

# A P&T Perspective on Adoption of Clinical Guidelines by Payers

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The Zitter Group conducted a Pharmacy and Therapeutics Perspective Meeting (PTP) to understand the implications of clinical guideline adoption by payers. Following is a summary of that perspective.

## Introduction

As the cost of oncology continues to grow—and cancer incidence and treatment options increase—heightened spending has put additional economic pressure on private payers to evaluate therapeutic management for potential savings. Thus far, payers have been limited in their ability to regulate utilization of oncology drugs due to the political and medical sensitivity of its outcomes. In '08, United Healthcare adopted NCCN guidelines to help determine coverage of off-label use of oncology agents. We examine what impact this has on the financial well being of Managed Care Organizations (MCOs) and speculate on the process a private payer may follow when considering adoption of NCCN guidelines. We examine clinical, economic, employer considerations, and political issues. It is our assumption that these elements are symbolic of all payer considerations for guideline adoption regardless of origin.

The NCCN guidelines are developed by a cohort of 44 individual panels, representing 800 clinicians and researchers, and 21 NCCN member institutions whose base guidelines are a mix of clinical and consensus data. Unlike other listings, such as those of the American Society of Clinical Oncology which evaluate therapies using primarily evidence-based clinical data submitted for FDA review, the NCCN weaves consensus data into recommendations, including those for off-label use. Therapies are graded a composite score (e.g., 1, 2A, 2B) combining quality of evidence and level of consensus, and are recommended accordingly. Consequently, there is no prioritization of therapies and therefore no step edits.

In total, the NCCN guidelines account for 97% of patients with cancer (NCCN Compendium Revision Request - CAG -00389. Cms.hhs.gov. 2/8/2008). This methodology, which incorporates multiple sources of data, brings about questions concerning a possible quality/quantity trade-off for payers and the disadvantages of not having a stepped procedural recommendation. Questions to be asked by private payers when considering implementation of NCCN guidelines should include:

- To what extent can consensus outweigh label indications and FDA approval?
- How robust is research to support determinations?
- How do NCCN guidelines differ from those presently employed by payers?
- And, how do they differ from state mandates?

## Clinical Factors

In evaluating compendium integration, payers must consider the types of clinical data that are admissible for guideline adjudication, including methodology, breadth, sources of data, and comprehensiveness. During a PTP meeting, the credibility of a compendium should also be assessed to tease out any underlying bodies of influence.

The NCCN uses clinical trial data not included in FDA label submission to determine guidelines for off-label use, which can account for a large part of plan utilization, and the fluidity of guidelines means that they can be updated often. Guidelines don't have a tier structure, so payers are unable to enforce best practices and quality of care and may have to consign prescribing power to physicians, thus



losing treatment tracking transparency. If an MCO allows utilization of treatments according to guidelines without prior authorization (PA), tracking tumor type and therapy will become more difficult.

### **Economic Issues**

According to our evidence, the movement toward an MCO utilizing a set of guidelines implies a standardization of approval metrics, which is unprecedented in cancer management, and brings into question spending control, implementation cost, administrative pushes, shifts in manufacturer relationships, and patient cost-sharing. Any paradigm shift necessitates an initial investment, but in a category whose management has been relatively loose, standardization may have a large financial impact.

Increased drug spending as a result of expanded off-label coverage determinations is a primary economic

concern in guideline adherence. Our data show each approval can cost over \$100,000 a year. Payers must identify areas of the NCCN guidelines that project an increase in approvals/coverage compared to their current coverage, and areas that could lead to cost savings. For example, the NCCN broadens Avastin's indications to include invasive breast, ovarian, kidney, and CNS tumors, but limits Erbitux and Vectibix to only wild type K-ras positive tumors (data on file Zitter Group). Data from our "Managed Care Oncology Index" also suggests, thus far, payers have been unable to track therapies and indications to the level of granularity that facilitates cost assessments; and yet, payers must consider fiscal gains/losses in addition to those repercussions associated with dissolving past paradigms. Furthermore, by incorporating NCCN guidelines, payers effectively lose therapy prioritization

and must forecast on the potential for manufacturer and physician preferential status contract dissolution.

### **Employer Considerations**

An additional concern for managed care is their fiduciary responsibility to their clients, such as employers, to ensure that healthcare dollars are being spent appropriately. If an MCO chooses to cover all treatments included in NCCN guidelines without prior approval, how can they ensure appropriate utilization? While this cannot be directly achieved, the answer is to incentivize physician guideline compliance. Tactics utilized in the past to induce compliance include retroactive claim reviews and pay for performance bonuses. Furthermore, new physician contracts may have to be re-drawn or re-negotiated to include these accountability metrics and any changes in treatment coverage reimbursement.

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Another such alternative to regulate physician compliance is to develop a hybrid model where prior authorization is maintained, but its criteria are changed to mirror guidelines. In the hybrid model, physicians can be confident in coverage approval while payers can ensure accountability. Regardless of PA implementation, there is a host of implementation costs associated with changing system-wide management.

Guideline adoption also has to include intra- and inter-company communications and education, which could be costly to many departments including provider relations, pharmacy, claims, and medical personnel. As mentioned earlier, the fluidity of guidelines means that MCOs have to have the operational capability to accommodate policy updates and integrate state mandates. Externally, the MCO should assess how they will communicate changes to providers and oversee pull-through, while mitigating potential pushback.

### Political Issues

As cancer treatment options continue to grow, so does the political sensitivity of payer decisions. Any attempt to manage therapeutic options is popularly associated with the denial of coverage. When payers are transitioning from loose regulatory controls to policy standardization, their approval process can come off as mechanic, definitive, and binary in willingness to provide coverage, and could open a political firestorm with customers and providers.

However, by using third party compendia or guidelines in determining

appropriate utilization, payers are able to distance themselves from bias and liability. Whether viewed in a positive or negative light, guideline adoption will undoubtedly impact the larger political context of cancer treatment.

Additional challenges may arise with direct stakeholders, such as manufacturers and physicians. Not only will the non-prioritization of therapies affect contracts on a product level, but it could also affect contracts on a manufacturer level. Large physician groups are equally capable of pushing back in some geographic areas, if they carry enough clout to challenge decisions. In some cases, these providers may end up leaving payer networks. To preclude political repercussions, managed care must work with stakeholders early on in the transition process.

### Suggestions for Oncologists

Many health plans are looking to establish treatment protocols by either developing policies internally or adopting compendia listings. Oncologists should be able to alleviate the impact of such changes by understanding their options and getting involved early on in the process.

Oncologists need to remain cognizant of policy changes by understanding the policies of patient plans, observing any changes in policy, and assessing how additional adjustments would impact their practice. Once physicians have calibrated the impact of change for their respective payer networks, they can prioritize their next steps and voice their opinions through a range of avenues, either as a network physician or local thought leader.

Oncologists who want to assume a larger role in payer decision making can consult as volunteer members of payer committees.

Payers have a number of committees open to community healthcare providers such as their P&T, quality improvement, and contracting committees. Oncologists who actively participate in health plan committees will become local experts and sought out by payers when they consider broad changes to oncology coverage policies.

Early participation in these types of discussions is likely to have more impact than retroactive complaints. Health plans will have to invest heavily in staff-training and infrastructure changes to accommodate policy changes; therefore they will be reluctant to make any major changes once the decision is final. When policies change, oncologists should feel sufficiently prepared to present supporting data and information used in contracting negotiations. **KK** **MCH**

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With 20 years of experience, The Zitter Group helps life sciences and medical product manufacturers work more effectively with managed care companies.

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The National Institutes of Health estimate that \$89 billion was spent treating cancer in 2007. (CDC, "Preventing and Controlling Cancer," 2008)