Covid-19 Vaccination Immediate Allergic Reaction – Referral Protocol for State-operated Mass Vaccination Sites

Background: Vaccine-related allergic reactions, while infrequent, have been reported following vaccination with mRNA and Janssen COVID-19 vaccines. Although research is still ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA or Janssen COVID-19 vaccines. New York State (NYS)- operated Mass Vaccination Site (MVS) procedures for preventing and managing anaphylaxis have been informed by, and is aligned with, Food and Drug Administration (FDA)-issued Fact Sheets for each approved vaccine and current Centers for Disease Control and Prevention (CDC) guidance https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html The following protocol addresses procedures to support individuals deferred from a NYS MVS prior to first dose of vaccine, or after immediate allergic reaction to a first dose of an mRNA vaccine.

This guidance utilizes the CDC's definition of an immediate allergic reaction to a vaccine or medication as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis **that occur within four hours following vaccine administration.**

Individuals with a contraindication to a vaccine should not receive that vaccine at any site in New York State unless they have been **assessed by an allergist-immunologist** and determined not to have a contraindication. Assessment by an allergist-immunologist is a component of the CDC guidance. Current known contraindications to COVID-19 vaccines are documented at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications. Clinical guidance related to COVID-19 vaccines is evolving and may be subject to change; therefore, determination of whether a contraindication exists must be consistent with current CDC clinical guidance at the time of vaccination.

In addition, 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) and vice-versa. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, the CDC and NYS Department of Health (NYSDOH) recommend consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

NYS-operated MVSs are not an appropriate clinical setting for COVID-19 vaccination of individuals with a contraindication to a COVID-19 vaccine – either the vaccine being administered or another COVID-19 vaccine with potential cross-reactive hypersensitivity – and therefore persons such individuals may **not** be vaccinated in a NYS-operated MVS unless they have been assessed by an allergist-immunologist and found not to have a contraindication. Note: recommendation by a clinician that an individual with a known contraindication to a given vaccine, should nonetheless receive such vaccine contrary to current CDC recommendations, shall not suffice as "clearance" for vaccination at a NYS-operated MVS.

A current list of COVID-19 vaccine components is available on the CDC's website at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-C

This protocol identifies processes for the NYS-operated MVSs to manage and refer these individuals who are unable to be vaccinated at a NYS-operated MVS for COVID-19 vaccination.

Process for persons deferred by NYS-operated MVS from initial vaccination based on allergy history on screening form/medical evaluation: This includes individuals who have had an immediate allergic reaction of any severity, including anaphylaxis, to a component of any COVID-19 vaccine OR who have a known (diagnosed) allergy to a component of any COVID-19 vaccine. These individuals should have a consultation with an allergist-immunologist to help determine if they can safely receive vaccination. These individuals should be offered a referral to a HUB for further evaluation. If they agree, MVS leadership will package all relevant patient information (including the type of vaccine received, reaction identified, and another other relevant outcomes) to the respective regional HUB for further allergy/immunology assessment. This referral packet should be copied to the following email: COVIDVaccineAllergyReferral@health.ny.gov. If mRNA or Janssen vaccine is indicated, it can be given at designated clinical site.

Process for persons with an immediate allergic reaction of any severity, including anaphylaxis, to their first dose of mRNA COVID-19 vaccine: First dose vaccine recipients with an immediate allergic reaction, as defined on page 1 of this document, will fall into two general categories: 1. Reaction occurs in post-vaccine observation area of the MVS site; 2. Reaction occurs after the vaccine recipient has exited the MVS site. For both groups, the second dose should be deferred until they have been evaluated by an allergist-immunologist who has determined that the person can safely receive the Janssen COVID-19 vaccine under observation and in a safe location with advanced medical care and adequate emergency services. These individuals should NOT receive their second mRNA vaccine dose or Janssen COVID-19 vaccine at the NYS -operated MVS site.

On-site first dose reactions: The following protocol will be utilized if the vaccine recipient has a first dose immediate allergic reaction at the MVS site:

1. Allergic reaction identified and managed clinically onsite. Vaccine recipients with an immediate allergic reaction of any severity, including anaphylaxis, to an mRNA COVID-19 vaccine are not eligible to receive a second dose of mRNA vaccine or Janssen COVID-19 vaccine at the NYS-operated MVS site.
2. The immediate allergic reaction is flagged in patient's Countermeasure Data Management System (CDMS) Clinical Report, or other scheduling systems, and will ensure all future second dose appointments are canceled until an outcome is determined.
3. Vaccine recipients will have a consultation with an allergist-immunologist to help determine if they can safely receive a subsequent COVID-19 vaccination. These individuals may choose to follow up with their own care provider but should be offered a referral for further allergy assessment if needed. Note that, in accordance with HIPAA standards, all vaccine recipients at state-operated MVS sites acknowledge receipt of a Notice of Privacy Practices (effective January 28, 2021) (Attachment 1) which authorizes the Department to disclose PHI for purposes of obtaining treatment and the coordination of healthcare and related services for the vaccine recipient. Such information may be disclosed to a healthcare provider of the patient' choosing, or to a healthcare provider referred through the NYS-operated MVS. NYS-operated MVS-related records from CDMS, EMS, and/or VAERS will be consolidated into a referral packet that will be

shared by secure file transfer to the HUB provider, and that can also be directly provided to the individual. Referral to the HUB will be made by the state MVS Regional DOH lead or MVS Medical Lead, or their designee, directly to the regional HUB point of contact. That referral should cc the State DOH BML for reference: COVIDVaccineAllergyReferral@health.ny.gov. The regional HUB then identifies the closest hospital vaccination site and assumes management of second vaccine dose appointment planning and administration.

4. Vaccine recipient is contacted by regional HUB coordinator within 72 hours of patient information transfer to HUB to confirm that the vaccine recipient would like to proceed with assessment of whether they can safely receive another dose of COVID-19 vaccine.
5. Local hospital liaison coordinates an evaluation by allergist-immunologist. If allergist-immunologist does NOT approve the vaccine recipient for another COVID-19 vaccination, the vaccine recipient will not be eligible to receive a second vaccine from either the hospital or any NYS-operated MVS. Neither the hospital, the HUB, nor NYSDOH will be responsible for arranging for second opinion consultations nor vaccination of persons who have been evaluated by an allergist-immunologist and not approved for COVID-19 vaccination.
6. If allergist-immunologist approves the vaccine recipient for another COVID-19 vaccination, the hospital will promptly schedule the dose in the appropriate setting approved by the allergist. The second vaccine should occur in a setting that can provide an appropriate level of care. NYS MVS are not equipped to provide higher levels of care or interpret medical clearance forms. The second vaccine appointment should be scheduled within the timeframes identified by the Centers for the Disease Control and Prevention for COVID-19 vaccine administration.
7. The vaccine recipient should be monitored for a time consistent with allergist recommendation.

Off-site first dose reactions: Certain vaccine recipients will have allergic reactions to vaccine after leaving the vaccination site. They should be instructed to call the regional HUB vaccine hotline and self-report so that they can be entered into the process to ensure safe administration of their second vaccination. After a vaccine recipient contacts their respective region's vaccine hotline, the regional HUB assumes management in the same manner as for patients with on-site dose reactions.

First-dose reactions identified when the person presents to the NYS-operated MVS for their second-dose appointment: A certain number of vaccine recipients will experience a first-dose immediate allergic reaction off-site but not report the event as instructed. If an immediate allergic reaction is reported when presenting for the second dose, the vaccine recipient cannot receive a second dose at a NYS-operated MVS, and the vaccine recipient should be offered to be referred through the HUB referral process.

Referral process from a NYS MVS to a Regional HUB:

1) NYS MVS incident report will be completed.
2) CDMS Clinical Report will be updated to include summary of clinical presentation and any treatment required. Hold will be placed in CDMS and will ensure all future second dose appointments are canceled until an outcome is determined Regional MVS DOH lead or MVS Medical Lead will submit the clinical referral packet directly to HUB coordinator with a copy to the COVIDVaccineAllergyReferral@health.ny.gov BML and include all relevant documentation including the CDMS Clinical Report and VAERS report once completed.
3) Regional HUB Point of Contact will connect individual to referrals (e.g., allergist-immunologist).

a. If specialists agree that the individual should receive COVID-19 vaccination, then the administration will occur with a designated specialist in a specified setting.

Non-Allergic Reactions

In addition to referrals for documented allergic reactions, the NYS MVS may also refer vaccine recipients to their regional HUB hospital for evaluation of reactions of questionable allergic nature or unusual post-vaccination reactions not addressed by CDC guidance at the request of the MVS Medical Lead. If an allergist or other specialist consultant determines the adverse reaction not to be a contraindication or precaution to further doses of COVID-19 vaccine nor to require vaccination in a higher-level setting, then these individuals may receive second dose at a NYS-operated MVS, provided such medical documentation is given back to NYS DOH that supports this medical conclusion.