Impact of the NCCN Biomarkers Compendium on Managed Care Pharmacy

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In December 2012, the National Comprehensive Cancer Network (NCCN) announced the availability of its NCCN Biomarkers Compendium, a new tool developed to support decision making related to biomarker testing in oncology patients. Biomarker testing, commonly referred to as molecular testing, is performed to identify specific types of gene expression or mutations that may lead to particular diagnoses or treatment decisions for patients. Often, these tests are undertaken to assess risk, diagnose or classify disease, and/or assess potential response to therapy. By utilizing certain biomarker tests to identify the most appropriate patients for therapy, better patient outcomes may result.

With the number of biomarker tests growing substantially (approximately 2,000 tests are on the market currently, with an additional 1,000 tests becoming available per year), a need existed to develop a tool to help providers and managed care organizations determine the clinical utility of these tests. In a December 2012 interview with representatives from NCCN, Senior Vice President of Clinical Information and Publications Joan McClure stated, “The use of biomarkers is evolving. We wanted to develop a compendium that would be an easy reference tool that would allow payers and physicians to determine if testing would be useful.” Andrew D. Zelenetz, Vice Chair of Medical Informatics, Department of Medicine, and Chief, Lymphoma Service at Memorial Sloan-Kettering Cancer Center, and Chair of the NCCN Guidelines Panel for Non-Hodgkin’s Lymphoma, added, “Biomarker testing should be used to establish accurate diagnosis and identify groups of prognostically useful patients and to support therapy decisions.”

The NCCN Biomarkers Compendium provides information on biomarker testing that is referenced in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Within the tool, users are able to select specific guidelines, diseases, molecular abnormalities, and gene symbols. The subsequent search results contain fields that can be selected by users, such as specific indication of the biomarker test, the test itself, chromosome, what the test detects, methodology, specimen types, test purpose, guideline page with recommendation, and notes.

From December 2012 to January 2013, Xcenda, a consultancy and business unit of AmerisourceBergen Specialty Group, conducted a survey with advisors who participate in Managed Care Network (MCN). The survey, which was fielded to medical and pharmacy directors, assessed the impact of the NCCN Biomarkers Compendium on managed care pharmacy decision making. Survey respondents represented 96 million covered lives from commercial (93.3%), Medicare (71.7%), and Managed Medicaid (56.7%) plans. The survey was initiated via a web-based format in December 2012, approximately 2 weeks after the NCCN Biomarkers Compendium became available. Surveys were concluded in mid-January 2013.

Awareness of the NCCN Biomarkers Compendium

A majority of respondents (71.7%) were not aware of the recent availability of the NCCN Biomarkers Compendium, and similarly, only 1 respondent indicated that the Compendium had been reviewed by the respondent’s health plan. Respondents were also asked when they anticipated that their plans would evaluate the Compendium for its potential use by the plans, if at all (Figure 1). Almost half of the respondents indicated they would evaluate the Compendium within the next 6 months, and approximately 85% said they plan to review the Compendium in the next 12 months.

Current and Future Access to Biomarker Testing

Currently, approximately half of the survey respondents specified that they evaluate biomarker testing in oncology on a “per-case” basis, while 20% indicated that they allowed all biomarker testing at their plans, and 20% allowed any biomarker test listed within the NCCN Drugs & Biologics Compendium (NCCN Compendium); 13.3% were not sure. While a majority (66.7%) of respondents felt that it is still too early to tell whether the NCCN Biomarkers Compendium would change access (i.e., coverage) of biomarker testing for
their plans, approximately one-fourth of the respondents suggested that access to biomarker testing would increase due to the Compendium (Figure 2). Approximately 22% of respondents also felt that the Compendium would be used to gain access to biomarker testing that was not currently available to their members.

The use of biomarker testing in solid tumors seems to be a particularly fast-growing area of research based on recent approvals by the U.S. Food and Drug Administration of agents in solid tumor types, such as the approval of XALKORI (crizotinib) in 2011 for treatment in non-small cell lung cancer patients with a defect in the anaplastic lymphoma kinase (ALK) gene. However, both Ms. McClure and Dr. Zelenetz indicated that solid tumor biomarker testing is still in its infancy. In light of the growth in this specific area, MCN respondents were asked if they anticipated that the NCCN Biomarkers Compendium would inform coverage decisions for drugs, biologicals, and their associated diagnostic tests. A majority (61.7%) of the payer respondents felt that the Compendium would inform coverage decisions for drugs, and an additional 35% of respondents were unsure (only 3.3% said it would not be used). Overall, two-thirds of respondents felt that the NCCN Biomarkers Compendium would be valuable in terms of informing coverage decisions for biomarker testing in their health plans. The survey showed that payers, the majority of whom have not reviewed the Compendium, may seek it as a resource when making coverage decisions for access to biomarker testing in the future. The Compendium could also be utilized to decrease access to specific biomarker tests that have previously been accessible, based on the data provided. Limitations, such as time from the Compendium availability to survey adjudication or the small number of payers sampled, may have skewed results. Xcenda will consider conducting another survey in 3 to 6 months in order to verify response from managed care payers and assess the continued impact of the Compendium.

While the NCCN Biomarkers Compendium may be valuable to decision makers within managed care organizations, it may be more useful for practitioners in determining which tests should be utilized. The Compendium may be employed by practitioners in order to increase access for the testing that they would like to use in their patient populations. Additionally, manufacturers may target the Compendium in order to promote specific biomarker testing that may lead to certain therapy selections based on the outcome.

The goal of the NCCN Biomarkers Compendium is to provide clinical information and scientific details for biomarker uses that are currently listed in the NCCN Guidelines. The NCCN Biomarkers Compendium will continue to evolve as both payers and providers provide feedback on its use in practice.

**DISCLOSURES**

The study was conceived and designed by the 3 authors. Denno interpreted the data and revised the manuscript. Denno collected the data and wrote the manuscript with the assistance of Brown.

The authors report no financial conflicts of interest related to the subjects or products discussed in this article.

**REFERENCES**

5. The survey conducted by Xcenda is PayerPulse, a monthly survey among payers that participate in a Managed Care Network.

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