

## Recommendations of the National Comprehensive Cancer Network® (NCCN®) Advisory Committee on COVID-19 Vaccination and Pre-exposure Prophylaxis\*

- The committee endorses vaccination for all eligible persons based on FDA-approved indications or emergency use authorization (EUA).
- The committee prefers the use of mRNA vaccines for the primary series and boosters.
- Specified immunocompromised individuals are recommended to receive 3 doses for their primary vaccination series, plus an additional 2 booster doses.
- Most patients with cancer can receive COVID-19 vaccination as soon as possible, regardless of their cancer treatment, with the exceptions to consider in Table 1. Vaccine delays in patients with cancer should also include those recommended by the [CDC](#) for the general public (eg, recent exposure to COVID-19).
- COVID-19 vaccinations can be given without regard to timing of other vaccines.
- Revaccination (of the 3-dose primary series and booster) is recommended 3 months following HCT or CAR T-Cell Therapy, if a patient was vaccinated before such therapy.
- Pre-exposure prevention with tixagevimab plus cilgavimab is recommended for specified immunocompromised individuals (including all persons undergoing active cancer therapy); however, it is not a substitute for vaccination.
- COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies, including prophylactic tixagevimab plus cilgavimab.

**Table 1. Unique COVID-19 Vaccination Timing Considerations for Selected Patients with Cancer**

All patients should otherwise receive their vaccination as soon as possible

<b>Patients Treatment/Cancer Type</b>	<b>Timing to Start Series</b>
<b>Hematopoietic Cell Transplantation (HCT)/Cellular Therapy</b>	
Allogeneic/autologous transplantation Cellular therapy (eg, CAR T cell)	At least 3 months post-HCT/cellular therapy <sup>a</sup>
<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 <sup>b</sup> or for those not expected to recover, as soon as possible
<b>Solid Tumor Malignancies</b>	
Major surgery	Separate date of surgery from vaccination by at least a few days <sup>c</sup>

a) Graft-versus-host disease (GVHD) and immunosuppressive regimens to treat GVHD (eg, systemic corticosteroids and targeted agents) are expected to blunt immune responses to vaccination. Delay of vaccination until immunosuppressive therapy is reduced and/or based on immunophenotyping of T-cell and B-cell immunity can be considered.

b) The committee recognized that granulocytopenia does not, in itself, significantly affect immunologic response to vaccination. It is used in the setting of profound immunosuppression for patients with hematologic malignancies as a surrogate marker for recovery of adequate immunocompetence to response to vaccines.

c) The primary reason for avoiding vaccine in the perioperative period is so that symptoms (eg, fever) can be correctly attributed to surgery versus vaccination. For more complex surgeries (eg, splenectomy or which may lead to an immunosuppressive state), surgeons may recommend a wider window (+/- 2 weeks) from the time of surgery.

**ADDITIONAL PRIMARY SERIES VACCINE DOSE:**

The FDA issued an update to the EUA for the BNT162b2 (Pfizer/BioNTech) mRNA vaccine (Comirnaty®) and the mRNA-1273 (Moderna) mRNA vaccine to include an additional dose after an initial 2-dose series for moderately to severely immunocompromised patients. The amendment applies to mRNA COVID-19 vaccines and was based on a growing body of literature showing that immunocompromised patients can have impaired immune responses to vaccination. Limited data in solid organ transplant recipients show a substantial effect of an additional dose in augmenting antibody responses to vaccination after completion of a 2-dose series.<sup>1</sup> The additional primary dose of an mRNA COVID-19 vaccine is intended to improve immunocompromised people's response to their primary vaccine series.

The CDC recommends a third dose of the mRNA vaccines for moderately to severely immunocompromised people, defined as:

- Those who have been receiving active cancer treatment for tumors or cancers of the blood
- Those who have received an organ transplant and are taking medicine to suppress the immune system
- Those who have received an HCT within the last 2 years or are taking medicine to suppress the immune system
- Those with moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Those with advanced or untreated HIV infection
- Those on active treatment with high-dose corticosteroids or other drugs that may suppress immune response

The NCCN Committee fully supports a third dose for immunocompromised patients. Below, we provide consensus recommendations on patients with cancer who should be prioritized for a third dose.

- a) Solid tumor malignancies:** We recommend a third dose for patients who received cancer therapy within 1 year of the initial vaccine administration. Realizing that specific therapies have different effects on the immune system, this recommendation applies to all cancer therapies, including but not limited to chemotherapy, targeted therapy, immunotherapy, hormonal therapy, surgery, radiation, and investigational agents. These criteria do not apply to non-melanoma skin cancers or superficial mucosal lesions treated solely with local therapy. In addition, patients with newly diagnosed cancer or recurrent cancer who will receive cancer therapy are included among patients prioritized for a third dose.
- b) Hematologic malignancies:** We recommend that all patients with active hematologic malignancies receive a third dose regardless of whether they are receiving cancer therapy. The reason for this recommendation is that patients with hematologic malignancies are at high risk for poor serologic responses to vaccination both as a result of immunodeficiency due to the malignancy and their associated cancer therapies (eg, B-cell-depleting agents such as anti-CD20 antibodies and Bruton tyrosine kinase inhibitors).<sup>2-10</sup> As examples, patients with Hodgkin and non-Hodgkin lymphoma, chronic lymphocytic leukemia, multiple myeloma, myelodysplastic syndrome, or chronic myeloproliferative neoplasms should be prioritized for a third dose even if not on active therapy for these malignancies.
- c) Hematopoietic cell transplant and cellular therapy:** We recommend a third dose in HCT recipients and those who received engineered cellular therapy (eg, CAR T cells), prioritizing those who are ≤2 years post-procedure. A third dose is recommended for all allogeneic HCT recipients who are actively receiving immunosuppressive therapy or with a history of GVHD regardless of the time post-transplant.

- d) **Cancer and other immunosuppressive conditions that do not meet other criteria:** We recommend a third dose for patients with cancer who have other concurrent immunocompromising conditions, such as HIV infection or autoimmune diseases. In addition, patients with cancer treated with systemic corticosteroids and other immunosuppressive agents separate from cancer therapy should be prioritized for a third dose.

**Timing of Administration of Third Primary Series Dose:**

The CDC recommends the additional dose of an mRNA COVID-19 vaccine (for immunocompromised individuals) be administered 4 weeks after a second dose of the BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) vaccine. A detailed timing schedule can be found on the [CDC's website](#)<sup>63</sup>. For people who received the BNT162b2 (Pfizer/BioNTech) or mRNA-1273 (Moderna) COVID-19 vaccine series, a third dose of the same mRNA vaccine should be used if possible. If the same mRNA vaccine isn't available for the third dose administration or if the prior vaccine is unknown, either mRNA COVID-19 vaccine may be used.

- We do not recommend (outside of a research study) the use of antibody titers to determine if patients should receive additional doses of vaccine.
- Selection of patients with cancer to receive a third dose and additional booster should be made based on the underlying cancer, therapy, and other immunocompromising conditions.
- Patients who have a history of COVID-19 following their initial vaccine series should also receive a third dose (delayed >28 days post completed vaccine series and until recovery from the acute illness [if symptoms were present] and criteria to discontinue isolation have been met).

**VACCINE BOOSTERS:**

A booster is administered when a person has completed their vaccine primary series to augment immune responses that may have decreased over time. The CDC's recommendation on third dose vaccine administration for immunocompromised patients (full dose for both mRNA vaccines – 100 ug mRNA-1273 and 30 ug BNT162b2) was soon followed by a recommendation for booster vaccines for the general public. For the general public, the first booster is administered at least 5 months after completing the primary vaccine series; for patients with cancer and other immunocompromised persons, the first booster (fourth vaccine dose) may be administered sooner, as soon as 3 months after the primary series. The rationale for a booster is the reduction of vaccine effectiveness over time that is likely due to waning immunity and the greater infectiousness of the Delta variant and more recently the Omicron variants. In the case of the mRNA-1273 (Moderna) COVID-19 vaccine booster dose, the booster is half the dose of that given for the primary series. Boosting with the BNT162b2 (Pfizer/BioNTech) vaccine reduced COVID-19 incidence and severe illness, including mortality.<sup>48-50</sup> Among patients with a history of cancer, those who do not meet the criteria to receive a third primary series vaccine dose should be offered a booster similar to the general population at least 5 months after completion of their primary series. Specific guidance for pediatric patients is included in [CDC guidelines](#).

The CDC recommends a second booster with an mRNA COVID-19 vaccine for all adults 50 years and older. This recommendation for a second booster (fourth vaccine dose) was based on recent waves of the Omicron variants and data from Israel showing a reduction in rates of SARS-CoV-2 and severe COVID-19 after the second booster was administered to persons 60 years and older.<sup>58-59</sup> An mRNA COVID-19 vaccine is preferred as the first booster, while the second booster must be an mRNA vaccine. The NCCN Committee supports the recommendation for a second booster based on age.

Additionally, CDC guidelines state that immunocompromised persons who may be younger than 50 (but  $\geq$  12 years old) can choose to receive a second booster (fifth dose) of an mRNA vaccine at least 4 months after the first booster. Due to the waves of Omicron subvariants we continue to experience and the excess morbidity and mortality of COVID-19 among patients with cancer, the NCCN Committee endorses the CDC

guidelines for a second booster for patients with cancer. Further, we recommend a second booster for all patients with hematologic malignancies regardless of whether they are on active therapy. The same advice applies to patients who received stem cell transplantation or engineered cellular therapy within the past 2 years or who are receiving immunosuppressive agents. Although patients with solid tumors are more likely to mount immune responses to vaccination, we recommend a second booster for patients who received cancer therapy within 1 year of the initial vaccine administration.

For patients receiving immune checkpoint inhibitors (ICI), the data show that mRNA COVID-19 vaccines are safe<sup>60</sup>. Further, the committee considered the risk of severe COVID-19 (including cardiac complications) to be greater than the potential risk of a fifth vaccine dose, and therefore recommends the second booster for these patients.

### **Johnson & Johnson Vaccine as initial single-dose primary vaccination**

In most situations, the mRNA vaccines (Pfizer-BioNTech or Moderna) are preferred over the JNJ-78436735 (Janssen/Johnson & Johnson) vaccine after reports of thrombosis with thrombocytopenia syndrome among Johnson & Johnson vaccine recipients<sup>57</sup>. All people ages 12 years and older should receive 1 booster dose of a COVID-19 vaccine, preferably an mRNA vaccine, at least 2 months after the primary JNJ-78436735 (Janssen/Johnson & Johnson) vaccine. People who are 50 years or older may choose to receive a second booster dose at least 4 months after the first booster. For immunocompromised patients who receive an initial JNJ-78436735 (Janssen/Johnson & Johnson) dose, the primary series should include a second dose of an mRNA vaccine one month later.

In updated guidelines, the CDC stated that moderately or severely immunocompromised persons 18 years and older who received the 1-dose JNJ-78436735 followed by an mRNA vaccine to complete the primary series and a subsequent mRNA vaccine booster can choose to receive a second booster of an mRNA vaccine at least 4 months after the first booster<sup>61</sup>. For the first booster, an mRNA vaccine is preferred in most situations, while the second booster must be an mRNA vaccine. Unless there is a contraindication to an mRNA vaccine, the NCCN Committee recommends that immunocompromised patients receive an mRNA vaccine for both the first and second boosters.

### **Mix and Match Dosing**

Heterologous prime–boost strategies, in which the booster is a different formulation than the vaccine used in the primary series, has the potential to extend immune protection and could simplify the logistics of vaccine administration if the selection of the booster formulation is not restricted to the vaccine used in the primary series (homologous booster). Initial data from the phase 1–2 study showed that heterologous boosters were safe and immunogenic in adults who had completed a primary Covid-19 vaccine regimen at least 12 weeks earlier.<sup>47</sup> A heterologous booster resulted in similar or higher antibody responses than a homologous booster. Based on initial data from this study, the FDA has authorized the use of heterologous boosters for currently available COVID-19 vaccines. The NCCN Committee considers both homologous and heterologous boosters to be appropriate options.

Moderately or severely immunocompromised people who received COVID-19 vaccines not available in the United States should either complete or restart the recommended COVID-19 vaccine series, including boosters, in the United States. The CDC provides detailed guidelines on specific scenarios for persons who received a COVID-19 vaccine listed for emergency use by the WHO, but not approved or authorized by the FDA.<sup>62</sup>

### **Revaccination Following HCT or CAR T-Cell Therapy:**

In patients who received COVID-19 vaccination prior to HCT or engineered cellular therapy, there is major concern for loss of immunity. Loss of vaccine-induced immunity following these therapies is observed in

several childhood vaccines (eg, measles, mumps, and rubella vaccine), necessitating re-vaccination post-therapy. The same depletion of immunity is expected for COVID-19 vaccines. These patients are expected to have attenuated responses to COVID-19 vaccination post-transplant, particularly in the setting of GVHD. In addition, lymphodepletion prior to CAR T-cell and other cellular therapy regimens is expected to attenuate post-therapy immune responses to vaccination.<sup>51</sup> Recognizing these limitations, the CDC, American Society for Transplantation and Cellular Therapy (ASTCT), and American Society of Hematology (ASH) recommend that patients completing these therapies should receive a repeat vaccination series (3 dose primary series and booster) starting at 3 months post-treatment. We support these recommendations. As we learn more about vaccine-induced immunity in these settings, these recommendations on revaccination may be modified.

**Prioritization if Local Supply Issues Occur:**

The above recommendations for a third dose and boosters are based on adequate vaccine supply, which is the case in the vast majority of regions in the United States. With adequate supply, we strongly endorse that patients with cancer who meet these eligibility criteria obtain the third dose and boosters where available and most convenient, including at local pharmacies, but would also prioritize allocation to cancer centers to assure ease of distribution to high-risk patients. In situations of limited vaccine availability, individual cancer centers and oncologists may need to prioritize a third dose to those patients who are least likely to respond to the standard two-dose series, such as:

- a) HCT/cellular therapy recipients
- b) Patients with hematologic malignancies on active therapy
- c) Patients with solid tumor malignancies receiving active intravenous chemotherapy

**OVERVIEW:**

Large cohort studies have demonstrated that patients with cancer are at high risk for COVID-19–associated complications.<sup>11-14</sup> As an at-risk population, there is a clear need for vaccinating these patients to avoid excess morbidity and mortality during the SARS-CoV-2 pandemic. In addition, since immunosuppressed patients may be sources of prolonged viral shedding and development of variants,<sup>15,16</sup> prioritizing vaccinations to these vulnerable patients may provide an additional societal benefit. Individuals with active cancer or with active, recent (<6 months), or planned cancer treatment should be considered highest priority to receive one of the currently available COVID-19 vaccines.<sup>17-19</sup> This document, while focusing on approved vaccines in the United States, can also be used to support vaccination approaches in patients with cancer using vaccines approved in other parts of the world.

The NCCN Committee recommends that COVID-19 vaccines should be given to all patients with cancer, as well as household contacts and caregivers; the committee believes that mRNA vaccines should be offered as the preferred vaccine(s). Data from vaccine trials have demonstrated that vaccines decrease the incidence of COVID-19 disease and complications, and data suggest that these vaccines may additionally prevent SARS-CoV-2 infection and subsequent risk of transmission.

***Due to emerging data relating to vaccination efficacy in patients with active malignancy, recommendations are based on the expert opinion of the committee; as data continue to become available, our approach will be modified accordingly.*** Decisions about when to offer COVID-19 vaccines should also take into account the National Academies of Sciences, Engineering, and Medicine (NASEM) Framework for Equitable Allocation of COVID-19 Vaccine that includes: risk of infection, severe morbidity and mortality, excess burden of COVID-19 on specific communities, and transmission to others.<sup>20</sup>

**VACCINE SAFETY AND EFFICACY IN PATIENTS WITH CANCER:**

Patients with cancer should be counseled that although these vaccines have been shown to be safe and effective in the general population, data on their effectiveness in immunosuppressed patients are emerging. The data on COVID-19 vaccine immunogenicity are mostly limited to measurement of post-vaccine antibody titers to the viral spike protein. Still, early data have demonstrated blunted antibody responses in patients with solid tumors and hematologic malignancies, particularly patients on active treatment;<sup>34-38</sup> data among other immunosuppressed populations also indicate more limited antibody responses.<sup>39</sup> Antibody responses are particularly poor among patients with hematologic malignancies, including those receiving monoclonal antibodies targeting CD20 and CD38 (eg, rituximab, daratumumab, isatuximab). Antibody responses should be interpreted with caution, as they are only a surrogate marker for vaccine protection. Some studies have demonstrated additional T-cell responses to vaccination,<sup>40</sup> although the strength and duration of neutralizing antibody responses or cellular immunity are not known at this point. Importantly, outcomes data (eg, COVID-19 disease, hospitalization, death) among fully vaccinated patients with cancer are not available.

There are no safety signals that suggest adverse events specifically among patients with cancer receiving currently available COVID-19 vaccines, although rare case reports have been reported in cancer populations.<sup>41</sup> Current SARS-CoV-2 mRNA vaccines (eg, Pfizer/BioNTech, Moderna) do not contain live virus and do not pose an immediate safety risk for immunosuppressed patients. The available single-dose SARS-CoV-2 viral vector (Adenovirus-type 26 [AdV-type 26]) vaccine (Janssen/Johnson & Johnson) is safe for use in immunosuppressed hosts, as the adenovirus vector has been modified to make it replication incompetent.<sup>21</sup> Although other vaccines are currently available in other parts of the world (eg, Astra-Zeneca COVID-19 vaccine, Sputnik [AdV-type 26, AdV-type 5 vaccine], Covaxin [killed whole virus vaccine with adjuvant], Sinovac [killed whole virus vaccine]), they are not currently available for use in the United States.

All three available vaccines (in the United States) have been shown to be safe in the general population, although post-vaccination arm soreness, fatigue, fever, and headache, among other side effects are not uncommon.<sup>17-19</sup> Short-term safety of the BNT162b2 (Pfizer/BioNTech) mRNA COVID-19 vaccine in patients with cancer treated with immune checkpoint inhibitors has been reported.<sup>33</sup> Anaphylaxis has been reported with both mRNA vaccines, although incidence is very low, ranging from 2.5 to 4.9 cases per million doses administered<sup>22</sup>; severe allergic responses have also been reported with the AdV-type 26 vector vaccine.

Although more data are required to evaluate the safety of COVID-19 vaccination in patients with cancer including those receiving immunotherapy, targeted regimens, and investigational therapies, the results so far show an acceptable safety profile of COVID-19 vaccination.

**Post-vaccine thrombosis:** The available single-dose SARS-CoV-2 viral vector (AdV-type 26) vaccine (Janssen/Johnson & Johnson) has been associated with an exceedingly rare risk of thrombosis with low platelets after vaccination (Thrombosis with Thrombocytopenia syndrome [TTS]); similar findings have been linked to the Astra-Zeneca (AdV-type 26) vaccine.<sup>42</sup> The mechanism that causes TTS is not fully understood. To date there have been no associations between TTS and patients with cancer, but patients who have a history of heparin-induced thrombocytopenia and/or thrombosis should be counseled to receive another vaccine.

**Post-vaccine lymphadenopathy and imaging studies in patients with cancer:** Reactive lymphadenopathy has been reported in up to 16% of patients following COVID-19 vaccination with the mRNA

(Pfizer/BioNTech, Moderna) vaccines; this side effect has not been reported to date with the AdV-type 26 vector vaccine (Janssen/Johnson & Johnson).<sup>23-25</sup> To reduce the number of unwarranted biopsies, several reports with guidance on imaging studies have been published. Vaccination history and site of injection should be included in medical history to provide the radiologists with the clinical background for accurate interpretation. The Society of Breast Imaging recommends consideration of scheduling screening breast imaging 4 to 6 weeks following the completion of the COVID-19 vaccination, when possible.<sup>26</sup> Unilateral lymphadenopathy noted on chest CT may likely be reactive following the vaccine unless it persists beyond 6 weeks following the second dose of the vaccine<sup>27</sup>; abnormal FDG uptake with PET scanning has also been reported.<sup>28</sup> With the currently available data, we recommend delay of imaging studies by 4 to 6 weeks following the COVID-19 vaccine if it will not result in a delay that will affect patient outcomes. For patients whose scans cannot be delayed in relation to the vaccination, careful consideration of the clinical context should be made by the treating oncologists and radiologists when interpreting the imaging studies. For patients who have a history of breast cancer, the vaccine should be administered in the contralateral arm whenever possible.

#### **IMPORTANCE OF COVID-19 VACCINATION AMONG PATIENTS WITH CANCER, THEIR HOUSEHOLD MEMBERS, AND THE GENERAL POPULATION:**

Patients with cancer face two major obstacles regarding vaccination: lack of effective immune responses due to their underlying disease and/or therapy; and vaccine hesitancy in the general population that impedes the development of herd (community) immunity. Emerging data demonstrate that certain patients with cancer (eg, those receiving B-cell-depleting agents) may not have protective antibody titers following vaccination. Although we strongly continue to recommend that these patients be immunized because the vaccine may confer some protection against COVID-19, the most effective protection for specific immunocompromised patients with cancer is likely to be through a reduction of community spread of SARS-CoV-2 by widespread vaccination. **We also note the particular importance for eligible household members and other close contacts of patients with cancer to be immunized.** Additionally, the committee strongly supports vaccination mandates for health care workers (see [statement](#)).

***Vaccination of patients with cancer enrolled/planning to enroll in clinical trials:*** Patients currently being treated on clinical trials, or considering enrollment on a clinical trial should not defer COVID-19 vaccination, or be ineligible for enrollment or continuation on a clinical trial because of COVID-19 vaccination, unless there is a specific scientific contraindication. The same should apply to COVID-19 antibody treatment. Clinical trials currently ongoing or nearing initiation should allow for COVID-19-related interventions without excluding candidacy or ongoing participation. The COVID-19 and Cancer Clinical Trials Working Group also recommended that patients with cancer enrolled in clinical trials be prioritized for COVID-19 immunization, which should not affect clinical trial eligibility.<sup>44</sup>

#### **SOCIETAL CONSIDERATIONS:**

It is imperative that all patients have equitable access to the vaccines. The NASEM guidelines have recommended the incorporation of social vulnerability indices to mitigate health inequities that have clearly arisen during the COVID-19 pandemic.<sup>20</sup> Notably, similar to the general non-cancer population, Black/African American, Hispanic/Latino, and Native American patients with cancer have been observed to have increased risk of developing COVID-19.<sup>30</sup> Consequently, we encourage health systems to incorporate social vulnerability markers tailored to their populations to address the myriad of health inequities that have arisen during this pandemic.<sup>31</sup> In addition, patients who may not have access to electronic health record platforms or email should be considered when vaccine invitation and scheduling

are being operationalized. Special efforts should also be made to engage and incorporate those patients with limited English proficiency. Finally, health systems are encouraged to collect—to the extent possible—both race-ethnic and socioeconomic data for patients who receive the vaccine, so that these data can be periodically reviewed, and if inequities develop, aggressively addressed.

**POST-VACCINE PREVENTION:**

The committee strongly recommends continued vigilance for patients with cancer after completion of COVID-19 vaccination. As patients with cancer are at increased risk for COVID-19 complications and may have less protection from available vaccines, patients should continue to wear masks, maintain social distancing, avoid crowds, and follow guidelines and other pre-vaccine recommendations for COVID-19 prevention. Efforts to protect patients should also expand to families, caregivers, and household contacts, where targeted vaccination approaches can help assure patients are less likely to acquire SARS-CoV-2 from those closest to them.<sup>45</sup>

**PRIORITIZATION AMONG PATIENTS WITH CANCER IN SETTINGS OF LIMITED VACCINE AVAILABILITY:**

Vaccine supply is currently not an issue in the United States. COVID-19 vaccine availability varies in different regions of the world, and limitations exist in ability to vaccinate large populations efficiently (eg, rural vs. urban communities). These realities may still necessitate prioritization of an order in which patients with cancer are offered immunization. This prioritization must be as evidence-based but also as value-based as possible; even so, debate and disagreements exist. In situations of vaccine shortage, risk factors for COVID-19–related morbidity and mortality (eg, advanced age, chronic lung disease, cardiovascular disease) and cancer-specific factors should be considered in prioritization. Those with active cancer and/or therapy should be prioritized over those who completed therapy and those without evidence of disease. For those addressing shortages, the committee cannot issue a recommendation on prioritization based on chemotherapy, surgery, radiation, targeted therapy, or immunotherapy; however, patients without active cancer who are only receiving hormonal therapy should have lower prioritization.

Prioritization is challenging to develop when considering the diverse population of patients with their varied comorbidities, demographic and social factors known to increase risk of COVID-19 acquisition, morbidity, and/or mortality. The following criteria can be used to help determine local guidance to consider when developing such decisions:

1. Prioritize patients with active cancer on treatment (*including HCT and cellular therapy*), those planned to start treatment, and those immediately (<6 months) post-treatment, except those receiving only hormonal therapy.
2. Consider additional risk factors for such patients and other factors linked to adverse COVID-19 complications including, but not limited to:
  - a. Patients with advanced age (eg, ≥65 years of age)
  - b. Patients with comorbidities (eg, chronic pulmonary, cardiovascular, or renal disease)
  - c. Social and demographic factors that include poverty, limited access to health care, and underrepresented minorities

**PRE-EXPOSURE PROPHYLAXIS:**

COVID-19 vaccination is a form of pre-exposure prophylaxis; the vaccination is designed to induce immune responses to prevent or diminish the severity of COVID-19 following a subsequent exposure to SARS-CoV-2. With the predominance of variant strains, vaccination remains the most effective approach to avert serious COVID-19 complications, including hospitalization and mortality. However, a major gap in vaccination is that many immunocompromised persons develop inadequate immune responses to

available COVID-19 vaccines. This gap in protection is addressed by a combination of vaccination that induces host responses directed against the spike protein (both humeral and cellular) and passive immunotherapy that confers protection independently of host immune responses.

Tixagevimab co-packaged with cilgavimab (Evusheld) is a long-acting monoclonal antibody combination directed against the spike protein. Tixagevimab plus cilgavimab was effective as prophylaxis in patients at risk for COVID-19 complications. In an ongoing phase 3 trial, adults with an increased risk of an inadequate response to COVID-19 vaccination, an increased risk of exposure to SARS-CoV-2, or both were enrolled.<sup>64</sup> Of the 5,197 subjects, 77.5% had baseline comorbidities or characteristics associated with an increased risk for severe COVID-19 (eg, obesity, diabetes, cardiovascular disease); a limitation in applying results to patients with cancer is that only 7.4% had cancer, and only 3.3% received immunosuppressive medications. Symptomatic COVID-19 occurred in 8 of 3441 participants (0.2%) in the tixagevimab plus cilgavimab group versus 17 of 1731 participants (1.0%) in the placebo group; extended follow-up at a median of 6 months showed a relative risk reduction of 82.8%. Adverse event frequency was similar in tixagevimab plus cilgavimab and placebo groups. The safety and effectiveness of tixagevimab plus cilgavimab continue to be evaluated. Early data suggest that tixagevimab plus cilgavimab maintains at least partial efficacy against Omicron variants including BA.2, and could provide additional protection for high-risk patients.

The FDA issued an EUA for tixagevimab plus cilgavimab for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals ( $\geq 12$  years of age weighing at least 40 kg) who have moderate to severe immune compromise and may not mount an adequate immune response to COVID-19 vaccination. Importantly, pre-exposure prevention with tixagevimab plus cilgavimab, however, is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended, so efforts to assure vaccination remain important.<sup>54</sup> Per the EUA, medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:<sup>55-56</sup>

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR T-cell therapy or HCT (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (eg, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection

The revised dose in the U.S. is an initial dose of 300mg of tixagevimab and 300mg of cilgavimab, delivered in two consecutive, sequential intramuscular (IM) injections. The previous dosage regimen of 150mg IM each of tixagevimab and cilgavimab was increased based on data on the *in vitro* neutralizing activity against the Omicron BA.1 and BA.1.1 subvariants.

The supply of tixagevimab plus cilgavimab is limited, but availability is improving. The U.S. Department of Health and Human Services is allocating product as it becomes available from the manufacturer, and individual states are distributing based on supplies and needs. Similar to the time when COVID-19 vaccine availability was limited, cancer centers must make difficult decisions about prioritizing which patients should be offered tixagevimab plus cilgavimab first. Patients with hematologic malignancies (including HCT and those receiving engineered cellular therapy) are more likely to have inadequate responses to COVID-19 vaccination and are at highest risk of major COVID-19 complications. The committee agreed that a reasonable option is to prioritize these patients for tixagevimab plus cilgavimab. In addition, centers should make efforts to assure equitable distribution of the drug when delivering their allocation. Some centers may choose to use vaccination or antibody status to help determine allocation, targeting those with poor

responses first. The committee remained agnostic on the use of antibody levels to determine priority, and such decisions should be determined at the local level until additional data become available.

By contrast, most patients with solid tumors are likely to respond to COVID-19 vaccination. These patients should be strongly recommended to receive third doses and boosters as the primary mode of prevention and those on active therapy should be offered tixagevimab plus cilgavimab when supply is available. Since tixagevimab plus cilgavimab is administered by deep IM injection, center-based policies regarding dosing in patients with thrombocytopenia or on anticoagulation should be followed.

To avoid interference with vaccine-induced immunity, tixagevimab plus cilgavimab should be administered at least 2 weeks after COVID-19 vaccination. Based on current CDC guidelines, COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies, including prophylactic tixagevimab plus cilgavimab. In the specific case of HCT and cellular therapy recipients, the prior administration of tixagevimab plus cilgavimab has the potential to reduce the efficacy of post-transplant/cellular therapy re-vaccination, but the extent of this effect (if any) is unknown. Knowing these limitations, the committee recommends the use of tixagevimab plus cilgavimab in these high-risk patients as soon as supply is available, and to re-vaccinate HCT and cellular therapy recipients according to the time-line described in the section on **Revaccination Following HCT or CAR T-Cell Therapy**.

\*The current vaccine recommendations and prioritization guidelines will be updated regularly based on availability of new data. There are important gaps in knowledge on vaccine immunogenicity in specific patients with cancer and therapies. We will learn more about specific therapies that limit vaccine efficacy and would warrant vaccine delay. The durability of vaccine protection is being investigated in the general population and is shown to be attenuated in immunocompromised patients with cancer.

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# NCCN Advisory Committee on Covid-19 Vaccination and Pre-exposure Prophylaxis

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**\*Steven Pergam, MD, MPH (Co-Leader)**

Infectious Disease  
Fred Hutchinson Cancer Research Center/  
Seattle Cancer Care Alliance

**\*Lindsey Robert Baden, MD (Co-Leader)**

Infectious Disease  
Dana-Farber/Brigham and Women's  
Cancer Center

**\*Brahm Segal, MD (Co-Leader)**

Infectious Disease  
Roswell Park Comprehensive Cancer Center

**\*Gregory Abel, MD, MPH**

Medical Oncology, Ethics  
Dana-Farber/Brigham and Women's  
Cancer Center

**Kerin Adelson, MD**

Medical Oncology  
Yale Cancer Center/Smilow Cancer Hospital

**\*Craig Bunnell, MD, MPH, MBA**

Medical Oncology  
Dana-Farber/Brigham and Women's  
Cancer Center

**\*Natalie Callander, MD**

Hematology Oncology  
University of Wisconsin  
Carbone Cancer Center

**\*Sanjeet Dadwal, MD**

Infectious Disease  
City of Hope National Medical Center

**John Glaspy, MD**

Hematology Oncology  
UCLA Jonsson Comprehensive Cancer  
Center

**\*Ayad Hamdan, MD**

Hematology  
UC San Diego Moores Cancer Center

**Aparna Hegde, MD**

Hematology Oncology  
O'Neal Comprehensive Cancer Center at UAB

**James Helstrom, MD, MBA**

Surgical Oncology  
Fox Chase Cancer Center

**Paul Hendrie, MD, PhD**

Hematology  
Fred Hutchinson Cancer Research Center/  
Seattle Cancer Care Alliance

**Ephraim Hochberg, MD**

Hematology Oncology  
Massachusetts General Hospital  
Cancer Center

**Carol Ann Huff, MD**

Hematology Oncology  
The Sidney Kimmel Comprehensive  
Cancer Center at Johns Hopkins

**Michael Hurwitz, MD, PhD**

Medical Oncology  
Yale Cancer Center/Smilow Cancer Hospital

**Matt Kalaycio, MD**

Hematology Oncology  
Case Comprehensive Cancer Center/  
University Hospitals Seidman Cancer Center and  
Cleveland Clinic Taussig Cancer Institute

**Robert Keenan, MD, MMM**

Surgical Oncology  
Moffitt Cancer Center

**\*Nikhil I. Khushalani, MD**

Medical Oncology  
Moffitt Cancer Center

**Robert McWilliams, MD**

Medical Oncology  
Mayo Clinic Cancer Center

**\*Sirisha Narayana, MD**

Internal Medicine, Ethics  
UCSF Helen Diller Family  
Comprehensive Cancer Center

**William Nelson, MD, PhD**

Medical Oncology  
The Sidney Kimmel Comprehensive  
Cancer Center at Johns Hopkins

**\*Esperanza Papadopoulos, MD**

Hematology Oncology  
Memorial Sloan Kettering Cancer Center

**Thomas Prebet, MD, PhD**

Hematology  
Yale Cancer Center/Smilow Cancer Hospital

**\*Gregory Riely, MD, PhD**

Medical Oncology  
Memorial Sloan Kettering Cancer Center

**\*Jennifer Saullo, MD**

Infectious Disease  
Duke Cancer Institute

**Sumit Shah, MD, MPH**

Medical Oncology  
Stanford Cancer Institute

**Lawrence Shulman, MD**

Medical Oncology  
Abramson Cancer Center at the  
University of Pennsylvania

**John Sweetenham, MD**

Hematology Oncology, Internal Medicine  
UT Southwestern Simmons  
Comprehensive Cancer Center

**\*Holly Tabor, PhD**

Ethics  
Stanford Medicine

**\*Tina Q. Tan, MD**

Pediatric Infectious Disease  
Northwestern Medicine  
Ann & Robert H. Lurie  
Children's Hospital of Chicago

**Ronald Walters, MD, MBA, MHA**

Medical Oncology  
The University of Texas  
MD Anderson Cancer Center

**\*Andrea Zimmer, MD**

Infectious Disease, Internal Medicine  
University of Nebraska Medical Center

**NCCN**

**\*Robert W. Carlson, MD**

**\*Wui-Jin Koh, MD**

Jessica Sugalski, MPPA

*\*Writing Committee*