**COVID-19 Vaccine**

**Policy & Procedure when Outside Vaccine Provider Administers COVID-19 Vaccines – Residents**

**Updated 05.19.2021**

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Policy

It is the policy of this facility that when the COVID-19 vaccine becomes available, all residents unless medically contraindicated or if already immunized will be offered to receive the COVID-19 Vaccine.

When the COVID-19 Vaccine will be Administered by Partner Pharmacy or Other Vaccine Provider in the Facility:

Supplies

* Partner Pharmacy or other vaccine provider will bring all supplies for administration of the COVID-19 vaccine
* Facility will have on hand supplies/emergency equipment for managing anaphylaxis (as allowed by State):
	+ Epinephrine prefilled syringe or autoinjector (at least 3 doses on hand)
	+ H1 antihistamine
	+ Blood Pressure Cuff
	+ Stethoscope
	+ Pulse Oximeter
	+ Oxygen CPR Mask

Procedure

* 1. Infection Preventionist or designee will:
		1. Coordinate vaccination program with Partner Pharmacy or other vaccine provider
		2. Communicate to nurses, dates and times when the COVID-19 vaccine will be administered to residents
		3. Assess if resident is moderately or severely ill with or without a fever. Do not administer the COVID-19 vaccine until the resident recovers
		4. Prior to administration of the vaccine, provide education (current EAU Fact Sheet for COVID-19 Vaccine) on the risks benefits and potential side effects of the COVID-19 vaccine to the resident/resident representative.
		5. Obtain written informed consent from resident/resident representative.
			+ - Attach EAU Fact Sheet for COVID-19 Vaccine being administered to the written consent form. The resident, resident representative has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision
		6. COVID vaccines and other vaccines may be administered without regard to timing. “This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.”1
		7. TB Tests and COVID-19 vaccines:

**“**COVID-19 vaccines should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the [tuberculin skin test (TST) or an interferon release assay (IGRA)](https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm), can be done before or during the same encounter as COVID-19 vaccination. When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled”2

* + 1. Residents with active COVID-19 infection: “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](https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html) 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”2 Coordinate with primary care physician.
		2. If resident had previously received passive antibody therapy for COVID-19, defer vaccination for at least 90 days.
		3. The COVID-19 Vaccine should not be administered to a resident who has had a severe reaction or allergy to a prior dose of COVID-19 vaccine or any of its components. Contact resident physician for direction.
			- * Precautions to vaccine require physician approval for administration and include:

History of a severe reaction to any vaccine (i.e., anaphylaxis)

History of a severe allergic reaction, such as anaphylaxis, to any injectable medication

* + 1. Partner Pharmacy or vaccine provider will administer the COVID-19 Vaccine.
		2. Partner Pharmacy or vaccine provider will provide documentation of COVID-19 Vaccine Administration (date, lot #, manufacturer, expiration date, and site given) to facility and provide a vaccination card or printout to resident identifying the COVID-19 vaccine received, date and where receive.
		3. Anaphylaxis:
			- * Resident will be observed for acute anaphylactic reaction for 30 minutes following administration if they have had “a history of immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause”. All other residents will be observed for 15 minutes.
				* Early identification of anaphylaxis:
* “**Respiratory**: sensation of throat closing or tightness, stridor (high-pitched sound while breathing), hoarseness, respiratory distress (such as shortness of breath or wheezing), coughing, trouble swallowing/drooling, nasal congestion, rhinorrhea, sneezing
* **Gastrointestinal**: nausea, vomiting, diarrhea, abdominal pain, or cramps
* **Cardiovascular**: dizziness; fainting; tachycardia (abnormally fast heart rate); hypotension (abnormally low blood pressure); pulse difficult to find or “weak”; cyanosis (bluish discoloration); pallor; flushing
* **Skin/mucosal**: generalized hives; widespread redness; itching; conjunctivitis; or swelling of eyes, lips, tongue, mouth, face, or extremities
* **Neurologic**: agitation; convulsions; acute change in mental status; sense of impending doom (a feeling that something bad is about to happen)
* **Other**: sudden increase in secretions (from eyes, nose, or mouth); urinary incontinence”3
	+ - * “Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear. Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, symptoms of anaphylaxis might be more difficult to recognize in people with communication difficulties, such as long-term care facility residents with cognitive impairment, those with neurologic disease, or those taking medications that can cause sedation. Not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions”.3
		- **Protocol for Management of Anaphylaxis**
			* Facility will follow protocol for Management of anaphylaxis in accordance with State guidance, to include:
				+ Assessment of airway, breathing circulation and mentation rapidly
				+ Call 911
				+ Place resident in a supine position with feet elevated unless upper airway obstruction is present or resident is vomiting.
				+ Administration of Epinephrine per Medical Director standing order.
			* \*\*For example: “Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
			* In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector in the mid-outer thigh.
			* The maximum adult dose is 0.5 mg per dose.
			* Epinephrine dose may be repeated every 5-15 minutes as needed to control symptoms while waiting for emergency medical services. .(document and report number of doses to EMS)
			* Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.”3
			* Residents who have been determined to have had a severe allergic reaction to an mRNA COVID-19 vaccine should not receive a second dose.1
		1. Update resident vaccination record.
		2. The facility IP will set up scheduling for second dose of the COVID-19 vaccine date (if required – dependent upon the COVID-19 vaccine. If 2 doses are indicated, the resident must receive the vaccine from the same manufacturer—it cannot be interchanged).
			- * “The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:
* Pfizer-BioNTech COVID-19: 3 weeks or 21 days after the first dose
* Moderna : one month or 28 days after the first dose

**“The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]).**However**,** second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose.”1

* The Johnson & Johnson’s Janssen COVID-19 Vaccine is a one dose Viral Vector Vaccine.
	+ 1. All adverse events occurring in a resident following COVID-19 vaccinations under Emergency Use Authorization, including anaphylaxis will be reported to the Vaccine Adverse Event Reporting System (VAERS): <https://vaers.hhs.gov/>

Vaccine administration errors

Serious adverse events (AE)4

Death

A life-threatening Adverse Event

Inpatient hospitalization or prolongation of existing hospitalization

Persistent or signification incapacity or substantial disruption in the ability to conduct normal life functions

A congenital anomaly/birth defect

An important medical event that may jeopardize the individual and require medical or surgical interventions to prevent the above AE’s

Cases of Multisystem Inflammatory Syndrome

Cases of COVID-19 that result in hospitalization or death.

* + 1. The residents medical record will include documentation that indicates, at a minimum:

Education received by the resident and/or resident representative regarding the benefits, risks and potential side effects associated with the COVID-19 Vaccine (i.e., EAU Fact Sheet for COVID-19 Vaccine)

Written consent

Resident refusal

If resident did not receive COVID-19 Vaccine due to medical contraindication

The COVID-19 Vaccine(s) administered:

Location (site) of COVID-19 Vaccine administration

Manufacturer, Lot Number, Date

Side effects or COVID-19 Vaccine reactions

* + 1. IP will report the participation of resident COVID-19 vaccinations to the QAA committee.
		2. IP will report resident COVID-19 vaccinations in NHSN

**COVID-19 Vaccines Administered Outside the Facility:**

If the facility is unable to arrange COVID-19 vaccinations in the facility (i.e. unable to coordinate vaccine administration in the facility with partner pharmacy, other vaccine provider or facility is currently not an approved vaccine provider):

The Infection Preventionist will:

* 1. Work with residents and/or resident representatives to coordinate vaccination program with outside vaccine provider for:
		1. New resident admissions
		2. Residents in need of a second mRNA COVID-19 Vaccination
		3. Residents who did not receive the COVID-19 vaccination (i.e. illness)
		4. Residents who now elect to receive the COVID-19 vaccine who previously had refused
	2. Coordinate with local public health department, local pharmacies or partner health systems.
		1. Document all efforts to access COVID-19 vaccine
	3. Communicate to nurses, dates, times, location and transportation arrangements when the COVID-19 vaccine will be administered to residents
	4. Provide education (current EAU Fact Sheet for COVID-19 Vaccine) on the risks benefits and potential side effects of the COVID-19 vaccine to the resident/resident representative.
	5. Obtain written informed consent from resident/resident representative. The resident, resident representative has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision
		1. Attach EAU Fact Sheet for COVID-19 Vaccine being administered to the written consent form.
	6. Assess if resident is moderately or severely ill with or without a fever. Do not send resident for a COVID-19 Vaccine until resident recovers.
	7. The residents medical record will include documentation that indicates, at a minimum:
		1. Education received by the resident and/or resident representative regarding the benefits, risks and potential side effects associated with the COVID-19 Vaccine (i.e., EAU Fact Sheet for COVID-19 Vaccine)
		2. Written consent
		3. Resident refusal
		4. If resident did not receive COVID-19 Vaccine due to medical contraindication
		5. The COVID-19 Vaccine(s) administered:
		6. Location (site) of COVID-19 Vaccine administration
		7. Manufacturer, Lot Number, Date
		8. Side effects or COVID-19 Vaccine reactions
	8. IP will report the participation of resident COVID-19 vaccinations to the QAA committee.
	9. IP will report resident COVID-19 vaccinations in NHSN

**NOTE: If** unable to obtain an appointment for a COVID-19 Vaccine for resident(s) document all efforts to obtain vaccine. Continue to investigate vaccination opportunities.

**References and Resources**

* 1Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently authorized in the United States. Last Reviewed: May 14, 2021: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html>
* 2Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, May 14, 2021: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
* 3Centers for Disease Control and Prevention. Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination. March 3, 2021: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>
* 4Vaccine Adverse Event Reporting System (VAERS) Frequently Asked Questions (FAQs): <https://vaers.hhs.gov/faq.html>
* Centers for Disease Control and Prevention. Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities. Updated Jan. 11, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html>
* Centers for Disease Control and Prevention. COVID-19 ACIP Vaccine Recommendations. Advisory Committee on Immunization Practices (ACIP): <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>
* Centers for Disease Control and Prevention. New COVID-19 Vaccination Provider Trainings. 03/24/2021: <https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccination-provider-trainings.pdf>
* Food and Drug Administration Fact Sheet for Recipients and Caregivers. Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older, December 2020: <https://www.fda.gov/media/144414/download>
* Food and Drug Administration Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) 12/2020: <https://www.fda.gov/media/144638/download>

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