Journal of the National Comprehensive Cancer Network

New NCCN Program Recognizes Organizations Supporting Coverage for Clinical Trials and Appropriate Off-Label Drug Usage

In an effort to formally recognize organizations that support the appropriate, effective, and efficient use of oncology agents and care of patients, NCCN has created the NCCN Recognition Program. The new program will recognize managed care organizations (MCOs) that establish and follow policies which cover both the routine costs of care for individuals enrolled in approved clinical trials, as well as the appropriate use of off-label drugs in oncology. The program also recognizes non-payor organizations such as those that provide case management, patient management, and other services that make good faith efforts to educate their clients about these issues.

"NCCN strongly supports the critically important option of participation in clinical trials for patients with cancer. However, the lack of coverage of routine costs associated with trials may cause patients to forgo enrollment. In addition, the availability of a broad therapeutic arsenal of innovative drugs and biologics with indications that are supported by evidence and compendia, but that are beyond the indications listed in the FDA label, is essential for the treatment of the vast array of diseases that we call cancers," said William T. McGivney, PhD, Chief Executive Officer, NCCN. "We are pleased to acknowledge and call attention to the admirable organizations that help ensure that their beneficiaries as patients have access to the best care."

MCOs eligible for recognition will be required to attest that they adhere to policies that cover the routine costs of care for individuals enrolled in approved clinical trials, as well as policies that cover the appropriate use of off-label drugs as indicated in the NCCN Drugs & Biologics Compendium (NCCN Compendium). Non-payor organizations will be required to attest that, while they do not establish or apply their own coverage policies, they encourage their clients to adopt these policies. Those meeting the requirements will be publicized on NCCN's Web site, NCCN.org.

National Business Group on Health Launches Major Initiative to Address Cancer in the Workplace

The National Business Group on Health, a non-profit association of more than 300 large U.S. employers, today announced the launch of a major, multi-year initiative to help employers address a growing healthcare challenge – cancer in the workplace. The 3-year project, which is being conducted in collaboration with NCCN, will result in a series of comprehensive resources and tools for large employers, including an Employer's Guide to Cancer Treatment and Prevention.

Cancer is a far-reaching problem in the United States. According to the American Cancer Society, almost 1.5 million new cancer cases were diagnosed in 2009 and more than 10 million Americans have a history of cancer. Additionally, cancer is the second leading cause of long-term disability (LTD) and the sixth leading cause of short-term disability (STD) in the United States. The indirect costs of cancer to employees include an estimated $136 billion in lost productivity each year.

"Employers are becoming more and more concerned about cancer in their employees and families," said Helen Darling, President and CEO of the National Business Group on Health. "Clearly, it is important that employers educate their beneficiaries about preventable forms of cancer. Moreover, employers need to implement strategies to manage and support employees who are diagnosed with cancer and also provide programs and services aimed at employee caregivers. This project will go a long way toward helping employers meet this challenge."

The ultimate goal of the 3-year project is to develop an Employer's Guide to Cancer Treatment and Prevention. This comprehensive set of tools and recommendations

for the entire spectrum of employer-sponsored benefits and programs will be based on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), which encompass clinical guidelines and recommendations based on evidence and expert judgment for every aspect of the cancer care continuum. As outlined by the Business Group, the project includes the following objectives:

- Establish a 25-member National Advisory Committee on Employer Services for the Cancer Continuum of Care that will develop recommendations for the design, quality assurance, structure, and integration of resources, programs, and services around the full range of benefits and programs to include the health plan, health and productivity programs, and health promotion/wellness services.
- Create a quick reference Summary Document on Employer-Sponsored Benefit Design, Pharmacy Benefits, and Contracting with Health Plans that will help employers determine whether their current benefits are consistent with evidence-based cancer care and will ensure access to care consistent with recommended NCCN Guidelines.
- Develop an Employer Cancer Health Benefits Toolkit covering general medical, pharmacy, and mental health benefits for the continuum of cancer care.
- Create a companion set of Benefit Manager Guides for other strategic audiences, such as disability managers, focused on the productivity indicators including incidental absence, short- and long-term disability, family medical leave, workers' compensation and EAPs.
- Develop Tools for Employees: Cancer Survivorship, Health Promotion and Wellness which will include fact sheets, information brochures and other literature on various aspects of cancer, treatment, and care.

"Our increasing understanding of cancer leads to the realization that cancer is really a multitude of disease states," said William T. McGivney, PhD, CEO of NCCN. "Further, because of innovative treatments, many cancers are becoming chronic diseases. It is critical that the purchasers and providers of care work together to assure that the services delivered along the continuum, from prevention through treatment through long term follow-up, are optimal in terms of safety, effectiveness and efficiency."

"While there is an abundance of information about cancer, currently there is a vacuum for the delivery of treatment, prevention, and support services associated with cancer in the workplace. The deliverables of this project are intended to eliminate this vacuum by providing systematic, evidence-based approaches to care design and delivery," Ms. Darling concluded.

NCCN Oncology Policy Summit: Biosimilars – Regulatory, Scientific, and Patient Safety Perspectives

The use of biologics is widespread in the active treatment of cancer and for supportive care management. As the use of biologics continues to grow and older biologics come off patent, consideration will need to be given to the incorporation of biosimilars into clinical practice and the safety and outcomes of patients with cancer. As the FDA implements elements of the BPCI Act, stakeholders must actively engage in discussions to ensure biosimilars are safe and effective for the treatment of patients with cancer.

The policy issues surrounding biosimilars have come to the forefront of discussion because of their potential to reduce health care costs (based on an extrapolation of the cost benefits from generic small-molecule drugs). However, there are significant scientific and manufacturing challenges to ensuring that a biosimilar is equivalent to the innovator product. Additionally, the FDA has not yet developed a robust biosimilar approval pathway, raising questions regarding the types of studies (pre-clinical and clinical) that would be required to gain FDA approval. Furthermore, biosimilars exude safety concerns related to immunogenicity. Coupling these concerns with a skepticism regarding whether

or not there is equivalent efficacy compared to the reference product, clinicians may be hesitant to utilize biosimilars. Potentially, a low uptake of biosimilars and a heavy investment in biosimilar development may minimize the cost benefit derived from a lower acquisition price of biosimilars.

In April 2011, NCCN will host an invitation-only NCCN Oncology Policy Summit: Biosimilars – Regulatory, Scientific, and Patient Safety Perspectives to provide a forum for in-depth discussion of the aforementioned regulatory, safety, and clinical issues surrounding biosimilars. Prior to the Policy Summit, NCCN will convene a multi-disciplinary, diverse work group to identify challenges and provide recommendations on the topic of biosimilars in oncology. The focus of the Policy Summit will be on illuminating the challenges and offering recommendations, from a multi-stakeholder viewpoint, for the best strategies to overcome these challenges.