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MEDICAL WRITING & RESEARCH
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GUIDELINES THIS WEEK...

National Cancer Comprehensive Network (NCCN)

Weekly Guideline Update

Each Wednesday, I bring you news concerning updates to guidelines and recommendations by professional societies. This list is not all-inclusive, of course, but the following recent updates caught my attention.

If there are any guidelines I have missed this week that you would like to see included, please email me at jerm@day-storms.com.

National Cancer Comprehensive Network (NCCN)

The NCCN guidelines can be found at www.nccn.org.

- Acute Myeloid Leukemia Version 2.2025 — Since Version 1.2025, the discussion section was modified to reflect changes within the algorithm.
- Ampullary Adenocarcinoma Version 2.2025 — The guidelines have been updated to clarify the use of nivolumab and hyaluronidase-nvhy in metastatic disease as a first-line therapy.

- Anal Carcinoma Version 2.2025 — The guidelines have been updated to allow nivolumab and hyaluronidase-nvhy subcutaneous injection as a substitute for IV nivolumab across all guideline indications, with clinicians advised to follow distinct dosing and administration instructions. Additionally, the NCCN has updated a table within the quality assurance and image-guided treatment delivery section to clarify the small bowel max point dose.

- Basal Cell Skin Cancer Version 1.2025 — The NCCN guidelines include key changes focusing on treatment and risk stratification. For low-risk BCC, the guidelines now specify that surgical excision should generally be performed instead of curettage and electrodesiccation (C&E) or shave removal if the tumor extends beyond the dermis. For high-risk BCC, Mohs or another form of peripheral and deep en face margin assessment (PDEMA) is preferred. In advanced BCC, multidisciplinary discussion is emphasized. There is a new recommendation to refer to the ASTRO guideline on definitive and postoperative radiation therapy.

- Biliary Tract Cancers Version 6.2024 — The guidelines have been updated to include nivolumab and hyaluronidase-nvhy subcutaneous injection as a substitute for IV nivolumab, with the caveat that dosing and administration differ between formulations. Additionally, the discussion section has been revised to align with changes in the treatment algorithm.

- Bladder Cancer Version 6.2024 — Similar to the guidelines for biliary tract cancers, the NCCN now recommends nivolumab and hyaluronidase-nvhy subcutaneous injection as a substitute for IV nivolumab, with the caveat that dosing and administration differ between formulations.

- Breast Cancer Version 1.2025 — The breast cancer guidelines have been extensively modified since the previous version. Key updates include changes to the surveillance/follow-up of DCIS, modifications to the imaging for systemic staging, and revisions to the section concerning breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and other rare implant-associated malignancies. Please see the full guidelines for the detailed changes made in this version.

- Castleman Disease Version 2.2025 — The NCCN has updated the wording regarding zidovudine + ganciclovir/valganciclovir for HHV8-positive (HIV-1-positive or HIV-1-negative) patients and has updated the discussion section to reflect algorithm changes.

- Central Nervous System Cancers Version 4.2024 — Changes include that subcutaneous nivolumab and hyaluronidase-nvhy may be substituted for IV nivolumab in monotherapy, but it is not approved for concurrent use with IV ipilimumab. Additionally, this substitution applies to leptomeningeal disease, with a reminder that dosing and administration differ between the subcutaneous and IV formulations.
- Cervical Cancer Version 2.2025 — Subcutaneous nivolumab and hyaluronidase-nvhy may also be substituted for IV nivolumab for cervical cancer.
- Colon Cancer Version 6.2024 — The guidelines for colon cancer have been updated with modifications to hepatic arterial infusion (HAI) eligibility, now specifying that prior liver radiation excludes eligibility. Additionally, checkpoint inhibitor therapy options have been modified: nivolumab ± ipilimumab, pembrolizumab, or dostarlimab-gxly are included, with nivolumab + ipilimumab designated as a category 2B option when intensive therapy is not recommended due to toxicity concerns. Furthermore, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab. For nivolumab monotherapy, subcutaneous nivolumab and hyaluronidase-nvhy may be substituted for IV nivolumab, with distinct dosing and administration requirements across all relevant guideline sections.
- Gestational Trophoblastic Neoplasia Version 2.2025 — The discussion section has been updated, and subcutaneous nivolumab and hyaluronidase-nvhy may also be substituted for IV nivolumab.
- Head and Neck Cancers Version 2.2025 — The guidelines have been updated to allow nivolumab and hyaluronidase-nvhy subcutaneous injection as a substitute for IV nivolumab across multiple sections. Additionally, for mucosal melanoma, adjuvant systemic therapy remains limited by available data, with nivolumab (category 2B) and cisplatin/temozolomide (category 2B) listed as options.
- Hepatocellular Carcinoma Version 4.2024 — Subcutaneous nivolumab and hyaluronidase-nvhy may also be substituted for IV nivolumab.

- Histiocytic Neoplasms Version 3.2024 — The discussion section has been updated to reflect algorithm changes.
- Hodgkin Lymphoma Version 2.2025 — The discussion section has been updated to reflect algorithm changes.
- Kaposi Sarcoma Version 2.2025 — Subcutaneous nivolumab and hyaluronidase-nvhy may also be substituted for IV nivolumab.
- Kidney Cancer Version 3.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. Additionally, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab.
- Melanoma: Cutaneous Version 2.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. Additionally, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab.
- Merkel Cell Carcinoma Version 1.2025 — Significant changes have been made to the Merkel cell carcinoma guidelines. Laboratory studies and genetics consultation (in patients under the age of 50) have been added to the additional workup. Assessing disease burden via circulating tumor DNA in either virus-positive or virus-negative MCC. Updates regarding excision in primary treatment have also been made. For a full list of changes, please read the entire guideline on the NCCN website.
- Mesothelioma: Peritoneal Version 2.2025 and Mesothelioma: Pleural Version 2.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. Additionally, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab.
- Neuroendocrine and Adrenal Tumors Version 4.2024 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. Additionally, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab.

- Non-Small Cell Lung Cancer Version 3.2025 — The NCCN guidelines for NSCLC have been updated to include nivolumab and hyaluronidase-nvhy subcutaneous injection as a substitute for IV nivolumab in neoadjuvant systemic therapy for patients eligible for immune checkpoint inhibitors. Clinicians should note that dosing and administration differ between the subcutaneous and IV formulations, requiring careful adherence to product-specific guidelines.

- Pancreatic Adenocarcinoma Version 2.2025 — The guidelines have been updated to include zenocutuzumab-zbco as a treatment option for locally advanced/metastatic disease and recurrent disease in patients with good performance status (PS 0–1) where *NRG1* gene fusion is present.

- Pediatric Central Nervous System Cancers Version 2.2025 — The discussion section has been revised to align with updates to the algorithm.

- Penile Cancer Version 2.2025 — The discussion section has been revised to align with updates to the algorithm.

- Rectal Cancer Version 5.2024 — The guidelines for have been updated to revise hepatic arterial infusion (HAI) eligibility, now specifying that patients with prior liver radiation are ineligible. Additionally, checkpoint inhibitor therapy options have been clarified, including nivolumab ± ipilimumab, pembrolizumab, and dostarlimab-gxly, with nivolumab + ipilimumab designated as category 2B when intensive therapy is not recommended due to toxicity concerns. Furthermore, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab. For nivolumab monotherapy, subcutaneous nivolumab and hyaluronidase-nvhy may be substituted for IV nivolumab.

- Small Bowel Adenocarcinoma Version 2.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. Additionally, nivolumab and hyaluronidase-nvhy is not approved for concurrent use with IV ipilimumab. Finally, the NCCN has updated the language regarding radiation therapy dosing.

- Small Cell Lung Cancer Version 4.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy. The discussion section has been revised to align with updates to the algorithm.

- Squamous Cell Skin Cancer Version 1.2025 — Considerable changes have been made to the NCCN guidelines since the previous version. These changes include the addition of MRI with and without contrast of the brain to rule out subclinical cortical involvement in cases with bone invasion as well as updates to the wording regarding treatment of low-risk, high-risk, and very-high-risk CSCC. For a full list of changes, please see the entire guideline on the NCCN website.

- Testicular Cancer Version 1.2025 — Likewise, the guidelines on testicular cancer have been significantly changed. The algorithm for pure seminoma has significant modifications as well as recommendations regarding imaging. Please see the entire guideline on the NCCN website for a detailed list of the updates.

- Thyroid Carcinoma Version 5.2024 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy.

- Uterine Neoplasms Version 2.2025 and Vaginal Cancer Version 4.2025 — Nivolumab and hyaluronidase-nvhy subcutaneous injection can be given as a substitute for IV nivolumab in monotherapy.

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