

NCCN Guidelines for Breast Cancer Updated; Bevacizumab Recommendation Affirmed

The National Comprehensive Cancer Network (NCCN) recently updated the NCCN Clinical Practice Guidelines for Oncology (NCCN Guidelines) for Breast Cancer to affirm the recommendation regarding the use of bevacizumab (Avastin, Genentech/Roche) in the treatment of metastatic breast cancer.

The NCCN Guidelines Panel for Breast Cancer affirmed its existing recommendation of bevacizumab in combination with paclitaxel (Taxol, Bristol-Myers Squibb Company) as an appropriate therapeutic option for metastatic breast cancer with the evidence designation 2A meaning that it is based on lower level evidence and uniform agreement of the panel as to its appropriateness.

The Panel revised the related footnote to read, “Randomized clinical trials in metastatic breast cancer document that the addition of bevacizumab to some first or second line chemotherapy agents modestly improves time to progression and response rates but does not improve overall survival. The time to progression impact may vary among cytotoxic agents and appears greatest with bevacizumab in combination with weekly paclitaxel.”

The NCCN Guidelines are developed and updated through an evidence-based process with explicit review of the scientific evidence integrated with expert judgment by multidisciplinary panels of expert physicians from NCCN Member Institutions. The most recent version of this and all the NCCN Guidelines are available free of charge at NCCN.org. The NCCN Guidelines for Patients: Breast Cancer is now available at NCCN.com.

Improving Safety for Patients with Cancer; NCCN Safety Summit Features Peter Pronovost, MD, PhD

Patient safety has long been recognized as an integral component of quality medical care. The stakes are especially high in oncology, where avoiding errors is imperative to delivering radiation therapy, chemotherapy, and other high-risk treatments. On the heels of intense media scrutiny about treatment errors, particularly related to radiation safety, NCCN has convened the NCCN 2010 Patient Safety Summit featuring keynote speaker Peter J. Pronovost, MD, PhD, an internationally acclaimed leader in patient safety from Johns Hopkins Medicine in Bethesda, MD on October 14, 2010.

The NCCN 2010 Patient Safety Summit provided an opportunity for clinical, administrative, regulatory, and industry professionals to discuss best practices in oncology patient safety and to disseminate advances in oncology patient safety systems and processes. Radiation safety, strategies to prevent oral chemotherapy errors, safety and accountability, and the prevention of health care associated infections were the focus.

“To reach our ultimate goal – providing safer care to patients – we need to embrace concepts that will systematically change the culture within hospitals and enhance communication about medical errors. If we don’t talk about the problem, how can we expect to make meaningful strides against it?” says Peter J. Pronovost, MD, PhD.

An advocate for empowering clinicians to speak freely and question their colleagues, one of Dr. Pronovost’s most notable contributions was the introduction of an intensive care checklist protocol that saved 1,500 lives and \$100 million in the state of Michigan during its first 18 months. In addition, he recently collaborated with fellow Hopkins’ colleagues to develop a system to identify points within the radiation treatment process where the potential for errors are greatest.

The NCCN 2010 Patient Safety Summit featured a robust agenda that sought to emphasize safety risks associated with new trends and practices in radiation oncology as well as strategies and methods to overcome some of these challenges.

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What's New With REMS?

On May 7, 2010, NCCN convened the NCCN Oncology Summit: Recommendations for REMS Stakeholders. At this meeting, NCCN highlighted some of the challenges with Risk Evaluation and Mitigation Strategies (REMS) in oncology and emphasized that, while drug safety should be ensured, REMS presents some significant challenges to provider workload and may have negative consequences regarding patient access to medications. Since that time, additional meetings were held by the FDA and other stakeholders to address issues related to REMS. An overview of some of these meetings is provided below.

On July 27 and 28, 2010, the FDA held a public meeting to obtain input from stakeholders on the issues and challenges in the development and implementation of REMS. Over the course of this meeting, the FDA heard presentations from a variety of providers and stakeholder groups. The presenters represented providers (physicians, pharmacists, nurses), patients, and the pharmaceutical industry. Six topics were presented at this meeting:

- 1) Requirements for REMS
- 2) Establishing goals for REMS
- 3) Issues regarding elements to assure safe use (ETASU)
- 4) Evaluating the effectiveness of REMS
- 5) Effects of REMS on generics
- 6) Protection of patient information

Overall, providers and provider groups agreed with the goal of REMS, which is to improve patient safety. However, there were major concerns in the areas of standardization, implementation, assessment, and provider burdens.

Among the topics discussed during the meeting in July was the issue of Medication Guides, one aspect of REMS. The FDA recognized the current limitations with Medication Guides (patient literacy, for example) and has decided to address patient medication information on a larger scale. The FDA convened a meeting on September 27 and 28, 2010, to obtain input about a new framework for developing and distributing a single patient medication information document. By doing so, the FDA seeks to consolidate the different types of information given to patients.

Most recently, on October 6 and 7, 2010, the American Pharmacists Association convened a stakeholder meeting with the overall goal of taking concrete steps towards designing a REMS system that is effective in mitigating medication risks, is efficient to providers, and maintains patient access to medications. Issues related to effective REMS tools, standardization of REMS, and business models for adequate financial compensation were discussed. The stakeholders at this meeting represented primarily pharmacists but included stakeholders from other provider groups (including NCCN), patients, and the health technology industry. Representatives from the FDA were present as observers. The outcome of the meeting will be a white paper containing consensus statements regarding the above issues.

Much work still remains as to the proper implementation of REMS. The sole responsibility does not rest with the FDA but with multiple stakeholders as well. Changes to the system will not happen overnight, and much data still needs to be collected regarding the impact (from a monetary and workload standpoint) of REMS on providers. Furthermore, the science of risk mitigation must be further developed and refined such that REMS programs can be evaluated to assess whether they are effective in mitigating risk. Lastly, in a technologically advanced society that has allowed us to pay bills and manage existing accounts online, the hope is that REMS processes could be similarly streamlined to minimize the inefficiencies that exist.