

<sup>1</sup>A 5/8"needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin. https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

#### **Triage of persons Presenting for COVID-19 Vaccination**

#### CONTRAINDICATION TO VACCINATION PRECAUTION TO VACCINATION **ALLERGIES ALLERGIES** ALLERGIES History of the following: Among people without a contraindication, a history Severe allergic reaction (e.g., anaphylaxis) after a of: precaution, a history of: previous dose or to component of the vaccine Any immediate allergic reaction to other . ٠ Allergy to oral medications, including vaccines (non-COVID-19) or injectable Known (diagnosed) allergy to a component of therapies injectable medication) . the vaccine Non-severe, immediate (onset <4 hours) allergic History of food, pet, insect, venom, ٠ reaction after a previous dose of a COVID-19 vaccine anaphylaxis . Family history of allergies Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa.

#### ACTIONS

- Do not vaccinate. •
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative if age . appropriate.

#### **ACTIONS**

- Risk assessment
- 30-minute observation period if vaccinated
- Consider referral to allergist-immunologist

#### MAY PROCEED WITH VACCINATION

Among persons without a contraindication or

- anaphylaxis (including the oral equivalent of an
- environmental, latex, etc., allergies, including

#### ACTIONS

- . 30-minute observation period: Persons with a history of anaphylaxis (due to any cause)
- 15-minute observation period: All other persons .

\* For additional information please see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

#### **Triage of persons Presenting for COVID-19 Vaccination**

•	CONTRAINDICATION TO VACCINATION History of the following: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine Immediate allergic reaction*-of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine	<ul> <li>PRECAUTION TO VACCINATION</li> <li>Among people without a contraindication, a history of:</li> <li>Any immediate allergic reaction* to other vaccines (non-COVID-19) or injectable therapies</li> <li>Non-severe, immediate (onset &lt;4 hours) allergic reaction after a previous dose of of COVID-19 vaccine</li> <li>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa.</li> </ul>	<ul> <li>MAY PROCEED WITH VACCINATION</li> <li>Among people without a contraindication or precaution, a history of:</li> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul>
• • •	Actions: Do not vaccinate. Consider referral to allergist- immunologist. Consider other vaccine alternative.	<ul> <li>Actions:</li> <li>Risk assessment</li> <li>30-minute observation period if vaccinated</li> <li>Consider referral to allergist- immunologist</li> </ul>	<ul> <li>Actions:</li> <li>30-minute observation period: people with history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: all other people</li> </ul>