

## Protecting People With Cancer From COVID-19: New Recommendations From Cancer Guidelines Organization

On January 4, 2022, NCCN published significant updates to the expert consensus recommendations on vaccination and pre-exposure prophylaxis of COVID-19 in people with cancer. The NCCN Advisory Committee on COVID-19 Vaccination and Pre-exposure Prophylaxis meets frequently to review all available research and provide evidence-based best practices for keeping people with cancer as safe as possible during the COVID-19 pandemic.

The updated guidance—available at [NCCN.org/covid-19](https://www.nccn.org/covid-19)—includes information on the preventive use of human monoclonal antibodies in addition to the following principals:

- Patients with cancer should get fully immunized, including third doses and/or any approved boosters;
- There is a strong preference for mRNA vaccines;
- Vaccination should be delayed for at least 3 months following hematopoietic cell transplantation or engineered cellular therapy (eg, CAR T cells) to maximize vaccine efficacy. Vaccine delays in patients with cancer should also include those recommended for the general public (eg, recent exposure to COVID-19, recent monoclonal antibody therapy);
- Full vaccination is also recommended for caregivers, household/close contacts, and the general public; and
- The committee strongly supports full vaccination mandates for health-care workers.

“All of us are called to do everything we can to save as many lives as possible during the ongoing pandemic,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “Vaccination is our most effective approach for avoiding serious COVID-19 complications, including hospitalization and death. However, research shows many immunocompromised people develop inadequate immune responses from vaccines. Thankfully, we now have additional tools to help people in active treatment for cancer, solid organ transplant recipients, engineered cellular therapy (eg, CAR T cell) or stem cell transplant recipients (ie, hematopoietic stem cells), and those with other immunodeficiency-causing conditions (such as HIV, DiGeorge syndrome, or Wiskott-Aldrich syndrome).”

The FDA has issued an emergency use authorization for the monoclonal antibody combination of tixagevimab + cilgavimab for pre-exposure protection from COVID-19 in adults and children starting at age 12 years (weighing at least 40 kg) who have moderate to severe immune compromise and may not be responsive to vaccination. Patients with blood cancers (including those receiving stem cell transplantation or 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 states that it is reasonable to prioritize these patients for tixagevimab + cilgavimab before patients with solid tumor cancers in the event of limited supply.

“We have new agents to prevent and treat COVID-19 that will benefit patients with cancer,” said Brahm Segal, MD, Roswell Park Comprehensive Cancer Center, Co-Leader of the NCCN Advisory Committee on COVID-19 Vaccination and Pre-exposure Prophylaxis. “An important challenge on a national level is to ensure drug availability to patients with cancer and others at high risk for COVID-19. The revised recommendations from the NCCN Advisory Committee on COVID-19

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Vaccination and Pre-exposure Prophylaxis will provide guidance on the use of these agents for patients with cancer, including prioritization when supplies are limited.”

The committee also supports recommendations from the CDC, American Society of Transplantation and Cellular Therapy (ASTCT), and ASH that previously vaccinated patients completing stem cell transplantation or engineered cellular therapy should receive a repeat vaccination series starting at three months post-treatment.

“The medical and scientific community’s response to the COVID-19 crisis continues to be extremely encouraging, even in the face of setbacks like new variants and surging infection rates,” said Dr. Carlson. “Rapid research, thoughtful analyses, and tireless care delivery is allowing us to save so many more people than we could have a year ago. We hope by sharing this simplified guidance highlighting the latest research and approvals, we can help make sure the very latest in evidence-based care reaches as many patients and providers as possible.”

The NCCN Advisory Committee on COVID-19 Vaccination and Pre-exposure Prophylaxis is comprised of leading multidisciplinary physicians from across NCCN Member Institutions, with particular expertise in infectious diseases, vaccine development and delivery, cancer management, and medical ethics. NCCN will continue to update recommendations to adapt to changing circumstances, including the growing body of evidence.

All of NCCN’s recommendations for cancer care during the pandemic can be found at [NCCN.org/covid-19](https://www.nccn.org/covid-19). A patient and caregiver guide to vaccinations is also available at [NCCN.org/patientguidelines](https://www.nccn.org/patientguidelines).

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## Global Recommendations for Colon Cancer Translated Into Multiple Languages as NCCN Expands Arabic Resources

On December 23, 2021, NCCN announced the publication of newly-translated recommendations for treating colon cancer in Arabic, plus updates in Chinese, French, Polish, Portuguese, and Spanish. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are the most frequently-updated guidelines in any area of medicine. They include the latest evidence and expert-consensus based recommendations from multidisciplinary panels of experts. NCCN Guidelines are used by healthcare providers worldwide to optimize treatment in order to improve cancer outcomes.

“Approximately half of the million-plus NCCN registered users are located outside the United States and NCCN Guidelines were downloaded >6 million times by people located outside of the United States in 2021,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “NCCN Guidelines were downloaded >2 million times so far this year by people in countries where these 6 languages are spoken predominantly. The NCCN Global program is always looking for new ways to make these resources even more accessible for our users around the globe to help them provide the best care possible for their patients.”

The Arabic translation of the NCCN Guidelines for Colon Cancer represents an important new language for NCCN’s growing library of International Adaptations and Translations, which already exist in Chinese, French, German,

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Indonesian, Italian, Japanese, Korean, Polish, Portuguese, Russian, and Spanish. NCCN is also expanding its patient information resources with the recent Arabic translation of the NCCN Guidelines for Patients: Chronic Lymphocytic Leukemia.

The newly published Arabic resources build on the English-language adaptations of NCCN Guidelines specifically tailored for the Middle East & North Africa (MENA) region led by the MENA-NCCN Regional Coordinating Center. Recently, Kanan Mamdouh Alshammari, MD, Department of Oncology, King Abdullah Specialized Children's Hospital, Ministry of National Guard, Riyadh, Saudi Arabia, was appointed as the Director of the MENA-NCCN Regional Coordinating Center. In 2022, the MENA-NCCN Regional Coordinating Center will develop three new adapted NCCN Guidelines for the MENA region focused on Ovarian Cancer; Genetic/Familial High-Risk Assessment for Breast, Ovarian, and Pancreatic; and Palliative Care.

"NCCN Guidelines are respected and utilized around the world," said Dr. Kanan Mamdouh Alshammari. "By collaborating and exchanging scientific knowledge to adapt the recommendations to the specific circumstances in our region, we can do an even better job of meeting the individual needs of people with cancer. In parallel, the newly published Arabic translation from NCCN represents a significant opportunity to promote greater access to evidence-based care for our patients."

View International Adaptations and Translations of NCCN Guidelines at [NCCN.org/global](https://www.nccn.org/global) and join the conversation with #NCCNGlobal.

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## NCCN Announces Funding for Prostate Cancer Research Projects, in Collaboration With Pfizer

The NCCN Oncology Research Program (ORP) recently announced a collaboration with Pfizer Global Medical Grants (Pfizer) that awards new grants to advance the understanding of the mechanisms of action, underlying biology, and clinical activity of talazoparib in prostate cancer.

"This research will involve innovative investigations of talazoparib and foster the development of PARP inhibitors in prostate cancer," said Crystal S. Denlinger, MD, Senior Vice President, Chief Scientific Officer, NCCN. "Congratulations to all of the grantees. We look forward to results that may guide the development of talazoparib alone or in combination with other therapies in prostate cancer."

The selected projects are:

- Adam Kibel, MD, and Oliver Jonas, PhD, Dana-Farber Brigham Cancer Center
  - "Intratumor Microdevice to Identify Biomarkers and Pathways Associated with Response to Talazoparib"
- Amado Zurita-Saavedra, MD, The University of Texas MD Anderson Cancer Center
  - "Presurgical Phase II Study of Talazoparib in Combination with Enzalutamide in De Novo Metastatic to Lymph Nodes Prostate Cancer"

"We have seen incredible progress in the treatment of prostate cancer over the last decade, however, there continues to be a need for ongoing innovation to support improved patient outcomes," said Dr. Roxanne Ferdinand,

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Genitourinary Global Franchise Medical Lead, Pfizer Oncology. “Pfizer is committed to collaborating with professional organizations like NCCN to fund research that helps to advance our understanding of how different therapies can address unmet needs. We look forward to seeing how these efforts help to progress patient care.”

Proposals were peer reviewed by a Scientific Review Committee, which consisted of leading expert oncologists from NCCN Member Institutions. The selected priority areas will focus on clinical development of talazoparib combinations, defining predictive biomarkers of clinical benefit. The studies are set to be completed within 2 years. Collectively, the total amount of grants awarded for this study are approximately \$1.5 million.

The NCCN ORP fosters innovation and knowledge discovery that improves the lives of people with cancer and supports preclinical, translational, and clinical research and quality improvement projects in oncology at NCCN Member Institutions. In an effort to improve collaboration in cancer research, the NCCN ORP also maintains a shared resources website, an informed consent database, and points to consider on the best practices for biorepositories, registries, and databases. For more information, visit [NCCN.org/orp](http://NCCN.org/orp).

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## New NCCN Guidelines Help Patients Better Understand and Participate in the Care of Their Cervical Cancer

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The NCCN Guidelines for Patients are an excellent tool for patients to use in conversation with healthcare providers so they can engage in shared decision-making about their care.

NCCN has published new NCCN Guidelines for Patients: Cervical Cancer to help people with cervical cancer become more informed, suggest what conversations to have with their doctor, and be active decision makers in their treatment. The cervical cancer guidelines are the latest in NCCN’s library of NCCN Guidelines for Patients, published through funding from the NCCN Foundation and available online free of charge. NCCN Guidelines for Patients provide information for nearly 60 of the most common cancers as well as topics such as side effects, mental distress, and survivorship.

“People who are diagnosed with cancer can feel lost and afraid,” said Catheryn M. Yashar, MD, UC San Diego Moores Cancer Center, Vice Chair of the NCCN Guidelines Panel for Cervical Cancer. “Having these guidelines empowers women to be stewards of their own care and ask appropriate questions.”

Cervical cancer is the fourth-most-common cancer worldwide among people with cervixes<sup>1</sup> and is usually caused by prolonged infection with human papillomavirus (HPV).<sup>2</sup> And although cervical cancer is usually treatable, especially when detected early, there will be an estimated 14,480 new cervical cancer cases diagnosed and 4,290 estimated deaths in the United States in 2021.<sup>3</sup>

A widely available vaccination against HPV dramatically reduces cervical cancer risk among those who have not yet been infected with the virus. Yet, while the United States is seeing fewer new cervical cancer cases compared to past decades, too many people—both younger and middle-aged—are not vaccinated and develop cancer from persistent HPV infection.

“Patients are often surprised and upset,” says Nadeem R. Abu-Rustum, MD, Memorial Sloan Kettering Cancer Center, Chair of the NCCN Cervical Cancer Panel. “They’ve been going to the doctor, but skipped a year or two and suddenly they have a problem that can disrupt their lives and reproductive function.”

The NCCN Guidelines for Patients can help the newly diagnosed orient themselves to the treatment options and reduce the fear of finding out they have cancer.

### More Options, More Targeted Treatment

Treatment options for cervical cancer have advanced significantly in recent years, and the new NCCN Guidelines for Patients share the most up-to-date information about them.

Hysterectomy—removal of the uterus—has traditionally been a standard therapy for cervical cancer, but many people who receive a diagnosis are surprised to learn there may be other options. If cervical cancer has spread, chemotherapy and/or radiation are often a better treatment choice, as explained in the patient guidelines. For those with very early-stage cancers, less radical surgical treatments may be available that spare the uterus and preserve fertility.

“Years ago, we had one chemotherapy drug,” said Dr. Abu-Rustum. “Now we have a lot more options and more precision in chemotherapy, surgery, and radiation techniques.”

In addition, immunotherapy has emerged as a therapeutic possibility for cervical cancer that has recurred or spread to distant parts of the body. These treatments are now used in some cases to boost the immune system’s ability to attack cancer cells.

Treatments that have less impact on a patient’s sexual function and fertility are a major goal for cervical cancer, as are improved therapies for cancer that has spread beyond the immediate area of the cervix. Radiation and chemotherapy are effective, but can have major side effects; researchers are investigating ways to reduce the collateral damage of such treatments, and exploring other methods of control—such as immunotherapy—for advanced cancers.

### Prevention Remains Key

Although the new patient guidelines focus primarily on cancer treatment rather than prevention, NCCN continues to stress the importance of HPV vaccination.

“If we are successful in increasing vaccination we can decrease the burden of cervical cancer quite a bit,” said Dr. Abu-Rustum. “But even if vaccinated, people should continue to be screened. And keep an eye out for symptoms like unusual discharge, bleeding after intercourse, or—if they are older—abnormal bleeding of any kind from the uterus. Don’t just blame bleeding on fibroids or endometriosis. Make sure someone takes a look.”

Regular pap smear screenings are also important, as cervical cancer is relatively easy to treat if caught early enough.

NCCN works closely with numerous patient advocacy organizations. In anticipation of this new publication, Morgan Newman, MSW, cervical cancer survivor and Community Engagement Liaison on behalf of Cervivor—a non-profit patient education and support organization—said, “Guidelines are not one-size-fits-all, but the NCCN Guidelines for Patients are an excellent tool for patients to use in conversation with healthcare providers so they can engage in shared decision-making about their care.”

Patients and caregivers can access NCCN Guidelines for Patients for free at [NCCN.org/patientguidelines](https://www.nccn.org/patientguidelines) and via the NCCN Patient Guides for Cancer App. The patient guidelines cover most major types of cancer, along with topics in cancer management for different age groups and issues facing survivors. They are based on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), which are updated frequently by multidisciplinary teams of

experts from across NCCN Member Institutions. The patient versions present unbiased expert guidance in an easy-to-read format—with clear language, charts, images, and a glossary of medical terms. Learn more at [NCCN.org/patients](https://www.nccn.org/patients).

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## NCCN Summit Explores How to Better Deliver on the Promise of Precision Medicine for People With Cancer

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On December 7, 2021, NCCN hosted its annual Patient Advocacy Summit. The 2021 online program included a recorded presentation from Congresswoman Debbie Wasserman Schultz (D-FL)—one of the bipartisan sponsors of the Reducing Hereditary Cancer Act of 2021 (HR 4110). The summit highlighted diverse perspectives for expanding precision medicine in order to improve cancer outcomes, including discussions on federal and local policies to broaden genetic/genomic testing access.

“Our understanding of precision medicine and how to equitably use biomarker testing is changing rapidly day-to-day,” said panelist Crystal S. Denlinger, MD, Senior Vice President, Chief Scientific Officer, NCCN. “Given the ever-changing landscape of biomarkers, it can be hard to remain current on indications, terminology, appropriate testing technology, and coverage. The NCCN Biomarkers Compendium is one resource to help us standardize access to expert-recommended testing and targeted treatment, but more work and awareness is needed to harness this evolving science in the most beneficial ways.”

The group of speakers also included patients, advocates, additional doctors, and payers. They stressed the importance of performing testing for biomarkers that can inform and improve patient outcomes, but acknowledged the various challenges faced around how to make sure that happens.

“Genetic and/or tumor biomarker testing are integral components of precision medicine, informing cancer treatment, screening, and risk-reducing interventions,” said Lisa Schlager, Vice President, Public Policy, Facing Our Risk of Cancer Empowered (FORCE). “Access to guideline-recommended testing can lead to better quality of life and outcomes for patients. We must institute public policies that facilitate equal, affordable access to these tests regardless of one’s age, health insurance, or socioeconomic status; this will ultimately reduce health disparities and save lives.”

“Access to cancer diagnostics always has a technical limitation—is the testing available to anyone—but also a social limitation—is the testing available to everyone,” said Dan Milner, MD, MSc, MBA, American Society of Clinical Pathology. “The challenge of biomarkers for patients today is not availability



but rather reliable systemic access and consistent workflow. We can solve this through coordination, collaboration, and placing the patient at the center of the process.”

Speakers also acknowledged a significant need for education of multiple stakeholders around biomarkers so physicians can make the best possible recommendations and patients are better able to advocate for themselves.

“The lack of education and awareness among patients is one of biggest challenges for precision-based medicine,” said Wenora Johnson, Patient Advocate. “One way to empower them is to ensure that patients understand their individual genetic information, with the help of genetic counselors. This allows patients and caregivers to make informed decisions regarding their healthcare and any related problems. Universally-accepted policies for sharing treatment and outcomes data will lead to better patient outcomes.”

Mary Lou Smith, JD, MBA, Research Advocacy Network, agreed: “Genomic testing can provide valuable information for shared decision-making; but both patients and their treating physicians often have a hard time understanding the reports showing the results. We need clearer, more understandable ways of reporting the results from genomic testing in order to determine the most effective treatment option for patients.”

Another recurring theme from the summit was the acknowledgement that the role of precision medicine in cancer care will continue to grow. Speakers were concerned that this progress could widen disparities in outcomes by leaving out too many patients.

“Biomarker testing is currently a fundamental step in the evaluation of patients with most cancers, in order to determine the best therapies available as well as clinical trial eligibility,” said Debora S. Bruno, MD, MS, Case Comprehensive Cancer Center, Member of the NCCN Guidelines Panel for Non-Small Cell Lung Cancer. “However, recent studies have demonstrated that many patients in the United States with advanced/metastatic cancers are not comprehensively tested and that racial disparities exist when it comes to this basic assessment. As science evolves and cancer treatments become more effective, we are creating disparities that need urgent attention so all segments of society have access to these innovative therapies.”

“In the last decade, there has been an explosion of new therapies in oncology which offer the promise of better outcomes,” concluded Bhuvana Sagar, MD, MBA, Evernorth. “It is critical that people diagnosed with cancer are tested to determine if they can benefit from these new treatments. By improving access to testing and using the test results to guide therapies, we can improve long-term outcomes for cancer patients.”

Additional speakers included State Representative Mary E. Flowers (D-IL), House Deputy Majority Leader, Illinois General Assembly; Hilary Gee Goeckner, MSW, American Cancer Society Cancer Action Network; Louis Jacques, MD, ADVI Health, LLC; Terrell Johnson, MPA, NCCN; Kristen Santiago, MS, LUNGevery Foundation; and James Warburton, Novartis Oncology.

The program also featured resource presentations from Monica Bryant, JD, Triage Cancer, on “Options When the Insurance Company Says No”; Peggy Cottrell, MS, CGC, Sharsheret, on “Genetics for Life Program”; Nikki Martin, MA, LUNGevery, on “No One Missed”; and Cassadie Moravek, Pancreatic Cancer Action Network, on “Know Your Tumor Program.”

More information on these resources to help improve access to precision medicine for the cancer community can be found at [NCCN.org/summits](https://www.nccn.org/summits). Join the conversation with the hashtag #NCCNPolicy.

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Addressing the impact of cancer-related distress and various underlying causes can help patients achieve their best possible outcome.

## Updated NCCN Distress Thermometer and Problem List Helps People Cope With Cancer Symptoms and Treatment

On December 6, 2021, NCCN announced updates to its widely used resource for enabling discussion and treatment of distress as part of routine care for people with cancer. The NCCN Distress Thermometer and Problem List is a free resource to help providers worldwide identify and address the unpleasant experiences that may make it harder to cope with having cancer, its symptoms, or treatment. The updated version includes the well-regarded thermometer tool alongside a revamped list of possible physical, mental, social, spiritual, and other practical concerns, to allow care teams to recommend specific resources that can provide support.

“Caring for cancer patients’ emotional well-being is just as important as addressing their physical symptoms,” said Michelle Riba, MD, MS, University of Michigan Rogel Cancer Center, Chair of the NCCN Guidelines Panel for Distress Management. “The NCCN Distress Thermometer makes it more viable to assess people’s distress during routine and unexpected doctors’ visits. With this update, we have made the tool even more streamlined and user-friendly while avoiding words that could be stigmatizing.”

The NCCN Distress Thermometer was first launched in 1997 to normalize and encourage discussion of distress as a standard part of oncology patient visits. This free resource has been downloaded >25,000 times in 2021 throughout >100 countries. It has also been translated into >50 languages (with updated translations coming soon).

The updates feature an expanded section on spiritual or religious concerns, as well as revisions to the list of social concerns—including a new option for patients to indicate if they are having difficulties communicating with their healthcare team. The simple checklist also includes revisions to the list of practical concerns, specifically new items related to ability to take care of oneself and others.

“Everyone with cancer experiences some distress at some point; it’s normal to feel sad, fearful, and helpless,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “The amount of distress can be very different from person to person, or in an individual at different points throughout diagnosis and treatment. Addressing the impact of cancer-related distress and various underlying causes can help patients achieve their best possible outcome. The NCCN Distress Thermometer opens up a necessary conversation, and the NCCN Guidelines for Distress Management provide evidence-based expert consensus recommendations for managing concerns.”

The NCCN Distress Thermometer is included in the NCCN Guidelines for Distress Management. It can also be found in the NCCN Guidelines for Patients: Distress During Cancer Care book intended for patients and caregivers, funded by the NCCN Foundation and sponsored by Good Days. Both are available free-of-charge for noncommercial use at NCCN.org or via Virtual Library of NCCN Guidelines App.