Leading Cancer Organizations Provide Guidance on Understanding and Managing Immunotherapy Side Effects

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ALEXANDRIA, VA, FORT WASHINGTON, PA. – Immunotherapy with immune checkpoint inhibitors is the first of a new generation of immunotherapy treatments, revolutionizing treatment for many different types of cancer. By unleashing the body’s immune system to attack cancer, these treatments can send even the most hard-to-treat cancers into lasting remission.

Patients who receive immune checkpoint inhibitors, however, may experience a unique set of side effects. These side effects can involve multiple organs of the body, and although they are typically mild, sometimes severe, irreversible, or even life-threatening reactions can occur. Given that these therapies have entered the clinic fairly recently, few clinicians are experienced in recognizing and treating associated side effects.

New guidelines developed collaboratively by the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network® (NCCN®) offer clinicians much needed recommendations for assessment and management of side effects related to immune checkpoint inhibitors.

“With rapidly increasing use of immune checkpoint inhibitors, it is imperative that clinicians are knowledgeable about their unique toxicity profiles,” said Clifford A. Hudis, MD, FASCO, FACP, ASCO Chief Executive Officer. “These new guidelines from ASCO and NCCN will help our
community continue to provide the highest quality of care to all patients as they incorporate these agents into routine care."

There are already several checkpoint inhibitors approved by the US Food and Drug Administration (FDA) for various cancers, including melanoma, Hodgkin lymphoma, and lung, liver, kidney, and bladder cancers. And the use of checkpoint inhibitors is continuously expanding to more indications, along with the development of new checkpoint inhibitors and combinations.

“The real winners here are patients whose health care teams now have high quality, collaborative guidelines from ASCO and NCCN to minimize treatment toxicity and optimize outcomes,” said Robert W. Carlson, MD, NCCN Chief Executive Officer. “While novel immunotherapies allow for life-extending therapy for selected forms of cancer, their success is associated with potentially substantial toxicity. These side effects are different from other forms of anticancer therapy and require rapid and appropriate recognition and treatment. NCCN has been pleased to collaborate with ASCO on developing strategies and collaborative guidelines for managing the toxicity of immunotherapies.”

Immunotherapy-related side effects can occur at any time and can affect any organ. The most common side effects are rash, diarrhea, low thyroid hormone, and fatigue, but they can also include inflammation of the lung, intestines or liver, hormonal abnormalities, and kidney, heart, or neurologic problems.

“If you take the brakes off the immune system and allow it to attack cancer, it may also attack the healthy tissue in a patient’s body,” said John A. Thompson, MD, co-director, Seattle Cancer Care Alliance Melanoma Clinic, Fred Hutchinson Cancer Research Center. Dr. Thompson is chair of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Panel on Management of Immunotherapy-Related Toxicity as well as co-chair of the expert panel that developed the ASCO guideline. “Fortunately, most of the side effects are reversible, but early recognition and proper treatment are critical.”

To the develop the guidelines, ASCO and NCCN convened multidisciplinary panels with representation from medical oncology, dermatology, gastroenterology, rheumatology, pulmonology, endocrinology, urology, neurology, hematology, emergency medicine, and nursing, as well as patient advocacy experts. The clinical recommendations are based on systematic review of literature and an informal consensus process. These guidelines pertain only to immune checkpoint inhibitors, not to other types of immunotherapy. NCCN will update its guidelines continuously as data evolve and plans to include toxicities of new CAR-T cell therapies later this year.
“Some people will brush their symptoms aside, but any unusual symptom should be reported to the doctor,” said Julie Brahmer, MD, chair of the expert panel that developed the ASCO guideline. “These guidelines will help all providers who care for patients treated with immune checkpoint inhibitors, not just oncologists, but also emergency room and primary care doctors, assess and manage these side effects.”

Key guideline recommendations:

- In general, checkpoint inhibitors can be continued with close monitoring for mild (grade 1) toxicities, with the exception of neurologic and some hematologic toxicities.
- For moderate (grade 2) toxicities, checkpoint inhibitors should be held until symptoms and/or lab values revert to grade 1 levels or lower. Corticosteroids may be offered.
- For severe (grade 3) toxicity, patients should receive high-dose corticosteroids for at least 6 weeks. Extreme caution when restarting immunotherapy after a grade 3 toxicity is recommended, if it is restarted at all.
- In general, very severe (grade 4) toxicity necessitates stopping checkpoint inhibitor therapy permanently.
- Consult the guidelines directly for more specific recommendations depending on which organ is affected.

The Management of Immune-related Adverse Events in Patients Treated with Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Clinical Practice Guideline and NCCN Guidelines® for Management of Immunotherapy-Related Toxicities were both published today in the Journal of Clinical Oncology and online at NCCN.org, respectively.

Patients can find information about side effects of immunotherapy at Cancer.Net, or download an infographic at NCCN.org/infographic. An educational video is available at https://youtu.be/BTrlDgaNyjQ.

ASCO and NCCN encourage feedback on their guidelines from oncologists, practitioners and patients through the ASCO Guidelines Wiki at www.asco.org/guidelineswiki or via the NCCN submission form at NCCN.org.

For embargoed copies of the guidelines, please contact Lada Krilov (ASCO), lada.krilov@asco.org, 571-483-1377 or Rachel Darwin (NCCN), Darwin@nccn.org, 267-622-6624.

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About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer.
Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at [www.ASCO.org](http://www.ASCO.org), explore patient education resources at [www.Cancer.Net](http://www.Cancer.Net), and follow us on Facebook, Twitter, LinkedIn, and YouTube.

**About NCCN**

The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 27 leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers.