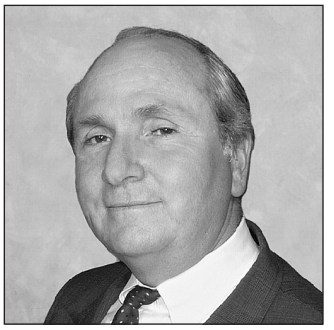
Journal of the National Comprehensive Cancer Network

The NCCN Drugs & Biologics Compendium™



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William T. McGivney, PhD, is the Chief Executive Officer of the National Comprehensive Cancer Network and a recognized expert in coverage policy and drug and device regulatory policy. Before joining the NCCN in 1997, Dr. McGivney directed the Division of Health Care Technology at the American Medical Association and worked for Aetna Health Plans as Vice President for Clinical and Coverage Policy. Awarded the FDA Commissioner's Medal of Appreciation in 1989, Dr. McGivney has served on numerous national boards and committees. He earned his PhD at the University of North Carolina at Chapel Hill and completed a postdoctoral fellowship in the Department of Psychiatry at the Harvard Medical School.

In the fast-moving field of cancer care, the use of drugs and biologic agents beyond the FDA-approved label accounts for 50% to 75% of the total use of such agents. Since the introduction of interferon in the late 1980s, the provision of coverage for such uses by insurers and managed care companies has been a major and, sometimes, contentious issue. This issue was highlighted again lately by the introduction of innovative, promising biologic agents with high price tags. Additionally, concerns have arisen regarding the adequacy of the 3 compendia recognized by federal and state statutes and federal regulation as mandated references for Medicare and private payors in the setting of coverage policies. One, *AMA Drug Evaluations*, went out of existence in the early 1990s, and further concerns exist about whether the others (*USP-DI, AHFS-DI*) can keep pace with innovation to reflect appropriate uses for new agents. Therefore constituencies of the cancer care community have been concerned that appropriate access to effective drugs and biologic therapies might be compromised.

The *NCCN Drugs & Biologics Compendium* (NCCN Compendium) can fill the breach as an authoritative, evidence-based, and timely source of recommendations for the appropriate use of drugs and biologic agents, including use beyond FDA-approved labeling. On March 30, 2006, a sub-committee of the Medicare Coverage Advisory Committee was convened to study the adequacy of existing compendia as basic mandated references for setting coverage policy. The NCCN testified in strong support of the need to recognize the NCCN Compendium as one of several mandated references. The NCCN testimony and comments focused on characteristics important for a compendium to serve the needs of patients and clinicians for appropriate access to drug and biologic therapy. The formal comments presented to the committee follow below.

NCCN is interested in your perspective and appreciates your support and that of relevant organizations in the quest to seek official recognition by the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) for the *NCCN Drugs & Biologics Compendium*.

NCCN Comments

The NCCN, a not-for-profit alliance of 20 of the world's leading cancer centers, is pleased to provide comments regarding the "authoritative drug compendia that may be used in determining the medically accepted indications of drugs and biologics used in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program" (FR vol.71, no.18, pp.4589-4590).

The NCCN shares with our colleagues at CMS the objective of providing access to effective therapies to Medicare beneficiaries. In a rapidly advancing area like cancer care, establishing of coverage policy based on the evaluation of safety and effectiveness can be challenging. This is particularly true for decisions about drugs and biologics. To inform and facilitate decision-making

about appropriate care, the NCCN strongly urges CMS to officially recognize and use the NCCN Compendium as one mandated reference among others for coverage decisions about the appropriate use of drugs and biologics in cancer care.

In the following comments, the NCCN will use the NCCN Compendium as a reference point to discuss and evaluate characteristics of a compendium that can be used to make informed and timely coverage determinations under Medicare and, thus serve to provide access to appropriate and effective drug and biologic therapy for Medicare beneficiaries diagnosed with cancer.

Recognition and Application as Standard of Care for Oncology: The recommendations of the NCCN Compendium are based directly on the recommendations of the NCCN Clinical Practice Guidelines in Oncology. NCCN Guidelines are widely recognized and applied as the standard of care for oncology in both the community practice setting and in academic practice. NCCN Guidelines cover the management of approximately 97% of all cancer patients, all major supportive care areas and prevention, screening, and early detection. NCCN Guidelines are widely referred to and used, as evidenced by the over 110,000 downloads per month of individual guidelines from the NCCN website. The recommendations in the individual Compendium chapters are derived directly from the corresponding guidelines.

It is important to note that NCCN Guidelines and, thus, the recommendations on the appropriate use of drugs and biologics in the NCCN Compendium are already used by Medicare (e.g., January 28, 2005 National Coverage Determination on Chemotherapy for Colorectal Cancer) and private payors (e.g., Aetna, May 3, 2005, oxaliplatin for pancreatic cancer) as an authoritative source in setting coverage policy.

Based on Available Scientific Evidence: NCCN Compendium recommendations are based on the explicit evaluation of scientific evidence integrated with expert judgment in a consensus-driven approach. The NCCN explicitly communicates the level of evidence and the degree of consensus that support each recommendation by designating 4 specific categories. Users of the NCCN Compendium can track back to the same recommendations in the NCCN Guidelines to see supporting references and to review discussions of supporting evidence or issues in management.

Input, Evaluation and Development by Multidisciplinary Panels of Experts: The NCCN Compendium provides recommendations about the appropriate and effective use of drugs and biologics from NCCN Guidelines panels, each composed of 15 to 22 experts representing involved specialties, subspecialties (medical oncology, surgery, radiation oncology), and clinical professionals. These experts are thought leaders from NCCN member institutions across the U.S. Patient representatives serve on select panels.

Presently, 46 NCCN panels focus on specific cancers, supportive care areas, and prevention and early detection. These panels meet at least annually, with some convening 3 times a year. The agenda for each regular annual meeting is based on new data that have been presented at major oncology meetings or published in the preceding year, panel member input, and broader expert input solicited from additional clinical faculty in NCCN institutions. Additionally, other interested parties, including patient advocacy groups, academic physicians from outside the NCCN, community physicians, and

industry, submit data to the NCCN for consideration according to a clearly documented policy.

Broad Participation to Diminish Bias: The representation of different subspecialties and clinical professionals serves to diminish opportunities for dominance by a single faction. The broad geographic distribution of representation expands the perspective of the panel. The large number of experts on each panel provides for the exposition of analyses and interpretations of data and evidence and presentation of experience from many clinicians with substantial stature both nationally and internationally. The expansion of formal input beyond the panel to more multidisciplinary experts based in NCCN Centers expands the sources and interpretation of evidence. As such, the NCCN has established a process that enhances the expression of divergent views and the identification of supportive evidence and, thus, the synthesis of broad-based and authoritative recommendations.

Recommendations Must Be Specific to Be Useful: NCCN Compendium recommendations are very specific; for example, listing patient stage and characteristics (stage IIA ER+/PR+ with tumor size 0.6-1.0 cm), and specific therapeutic application (e.g., neoadjuvant, adjuvant, second line metastatic).

Information and Recommendations Must Be Up-to-Date: The recommendations in the NCCN Compendium and in the NCCN Guidelines are the most up-to-date in any area of medicine. The NCCN Guidelines development and update process is a continual one as evidenced by the fact that 29 of 50 major NCCN guidelines have already been updated for 2006. Publication of new scientific evidence, actions on national trials, FDA actions, and others all may prompt calling a meeting of experts for any one of the 46 guideline panels.

Information and Recommendations Must Be Widely Available: NCCN Guidelines are made widely available free of charge across the U.S. and globally in a variety of formats. The most prevalent, up-to-date, and accessed format is online (www.nccn.org). Additionally, NCCN Guidelines are available in CD-ROM format and in paper versions such as publication in *JNCCN, The Journal of the National Comprehensive Cancer Network*, indexed by the National Library of Medicine. Additionally, NCCN collaborates with the American Cancer Society to develop and distribute user-friendly patient versions of the professional guidelines.

Other characteristics desirable and of high priority extant in the NCCN Compendium include:

- NCCN's publicly transparent online and published process for the development of guidelines including the process for acceptance and consideration of input, information, and data from all interested parties;
- Listing and description of appropriate combinations;
- Identification of sequence of use of chemotherapy/biotherapy regimens and of the sequence with the full continuum of care as outlined and defined comprehensively in the relevant NCCN guideline;
- Public identification of the NCCN guidelines panel members in all electronic and paper versions of the Compendium chapters and guidelines;

- Public review and publication of the aggregated potential conflicts of interests of panel members in both journal and electronic formats;
- Public declaration of sources of grants received by the NCCN to support distribution of material paper presentations of the Compendium chapters;
- Continuum and stratification of care presented in algorithmic format in NCCN Guidelines and translated and transposed into Compendium recommendations.

Importantly, the NCCN notes that the guidelines serve as the centerpiece for the Medicare 2006 Quality in Oncology Demonstration Program. Temporary G codes developed by CMS map directly to the NCCN Guidelines that delineate the continuum of care for the 13 cancer diagnoses and 85% of cancer patients as covered by the CMS demonstration program. Additionally, as mentioned previously, CMS characteristically references NCCN Guidelines in the establishment of national coverage determinations. As CMS moves more into the integration of processes for the setting of coverage policy, the establishment of reimbursement levels and the evaluation of the quality of care, it will be critical to assure decision-making for all 3 processes is consistent in terms of recommendations and sources of recommendations. Given the existing uses of NCCN information and recommendations by CMS, it is logical that the NCCN Compendium be officially recognized as one of several references mandated in the establishment of coverage policies for drugs and biologics.

NCCN information and informatics programs continue to develop. Presently 20 full time staff, including 7.5 full-time equivalent doctoral level scientists (4 MDs, 3 PhDs, 1 PharmD) are dedicated to the development of the guidelines, the Compendium, and related content. The NCCN is working on several enhancements to the current compendium to link recommendations electronically and directly to the continuum of care presented in the guideline recommendations and to the amplification and clarification of clinical issues in the accompanying guideline manuscripts. The NCCN is working to enhance specific annotation for the evidence supporting guideline recommendations both in terms of specific references and in terms of the graphic illustration of such references. The NCCN is working to directly link NCCN guidelines and compendium recommendations to the NCCN Oncology Outcomes Database that describes practice patterns, monitors concordance of practice to care, and evaluates the outcomes of such care.

In summary, the NCCN supports the efforts of CMS to improve the quality, effectiveness and efficiency of care made available to its beneficiaries. We believe that the NCCN Compendium provides sound, scientific, evaluative recommendations to support decision-making by CMS and its intermediaries and carriers. Thus, the NCCN requests official recognition by CMS of the *NCCN Drugs & Biologics Compendium* as a mandated reference for national and regional coverage decisions regarding the appropriate use of drugs and biologics in cancer care.