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## COVID-19 Vaccination, Treatment Recommendations and Special Considerations for Gynecologic Cancer Patients

*\*Disclaimer – The information outlined below is based on review of the literature and is meant to guide health care providers who treat patients with gynecologic cancer. With rapidly evolving scientific information related to COVID-19 immunization and the use of monoclonal antibodies and antiviral treatment, we encourage providers to use their best judgment based on available data when caring for their patients.*

### Introduction

The landscape of gynecologic cancer care changed dramatically over the course of the COVID-19 pandemic, caused by the SARS-CoV-2 coronavirus. Whether due to a compromised immune system from chemotherapy or potentially altered immune response with new cancer therapies, patients with gynecologic cancer have specific considerations in timing and use of vaccines and monoclonal antibodies.

Overall, vaccination should be encouraged for all patients against COVID-19 and adherence to guideline driven care. Vulnerable populations of patients have been found to have worse outcomes after COVID-19 infection.(1) This is especially true for Black and Hispanic patients with cancer.(2-4) Additional attention and care should be provided to vulnerable populations to encourage vaccination and adherence to data driven care.

Despite the fluidity of COVID-19 endemic strains, infection rates, and morbidity, it is clear this infectious disease is not an ephemeral clinical consideration for both patients and providers. The following is a resource of compiled data to provide guidance to gynecologic oncology providers; see Table at the end of the document for a summary of national society recommendations.

#### Summary of recommendations

- The benefit of vaccination outweighs the risks and is recommended for patients receiving immune checkpoint inhibitors (ICIs).
- ICI treatment can continue in the setting of COVID-19 vaccination.
- No significant immune-related side effects noted or exacerbation of existing immune-related side-effects with administration of COVID-19 vaccine.
  - The main concern remains that combined ICI therapy (anti-PD-1, anti-PD-L1 and anti-CTLA-4) may potentiate the risk of immune-related adverse events (irAEs) regardless of the vaccine. These patients should be closely monitored during the COVID-19 vaccination process. This concern is theoretical, with no data to suggest this currently.
- If a vaccine is designed to be given as two separate injections, a patient should receive both doses when possible, as there is improved efficacy over one dose.
- Even with two doses, immunogenicity is lower in cancer patients who are receiving cytotoxic chemotherapy than those who are receiving ICI and targeted therapy.
- Please reference specific trial protocols for updated information.
- In the setting of limited existing data, COVID-19 vaccination appears safe in patients undergoing CAR-T cellular therapy.
- Seroconversion with immune protection appears much lower in patients undergoing CAR-T cellular therapy compared to the general population.
- Patients should receive a re-vaccination series three months post anti-cancer therapy.
- CA-125 may be elevated in pulmonary diseases, including active COVID-19 infection.
- Severity of COVID-19 infection corresponds to the degree of CA-125 elevation.
- There is no published research indicating the impact COVID-19 vaccination has on serum CA-125 testing in patients with gynecologic malignancies.
  - It may be reasonable to obtain CA-125 testing for disease surveillance prior to or 4-6 weeks following vaccination to decrease the risk of COVID-19 vaccine interference on assessment of disease status.
  - No changes are recommended for the use of CA-125 testing for preoperative risk stratification; however, this result should be contextualized with COVID-19 infection and vaccination history.

- No changes are recommended for the use of CA-125 testing to monitor therapeutic response to treatment; however, this result should be contextualized with COVID-19 infection and vaccination history.
- Unilateral axillary adenopathy can occur in up to 16% of patients receiving COVID-19 vaccines and poses a dilemma as to the appropriate management and timing of radiological studies.
- The National Comprehensive Cancer Network (NCCN) has recommended pursuing a work-up of any lymphadenopathy on chest CT if it persists for six weeks after the second dose, as it is often reactive.
- Routine questioning of patients regarding vaccination schedules should be performed prior to ordering any radiologic screening studies. Scans should be administered prior to the first vaccination or 4-6 weeks after the second. If imaging cannot be delayed, adenopathy must be considered in clinical context by both the radiologist and treating physician.
- Novel therapeutic options to treat COVID-19 should be considered for cancer patients with COVID-19 in the context of their current treatment.
  - Consider nirmatrelvir/ritonavir treatment for those with mild-to-moderate COVID-19 infection who are at high risk for progression to severe COVID-19.
- Drug interactions should be checked to avoid toxicity, specifically avoid co-administration with vincristine, vinblastine, neratinib, among others.

**Can a patient being treated with immune checkpoint inhibitors receive a COVID-19 vaccine?(4-7)**

- The benefit of vaccination outweighs the risks and is recommended for patients receiving immune checkpoint inhibitors (ICIs).

The role of immune checkpoints is to prevent an overwhelming immune response that destroys healthy cells in the body. When immune checkpoint proteins (e.g., CTLA-4, PD-1) on T cells recognize and bind to proteins on foreign cells (e.g., tumor cells or unrecognized cells), the T cells may be inactivated, and the bound cells can evade T cell-mediated destruction. ICI are drugs that block checkpoint proteins, which subsequently allow T cells to proceed with destroying enemy cells (tumor cells).(5, 6)

Patients receiving ICIs are recommended to receive COVID-19 vaccination with any of the three COVID-19 vaccines authorized and approved in the United States including Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) vaccines. The American Society of Clinical Oncology, the European Society of Medical Oncology and the Associazione Italiana di Oncologia Medica all strongly endorse prioritization of such patients for COVID-19 vaccination. While limited, there are data supporting the safety of COVID-19 vaccination in this setting. Waissengrin et al. presented a case series of 134 cancer patients receiving ICI who also received the Pfizer BNT162b2 mRNA vaccine.(7) No new immune-related side-effects or exacerbation of existing immune-related side-effects were observed. There was no significant difference in the number of patients who reported systemic side-effects after the second dose of vaccine between those who had reported previous immune-related side-effects and those who had not (16 [34%] of 47 vs 30 [34%] of 87; p=0.96). Although there are limited long-term safety data, given the risk of COVID-19 for cancer patients, the benefit of vaccination outweighs the risk in this patient population. Further studies evaluating long-term outcomes are needed.

**Does immune checkpoint inhibitor treatment need to be held for a patient to receive a COVID-19 vaccine?(7, 9-13)**

- ICI treatment can continue in the setting of COVID-19 vaccination.
- No significant immune-related side effects noted or exacerbation of existing immune-related side-effects with administration of COVID-19 vaccine.
  - The main concern remains that combined ICI therapy (anti-PD-1, anti-PD-L1 and anti-CTLA-4) may potentiate the risk of immune-related adverse events (irAEs) regardless of the vaccine. These patients should be closely monitored during the COVID-19 vaccination process. This concern is theoretical, with no data to suggest this currently.

Patients can receive COVID-19 vaccination at any point in treatment with ICI based on available safety data with other viral vaccines. The Centers for Disease Control and Prevention (CDC) recommends, whenever possible, administering the COVID-19 vaccine at least two weeks before initiation or resumption of immunosuppressive therapies (such as cytotoxic therapy). Timing of COVID-19 vaccination should take into consideration optimization of both the patient's medical condition and response to vaccine.(10) Existing studies evaluating influenza vaccine safety during ICI treatment show no increased immune-mediated adverse events.(9, 11) There are no data to support specific timing of COVID-19 vaccination for patients receiving ICI, and clinicians should not pause ICI therapy for vaccination.(12) Further study is warranted for specific safety and potential timing recommendations with mRNA-based vaccines.

**Do patients receiving systemic cancer therapy need one versus two doses if the vaccine was designed to be given with two separate doses?(14, 15)**

- If a vaccine is designed to be given as two separate injections, a patient should receive both doses when possible, as there is improved efficacy over one dose.
- Even with two doses, immunogenicity is lower in cancer patients who are receiving cytotoxic chemotherapy than those who are receiving ICI and targeted therapy.

There are limited data on the number of doses of vaccine needed for patients receiving ICI therapy. Available data for the SARS-CoV-2 mRNA BNT162b2 (Pfizer) vaccine indicate two doses are better than one dose. In an observational study of 151 patients with cancer (95 patients with solid cancer and 56 patients with hematologic cancer) and 54 healthy controls, 38% (21/56) of solid tumor patients had any response to one dose of vaccine at 21 days, versus 94% (32/34) of healthy controls. Of those patients with solid tumors receiving ICI alone, only 3 (38%) of 8 patients were seropositive at 21 days following the first dose of the vaccine.(14) Non-responders were more common among those who received the vaccine within 15 days of cancer treatment, including those receiving chemotherapy in combination with immune checkpoint inhibition. A retrospective study of 326 patients with solid tumors treated with anti-cancer medications was designed to determine the proportion of cancer patients with immunogenicity against SARS-CoV2 following two doses of the BNT162b2 vaccine. This study found seronegativity proportions were higher in the chemotherapy treated group (19, 18.8%) compared to the ICI-treated patients (5, 9.1%) and to those treated with targeted therapy (1, 2.6%) ( $p=0.02$ ) [12]. Even with two doses, immunogenicity is lower in cancer patients, with seronegativity higher in the chemotherapy group than the ICI and targeted-therapy groups.(15)

**Do patients enrolled in clinical trials with immune checkpoint Inhibitors need to receive a COVID-19 vaccination at a specific time interval from the infusion?**

- Please reference specific trial protocols for updated information.

It is recommended that clinical trial teams confirm on a trial-by-trial basis if there are specific timing recommendations and specific types of COVID-19 vaccines allowed. Clinical trial timing requirements are set to avoid potential immune response adverse events occurring from a vaccine at the same time as a potential adverse event from a study drug infusion. Care in this setting should be individualized based on the patient and specific trial in which the patient is enrolled.

**Is the COVID-19 vaccination safe for patients undergoing CAR-T cellular therapy?(16-19)**

- In the setting of limited existing data, COVID-19 vaccination appears safe in patients undergoing CAR-T cellular therapy.
- Seroconversion with immune protection appears much lower in patients undergoing CAR-T cellular therapy compared to the general population.
- Patients should receive a re-vaccination series 3 months post therapy.

CAR-T cellular therapy is a type of treatment in which T cells are taken from a patient's blood to be altered. The gene for a special receptor called the chimeric antigen receptor (CAR) that binds to a certain protein on the patient's cancer cells is added to the T cells in the laboratory. These T-cells are infused back into the patient. Seroconversion rates (to antibody positive) following COVID-19 vaccination among patients with cancer are low. A 2021 study looking at rates of seroconversion following COVID-19 vaccination looked at three patients receiving CAR-T and found that none of the patients achieved seroconversion following vaccination.(17) Another study assessed safety and antibody response after one and/or two doses of BNT162b2 Anti-SARS-CoV-2 mRNA vaccine in patients treated by CAR T cells therapy compared to healthy controls.(17) Antibody response to the SARS-CoV-2 spike protein receptor-binding domain after first dose was tested at a median time of 29 days (range, 16-32) in 19 patients and at 23 days (range, 18-32) in controls. At that time, only four of 23 [CAR-T] patients (21%) had a positive anti-spike antibody response, while the response was 100% for controls ( $p < 0.001$ ). (18) The second serology assay was performed at a median interval from the second dose of 52 days (range, 21-99) for patients and 58 days (range, 32-71) for controls. This serology assay was positive in only six patients on CAR-T therapy (30%), while all controls (100%,  $p < 0.001$ ) had a positive response.(18) Vaccine injections appeared to be safe both in patients and controls as only grade 1 or 2 adverse events were observed. Surprisingly, reported reactions were significantly less frequent in CAR-T patients than in controls, both after dose one and dose two.(18) Several organizations including the CDC, American Society for Transplantation and Cellular Therapy, American Society of Hematology and the National Comprehensive Cancer Network (NCCN) recommend patients get re-vaccinated 3 months post treatment to ensure they have an expected response to vaccination.(18)

**What changes to the CA-125 value should gynecologic oncology providers and patients anticipate in the setting of COVID-19 infection or immunization?(20-23)**

- CA-125 may be elevated in pulmonary diseases, including active COVID-19 infection.
- Severity of COVID-19 infection corresponds to the degree of CA-125 elevation.
- There is no published research indicating the impact COVID-19 vaccination has on serum CA-125 testing in patients with gynecologic malignancies.
  - It may be reasonable to obtain CA-125 testing for disease surveillance prior to or 4-6 weeks following vaccination to decrease the risk of COVID-19 vaccine interference on assessment of disease status.
  - No changes are recommended for the use of CA-125 testing for preoperative risk stratification; however, this result should be contextualized with COVID-19 infection and vaccination history.
  - No changes are recommended for the use of CA-125 testing to monitor therapeutic response to treatment; however, this result should be contextualized with COVID-19 infection and vaccination history.

CA-125 is a non-specific tumor marker used for preoperative risk stratification, surveillance of, and monitoring therapeutic responses in gynecologic malignancies. This non-specific antigen may be elevated in pulmonary diseases and may also be used for risk stratification for patients with pulmonary artery hypertension and chronic obstructive pulmonary disease.(20, 21) Patients without cancer admitted for COVID-19 infection were more likely to have elevated serum CA-125 values than patients without the infection (mean value 28.9 U/mL vs 10.5 U/mL). These values increased in response to the severity of disease (mean values: mild 18.1 U/mL; severe 33.1 U/mL; critical 72.3 U/mL) and were positively correlated to serum C-reactive protein values.(22) Though COVID-19 infection-related changes to CA-125 values in patients with gynecologic malignancies has not been comprehensively investigated, a case report described a transient rise in CA-125 (2617 U/mL pre-infection to 4499 U/mL during active infection) in the setting of COVID-19 infection unrelated to disease progression in a patient undergoing active treatment for platinum-sensitive recurrent ovarian cancer.(23)

To date, no published research has investigated changes to serum CA-125 values in gynecologic cancer patients following COVID-19 vaccination. For patients undergoing CA-125 testing for surveillance of gynecologic malignancies, it may be reasonable to perform testing prior to or 4-6 weeks following vaccination to avoid false positive elevations as these can be associated with additional cost and patient / provider stress. There are inadequate data to suggest changes to the use of CA-125 testing for preoperative risk stratification or to monitor therapeutic response to treatment; however, these results should be contextualized with COVID-19 infection and vaccination history.

### **What is the role of monoclonal antibody infusions during active cancer treatment?(23-30)**

- Consider monoclonal antibody (mAb) infusion to treat COVID-19 in patients undergoing chemotherapy with mild to moderate symptoms.
- Providers should work closely with infectious disease providers to consider endemic strains at the time of infection as emerging variants may be resistant to monoclonal antibody infusion.

Monoclonal antibodies (mAb) are synthetic proteins designed to bind to one protein (spike protein) on the SARS-CoV-2 virus and stop it from entering cells for future replication and systemic infection. The use of mAb to treat COVID-19 has been found to reduce morbidity and mortality from the virus with the largest benefit to those age 65 and older.(24) Patients with active malignancy and those receiving immunocompromising chemotherapy are considered high risk for complications due to COVID-19 and should be considered for risk reducing interventions.

There are several mAb now available in the United States to treat COVID-19. The combination of casirivimab-imdevimab (11/21/2020) and bamlanivimab-etesevimab (2/9/2021) received emergency use authorization (EUA) by the FDA.(25, 26) Bamlanivimab was authorized (11/9/2020); however, later revoked secondary to emerging resistance with variant strains.(27) Sotrovimab (5/26/2021) and tocilizumab (6/24/2021) later received EUA. Tocilizumab is approved for hospitalized patients with severe disease only. Bebtelovimab (2/11/2022) is the most recent approval and can be used with the Omicron variant.(28)

Adverse events from mAb therapy can include fever, shortness of breath, weakness, arrhythmia, confusion, nausea, vomiting, hyperglycemia, and pneumonia. Toxicity varies by specific mAb and can also include more rare but serious hypersensitivity reactions including anaphylaxis and infusion-related reactions.

There are sparse data regarding the use of mAb in patients with active cancer. A case series of 42 patients with active cancer who also received mAb for COVID-19 found that receipt of mAb was not associated with any adverse events.(29) Within this case series, half of patients were female, 83% received bamlanivimab and there was a 12% rate of hospitalization. Hospitalization was found to be associated with CAR-T therapy and older age. Only 1/5 of hospitalized patients had a solid tumor diagnosis.(29) Another case series of 38 patients with active cancer also found no adverse events with receipt of mAb. Within this case series 73% were on active therapy, 47% had hematologic malignancy, 22 received casirivimab/imdevimab and all others received bamlanivimab.(30)

Unfortunately, with the emergence of the omicron variant, the FDA limited use of several mAb secondary to inactivity with this strain of COVID-19. Early data suggest that sotrovimab retains activity against the Omicron variant; however, this body of work is dynamic.(31) Careful consideration for mAb should be used and collaboration with infectious disease providers to determine appropriate candidates and treatments given the changing endemic strains.

### **What are the recommendations for nirmatrelvir/ritonavir in treating COVID-19 and cancer treatment?**

- Novel therapeutic options to treat COVID-19 should be considered for cancer patients with COVID-19 in the context of their current treatment.
  - Consider nirmatrelvir/ritonavir treatment for those with mild-to-moderate COVID-19 infection who are at high risk for progression to severe COVID-19.
- Drug interactions should be checked to avoid toxicity, specifically avoid co-administration with vincristine, vinblastine, neratinib, among others.

Nirmatrelvir 300mg/ritonavir 100mg received EUA (12/2021) for the treatment of mild-to-moderate COVID-19 infection in patients who are at high risk for progression to severe disease.(32) A large phase 2/3 randomized controlled trial found a significant reduction in hospitalization and death.(33) Medication should be started within five days of symptom onset. Dose reduction should be considered for those with moderate renal impairment and should not be used in those with severe renal or hepatic impairment. Nirmatrelvir and ritonavir are CYP3A substrates therefore have the potential to interact with other medications, including anticancer drugs which can

increase or decrease concentration of either medication depending on the co-administered drug. Administration with vincristine and vinblastine can increase hematologic and gastrointestinal side effects, for example. It should be avoided with several other targeted therapies, many of which are not approved in gynecologic cancer, and include abemaciclib, certinib, and neratinib, among others. Side effects include dysgeusia, diarrhea, hypertension, and myalgia. There is a paucity of data on using Nirmatrelvir/ritonavir in cancer patients on active therapy, however these patients would be high risk for severe disease and medication management should be considered.

**What are the radiologic considerations for gynecologic oncology patients after COVID-19 vaccination?(34-38)**

- Unilateral axillary adenopathy can occur in up to 16% of patients receiving COVID-19 vaccines and poses a dilemma as to the appropriate management and timing of radiological studies.
- The NCCN has recommended pursuing a work-up of any lymphadenopathy on chest CT if it persists for six weeks after the second dose, as it is often reactive.
- Routine questioning of patients regarding vaccination schedules should be performed prior to ordering any radiologic screening studies. Scans should be administered prior to the first vaccination or 4-6 weeks after the second. If imaging cannot be delayed, adenopathy must be considered in clinical context by both the radiologist and treating physician.

Unilateral adenopathy has been documented as an adverse effect following COVID-19 vaccination and poses a dilemma as to the appropriate management and timing of radiological studies. The incidence of unilateral axillary lymphadenopathy in the setting of a normal mammogram is rare with a published rate of 0.02-0.04%. While rates of unilateral adenopathy are relatively rare after vaccinations, it has been documented to occur in over 11% of patients receiving both the Pfizer-BioNTech and Moderna COVID-19 vaccines, with self-reported rates up to 16%.<sup>(35, 36)</sup> According to published data from Pfizer, lymphadenopathy occurred in the arm and neck within 2-4 days after administration of the vaccine and lasted for an average of ten days.<sup>(35)</sup> Mammographic findings can include a single or multiple enlarged lymph nodes, and soft tissue stranding.<sup>(36)</sup>

The Society of Breast Imaging (SBI) and the NCCN have offered recommendations for the management of mammograms based on the 5th Edition of the BI-RADS Atlas (37, 38):

- Unilateral axillary lymphadenopathy on a screening mammogram should be categorized as BI-RADS 0 and a further assessment of the ipsilateral breast should be performed.
- For those who had a COVID-19 vaccine within four weeks in the ipsilateral arm, repeat imaging is warranted 4-12 weeks after the second dose of the vaccine.
- If adenopathy persists on repeat imaging, then lymph node biopsy should be performed to exclude breast and non-breast malignancy.
- Routine questioning of patients regarding vaccination schedules should be performed prior to ordering any radiologic screening studies. Scans should be administered prior to the first vaccination or 4-6 weeks after the second.
- If a patient has a history of breast cancer, the vaccine should be administered in the contralateral arm to avoid a false positive finding.

The NCCN has recommended pursuing a work-up of any lymphadenopathy on chest CT if it persists for six weeks after the second dose as it is often reactive.<sup>(38)</sup> Similar findings may be noted on PET scans, as well. Therefore, physicians should delay testing for at least 4-6 weeks after vaccination if possible. If imaging cannot be delayed, then adenopathy must be put into clinical context by oncologists and radiologists.

**Useful Links:**

ASCO Patient Care Information:

<https://www.asco.org/covid-resources/patient-care-info>

NCCN COVID-19 Resources:

<https://www.nccn.org/covid-19>

CDC COVID-19 Treatments and Medications: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html>

NIH COVID-19 Treatment Guidelines:  
<https://www.covid19treatmentguidelines.nih.gov/>

**Summary of national guidelines for COVID-19 and cancer patients with solid tumors(19, 39, 40)**

	<b>CDC</b>	<b>ASCO</b>	<b>NCCN</b>	<b>NIH</b>
<i>Should cancer patients receive COVID-19 vaccine?</i>	√	√	√	√
<i>When is it appropriate to give COVID-19 vaccine to cancer patients on active myelosuppressive chemotherapy? (*If receive vaccine while on active treatment, repeat series once off treatment to optimize immune protection)</i>			As soon as possible	√ Prefer, if possible, to complete 2 weeks prior to myelosuppression
<i>Should immunocompromised cancer patients receive a 2<sup>nd</sup> COVID-19 vaccine booster?</i>	√ At least 4 months from first booster (Pfizer/Moderna)	√	√	√
<i>Do patients need to be tested for COVID-19 prior to chemotherapy?</i>		Test 48 to 72 hours prior to initiating treatment and screened for symptoms prior to each cycle		Screen for symptoms prior to treatment.
<i>Should COVID-19+ cancer patients receive myelosuppressive chemotherapy?</i>		Delay a minimum of 10 days from onset of symptoms	√	Decide on case-by-case basis based on intent of treatment
<i>Does a cancer patient need to test COVID-19 negative to receive chemotherapy/immunotherapy?</i>		No; may shed virus for over 30 days but should be symptom and fever free for at least 24 hours		Decide on case-by-case basis based on intent of treatment
<i>Do cancer patients on active chemotherapy need to wear a facemask in public places after vaccinated?</i>	√	√		
<i>Do cancer patients on active chemotherapy need to practice social distancing after vaccinated?</i>	√	√		

Abbreviations: NIH: National Institutes of Health

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