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### FAQs for Clinical Staff and Providers

#### 1) How should you counsel cancer patients who received the vaccine to protect themselves?

It is important to let your patients know that responses to the vaccine in cancer patients vary, and that data on individual types of cancer are still emerging. We know patients with hematologic malignancies do not respond as well to the vaccine as those with solid tumors, particularly:

- those receiving cytotoxic chemotherapy (e.g. cytarabine/anthracycline based regimens),
- those receiving anti-CD20 monoclonal therapies, and
- those undergoing hematopoietic cell transplant and cellular therapies.

It is important to note that data on individual chemotherapy regimens is less clear.

We recommend patients continue to:

- mask up,
- avoid crowds,
- avoid get togethers indoors with others outside their households, and
- to get tested if they develop symptoms.
- Contact their provider if they test positive

We also recommend all family, friends, and household contacts get vaccinated to prevent transmission to the patient.

#### 2) Are mRNA vaccines preferred over J&J/Janssen vaccine?

**Yes.** The Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19, expressed a clinical preference for individuals to receive a primary vaccine series with mRNA COVID-19 vaccine (Pfizer and Moderna) over Johnson & Johnson's COVID-19 vaccine. The Johnson and Johnson vaccine should only be used as a primary vaccine in individuals who are unable or unwilling to receive an mRNA vaccine. The Johnson & Johnson vaccine should not be used as a booster and moderate to severely immunocompromised people who received a Johnson and Johnson vaccine require additional doses of mRNA vaccines to complete their primary vaccine series and stay up-to-date with their boosters (see below).

### 3) What are the different recommendations for booster/additional doses based on the patient's immune status?

Please refer to the [Booster & Additional Dose Eligibility Flowsheet](#)

#### COVID-19 vaccination schedule for people with [moderate or severe immunocompromise](#)

Primary vaccination	Age group	# of primary vaccine doses	# of booster doses	Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> dose	Interval between 2 <sup>nd</sup> and 3 <sup>rd</sup> primary series dose	Interval between primary series and 1 <sup>st</sup> booster dose	Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> booster dose	Total # of doses
Pfizer-BioNTech	5–11 years	3	1	3 weeks	≥4 weeks	≥3 months	n/a	4
	≥12 years	3	2	3 weeks	≥4 weeks	≥3 months	≥4 months	5
Moderna	≥18 years	3	2	4 weeks	≥4 weeks	≥3 months	≥4 months	5
J&J/Janssen	≥18 years	2* <small>*1 J&amp;J, followed by 1 mRNA</small>	2	4 weeks	n/a	≥2 months	≥4 months	4

See COVID-19 vaccine schedule for the primary series for the general population on the next page

### COVID-19 vaccination schedule for the primary series in the general population<sup>^</sup>

Primary series vaccine manufacturer	Age group	# of doses in primary series	# of booster doses	Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> dose	Interval between primary series and 1 <sup>st</sup> booster dose	Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> booster dose	Total # of doses
Pfizer-BioNTech	5–11 years	2	1	3 weeks	≥5 months	n/a	3
	12-49 years	2	1	3 weeks	≥5 months	n/a	3
	≥50 years	2	2	3 weeks	≥5 months	≥4 months	4
Moderna	18-49 years	2	1	4 weeks	≥5 months	n/a	3
	≥50 years	2	2	4 weeks	≥5 months	≥4 months	4
J&J/Janssen	18-49 years	1	1‡	n/a	≥2 months	n/a	2‡ if primary & first booster was J&J, additional booster dose recommended; 3 total doses
	≥50 years	1	2‡	n/a	≥2 months	≥4 months‡	3‡ if primary & first booster was J&J, additional booster dose recommended; 4 total doses

<sup>^</sup>For the vaccination schedule for people who are moderately or severely immunocompromised, see table on the previous page

‡Anyone who received a J&J/Janssen COVID-19 vaccine for both their first dose and booster may receive an additional booster at least 4 months after their first booster, either Pfizer-BioNTech or Moderna COVID-19 vaccines

#### 4) Is an additional primary series dose the same thing as a booster dose?

**No.** An **Additional primary series dose** is a subsequent dose of mRNA vaccine used to complete the primary vaccine series in immunocompromised people. Immunocompromised people are more likely to mount a protective immune response if they receive an additional dose of mRNA vaccine after completing the primary vaccine series recommended for the general population.

- [Moderately to severely immunocompromised](#) people who received two doses of an mRNA vaccine should receive a third dose of mRNA vaccine to complete their primary series.

- Moderately to severely immunocompromised people who received one J&J/Janssen vaccine should receive one dose of mRNA vaccine to complete their primary series.

A **Booster dose** is a subsequent dose of vaccine administered to enhance or restore protection which might have waned over time after primary series vaccination.

- Patients  $\geq 12$  years old that are immunocompromised and received three mRNA doses as their primary series and should receive 5 doses total (3 dose primary series + booster dose at 3 months after the 3rd dose + second booster at 4 months after the 4th dose)
- Patients 5-11 that are moderately or severely immunocompromised should receive three mRNA doses as their primary series and four doses total (3 dose primary series + booster dose at least 3 months after third dose). A second booster is not currently recommended for any people aged 5-11 years old.
- Patients that are immunocompromised and vaccinated with J&J/Janssen may receive 4 doses total (1 J&J + 1 mRNA primary dose + first booster dose at 2 months after completing the primary series + second booster at 4 months after the first booster)

### 5) Who is eligible for a second booster dose? What type of vaccine is the second booster dose?

The Centers for Disease Control and Prevention (CDC) shared updated guidance for second mRNA booster doses. A second booster is recommended for the following groups:

- People aged 50 and older who are fully vaccinated and had an initial booster dose at least 4 months ago
- People aged 12 and older who are [moderately or severely immunocompromised](#), who are fully vaccinated and had an initial booster dose at least four months ago
- Adults who received Johnson & Johnson's Janssen COVID-19 vaccine and an initial booster dose at least four months ago

Only the mRNA vaccines, Pfizer-BioNTech and Moderna are approved for second booster doses. J&J/Janssen is **NOT approve** for second booster. A second booster dose is not currently recommended for people aged 5-11 who are moderately or severely immunocompromised

### 6) How does the CDC/FDA define 'immunocompromised'?

The [CDC/FDA defines immunocompromised](#) as :

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)

- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e.,  $\geq 20$ mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

The patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination, with specific attention paid to current or planned immunosuppressive therapies. The majority of cancer patients are recommended to get booster doses by the [National Comprehensive Cancer Network guidelines](#).

### **7) My patient has/had COVID-19, when can they get vaccinated?**

COVID-19 vaccination is recommended for everyone over age 5, regardless of history of COVID-19. People with known COVID-19 can get vaccinated as soon as they have recovered from acute illness and criteria for discontinuation of isolation precautions have been met.

### **8) My patient received monoclonal antibody treatment, when can they get vaccinated**

The CDC guidance indicates that people who previously received anti-SARS-CoV-2 monoclonal antibodies as part of COVID-19 treatment or pre-exposure prophylaxis (e.g. Evusheld) can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies.

### **9) Should I test a patient who is vaccinated and symptomatic (or who has had a high-risk contact)?**

**Yes.** Anyone who is vaccinated with symptoms should get have a diagnostic test for SARS-CoV-2 performed (e.g., PCR test), as despite vaccination, breakthrough infections are increasingly being seen due to currently circulating variants. Patients with cancer who are diagnosed with COVID-19 early in their disease may be eligible for treatments that reduce the risk of hospitalization or death. Getting tested as soon as possible after symptom onset or a high-risk exposure is important to ensure early diagnosis and access to potential treatments. Can symptoms develop is an important at

Depending on the time of year and other circulating viruses, testing for other community acquired viral pathogens (e.g., influenza, RSV) can be considered as well. Patients with symptoms should be seen in appropriate isolation precautions while in clinic.

**10) If patients are getting other vaccines, can they also get the COVID-19 vaccine at the same time?**

**Yes.** [Guidelines](#) allow for COVID-19 vaccines to be given with other vaccines, including influenza vaccines.

11) If a patient hasn't been vaccinated and wants to get vaccinated, what are the currently recommended vaccination guidelines?

**COVID-19 Vaccination Recommendations for Cancer Patients**

<b>Patients Treatment/Cancer Type</b>	<b>Timing</b>
<b>Hematopoietic Cell Transplantation (HCT)/Cellular Therapy</b>	
Allogeneic transplantation Autologous transplantation Cellular therapy (eg, CAR T-cell)	At least 3 months post-HCT/cellular therapy
<b>Hematologic Malignancies</b>	
Receiving intensive cytotoxic chemotherapy (eg, cytarabine/anthracycline- based induction regimens for acute myeloid leukemia)	Delay until absolute neutrophil count (ANC) recovery
Marrow failure from disease and/or therapy expected to have limited or no recovery	As soon as able
Long-term maintenance therapy (eg, targeted agents for chronic lymphocytic leukemia or myeloproliferative neoplasms)	As soon as able
<b>Solid Tumor Malignancies</b>	
Receiving cytotoxic chemotherapy	As soon as able
Targeted therapy	As soon as able
Checkpoint inhibitors and other immunotherapy	As soon as able
Radiation	As soon as able
Major surgery	Separate date of surgery from vaccination by at least a few days
<b>Caregivers and Household/Close Contacts</b>	
Encourage, as soon as able	

### **12) Should we order antibodies on patients to determine if they have responded to the vaccination?**

**No.** Currently, national recommendations don't recommend checking antibodies, as these results can be hard to interpret. A cancer patient with has a positive COVID-19 antibody, may have a level that is significantly lower than normal hosts. Lower levels may be less protective against variants (e.g. Delta), and, even if initially protective, with decay, may lose effectiveness faster than in normal hosts.

In contrast, antibody testing only addresses a component of the immune response, so a negative test cannot address important T-cell responses, which may be important in preventing COVID-19 related complications. Since antibodies can give false security and may not address full immune responses, we don't recommend them at this time. NCCN guidelines are also consistent with this recommendation. Outside of research studies, antibody testing is not recommended to guide decision-making about need for a booster and should not be obtained following the booster dose. Instead, it is important that all patients be educated to mask up, avoid crowds, avoid get togethers indoors with others outside their households, and to get tested if they develop symptoms. They should also strongly encourage family, friends, and household contacts to get vaccinated.

### **13) How do I counsel patients who have had antibody testing that returned negative?**

Many patients are seeking antibody testing and some may either have them ordered within the SCCA or through outside providers. There is significant concern for many of these patients that they remain unprotected. Having a poor antibody response is concerning, so it is important to validate their concerns. However, antibody testing is only part of the immune response to vaccines, so a negative test cannot address important T-cell responses, which may be important in preventing COVID-19 related complications.

For patients who have not received a booster, encourage this additional dose if appropriate. We continue to recommend that the addition of other mitigation strategies to prevent potential exposures, including masking, avoiding crowds, etc. (see above questions). Vaccinating close contacts is a crucial step to protecting themselves as household transmission is one of the highest risk exposures for patients – and more likely to lead to illness than sporadic community exposures.

Anyone who is vaccinated with symptoms should get have a diagnostic test for SARS-CoV-2 performed (e.g., PCR test), as despite vaccination, breakthrough infections are increasingly being seen due to currently circulating variants. Since cancer patients are less likely to have a robust response, getting tested is key to early diagnosis.

### **14) Should patients who received COVID-19 vaccines prior to a hematopoietic cell transplant or CAR-T cell therapy be revaccinated?**

**Yes.** Revaccination is defined as repeating a dose(s) of vaccine. Recipients of HCT or CAR-T-cell therapy who received one or more doses of COVID-19 vaccine prior to or during treatment should be revaccinated after treatment (i.e., complete primary vaccination and any recommended additional or booster doses) Any revaccination doses should be given with an mRNA vaccine, regardless of vaccine administered for initial vaccination, and should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. A patient's clinical team is best positioned to determine the degree of immune compromise, need for revaccination, and appropriate timing of revaccination.

### **15) Where can I find additional clinical information about COVID-19 Vaccines?**

[CDC's Clinical Considerations for Use of COVID-19 Vaccines:](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

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