

Exemption COVID-19 Vaccination for Medical Contraindication

Sun Health requires that I receive a COVID-19 vaccination to protect myself and others. *Only evidence*based medical contraindication against COVID-19 vaccination confirmed by a licensed health care provider (MD, DO or NP) will be accepted as an exemption to the mandatory COVID-19 policy. Medical contraindication must be re-assessed each year and an updated exemption form must be completed and submitted yearly.

This Medical Exemption form (pages 2-4) must be completed by the team member or contract personnel's primary physician (MD, DO or NP) and pages 1-4 submitted to Sun Health Human Resources in person or emailed to <u>HRSupport@sunhealth.org</u>.

I request to be exempted from the COVID-19 vaccination due to a medical contraindication. All	
statements below must be initialed by the team member to be considered for a medical exemption.	

	I understand that be and co-workers at ris	cause I work in a health care or senior liv sk if I work while infected with the COVID	ing environment, I may place residents -19 virus or any of its variants.		
	I understand that as I am not vaccinated, to protect my own health and the health of others, I wi				
	I understand that sin to wear a mask <u>upor</u>	ce I have been exempted from the COVID entry to all Sun Health locations and res	0-19 vaccination that I will be required ident homes. My mask must be worn		
at all times during my scheduled shift, except while eating in a designated break room, until s mask restrictions are lifted. I understand that masking is required to support the infection prevention policies and practices at Sun Health.					
	I understand that in the event of an outbreak or threatened outbreak, I may be temporarily excluded or reassigned from Sun Health's locations and approved activities. I agree to comply with these restrictions and accept responsibility for communicating with my supervisor as appropriate to allow compliance with health and safety requirements for unvaccinated individuals. I understand and agree to comply with and abide by all Sun Health COVID-19 policies and procedures and have read the CDC COVID-19 vaccine information on the Sun Health portal.				
	I authorize my licensed healthcare provider to provide Sun Health with medical information about my medical exemption for the COVID-19 vaccine. I understand that, if approved, this exception is only valid for the current year, and I may be required to resubmit a new request in the future.				
	Should I contract COVID-19, I will immediately report it to Human Resources and comply visolation and quarantine requirements.				
Tea	am Member	Contracted Personnel			
Name (print)		Location and Department	Signature		
Date		Supervisor's Name (print)	1		



STOP

THIS SECTION SHOULD BE COMPLETED BY THE TEAM MEMBER'S PHYSICIAN (MD, DO or NP)

I have read the vaccine information provided, evaluated ______and attest that this team member has one or more of the medical contraindications to COVID-19 vaccination as outlined in the Health Care Provider Certification.

Physician (MD, DO or NP) Name (print)

Date

Phone

Number Physician (MD, DO or NP) Signature

Questions regarding medical contraindications? Call your local Human Resources representative.

Sun Health will make the following links to the Centers for Disease Prevention and Control's vaccine Fact Sheets available on the employee portal, or they can be printed out for team members upon request from Human Resources:

COVID-19 Pfizer BioNTech Vaccine EUA Fact Sheet for Recipients COVID-19 Moderna Vaccine EUA Fact Sheet for Recipients COVID-19 AstraZeneca Vaccine EUA Fact Sheet for Recipients COVID-19 Janssen Vaccine EUA Fact Sheet for Recipients STOP



Medical Certification in Support of COVID-19 Vaccination Exemption Request

Sun Health requires all team members and contracted staff to receive a COVID-19 vaccination. ______ (Insert Patient's name) is requesting a medical exemption from this vaccination requirement. A medical exemption may be allowed for certain recognized contraindications.

Please certify below the medical reason that your patient should not be vaccinated for COVID-19 by completing this form and attaching available supporting documentation. Information provided on this form will be reviewed in consideration of the exemption request.

Option 1 - Allergy

A documented history of a severe allergic reaction to any component of a COVID-19 vaccine or to a substance that is cross-reactive with a component. Please indicate which of the following vaccines are contraindicated and name the components, by vaccine.

- Moderna List the component(s):
- Pfizer List the component(s):
- Janssen/Johnson&Johnson List the component(s):

A documented history of a severe allergic reaction after a previous dose of the COVID-19 vaccine. Please indicate to which vaccine the patient had a reaction and the date of the vaccine & reaction.

- Moderna Date of Vaccine & Reaction:
- Pfizer Date of Vaccine & Reaction:

Option 2 – Physical Condition/Medical Circumstance

The physical condition of the patient or medical circumstances relating to the individual are such that vaccination is not considered safe. Please state, with sufficient detail for independent medical review, the specific nature and probable duration of the medical condition or circumstances that contraindicate vaccination with the COVID-19 vaccine.

Explanation:

Option 3 - Other

Other. Please provide this information in a separate narrative that describes, in detail, the medical condition or disability in detail that you opine would exempt this individual from vaccination:

Explanation:

This individual should delay receip	of the COVID-19 vaccination	due to the following:
-------------------------------------	-----------------------------	-----------------------

Certification

I certify that (patient name) has the above contraindication and support the request for a medical exemption or delay from the COVID-19 vaccine requirement at Sun Health. **Provider Information**

Medical Provider Name:

Medical Provider Specialty:

Signature:

Provider License Number:

Date:

Name of Provider Company: Address: Email: Phone number:

Patient Information

Patient Name: Date:

Phone number:

Once you have completed this document, please provide to your Human Resources representative.

Provider Fact Sheet

Guidelines for Determining Contraindications or Clinical Considerations for possible delays in receipt of COVID-19 vaccine

Information Source: Centers for Disease Control and American College of Obstetricians and Gynecologists.

Vaccine Ingredients: Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, people with a contraindication to mRNA COVID-19 vaccine, and vice versa, provided certain measures are taken (see "precautions" below). Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

Contraindications: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine, **OR** an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

Precautions: Most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination appointment can and should be administered vaccine. CDC considers a history of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) as a precaution but not a contraindication to vaccination. People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination.

Neither contraindications nor precautions: Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), are **not** a contraindication or precaution to COVID-19 vaccination. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. In addition, because the COVID-19 vaccines do not contain eggs or gelatin, people with allergies to these substances do not have a contraindication or precaution to vaccination.

Co- administration with other vaccines: COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, vaccination providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

People with prior or current SARS-CoV-2 infection: People should be offered vaccination regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection; this includes people with prolonged post-COVID-19 symptoms. Data from clinical trials indicate that the currently authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection is not recommended for the purposes of vaccine decision-making.

Vaccination of people with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation. This recommendation applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of an mRNA vaccine but before receipt of the second dose.

While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity.

People with a history of multisystem inflammatory syndrome in adults (MIS-A): People with a history of MIS-A should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

For people who develop MIS-A that is associated with a confirmed SARS-CoV-2 infection but occurs after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax.

People who previously received passive antibody therapy: Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to people who receive passive antibody therapy before receiving any vaccine dose and to those who receive passive antibody therapy before and to the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy. Receipt of passive antibody therapy in the past 90 days is not a contraindication to receipt of COVID-19 vaccine. COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated.

For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

Myocarditis or pericarditis after receipt of the first dose of an mRNA COVID-19 vaccine (i.e. Pfizer and Moderna) series but before administration of the second dose: It is unclear if people who developed myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine may be at increased risk of further adverse cardiac effects following a second dose of the vaccine. Until additional safety data are available, experts recommend that people who develop myocarditis or pericarditis after second dose.

Thrombosis with thrombocytopenia syndrome (TTS) associated with the Janssen COVID-19 vaccine: Women aged <50 years can receive any FDA-authorized COVID-19 vaccine. However, they should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). The highest rates of TTS per vaccine doses administered were identified in women <50 years of age. At the time of ACIP's review, TTS reporting rates to VAERS were 7.0 cases per million Janssen COVID-19 vaccine doses administered to women ages 18–49 years and 0.9 per million to women ages ≥50 years.

Although the etiology of TTS associated with the Janssen COVID-19 vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that persons with a history of an episode of an immunemediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine, i.e., Pfizer or Moderna) if it has been ≤90 days since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine. Thus, there is no need to delay vaccination in women <50 years of age.

Vaccination of pregnant or lactating people: Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference. However, pregnant, lactating, and post-partum people aged <50 years should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is no evidence that any of the COVID-19 vaccines affect future fertility. The American College of Obstetrics and Gynecology (ACOG) recommends that pregnant individuals have access to COVID-19 vaccines. While limited, current safety data on the use of COVID-19 vaccines in pregnancy do not indicate any safety concerns.

Immunocompromised people: The currently FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people, including people with HIV infection or other immunocompromising conditions or people who take immunosuppressive medications or therapies.

People with autoimmune conditions: People with autoimmune conditions may receive any FDA-authorized COVID-19 vaccine.