

ISSUES

Not to Be Forgotten— Off-Label Use in Oncology

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With everything that is happening in healthcare policy, it is easy to overlook some of the everyday issues that ACCC members face with regard to providing quality cancer care. Today's busy healthcare practitioners are continually buffeted by concerns such as government shutdowns, the sequester, the SGR fix, and challenges related to ACOs, Health Insurance Exchanges, and Health Information Exchanges. However, one issue has remained a constant for the past five years—off-label therapy. Off-label therapies play a critical role in a physician's ability to provide quality care. Despite the fact that the oncology community as a whole understands the importance of off-label therapy, these services still face significant payment and reimbursement challenges.



In August-September 2013, ACCC and PhRMA released results of a joint survey on the impact of payer coverage and reimbursement policies on off-label use of anticancer therapies. This survey was a follow-up to a survey conducted five years ago, which measured the same issues. One hundred and sixty-five ACCC members responded to the 2013 survey and, as expected, a vast majority (91 percent) responded that they find off-label therapy important to their ability to provide quality care to their patients.

We did find some interesting differences between the two surveys. For example, using a 5-point scale with 5 being extremely important, this year's respondents rated the importance of off-label therapy an average of 3.6, compared to 4.1 in the 2008 survey. In what may be a related change, this year's respondents also assigned less importance to drug compendia—one of the main sources practitioners use to help justify off-label therapies with payers. In 2013 respondents rated the importance of drug compendia as 3.7, down from 4.2 in 2008.

Despite these survey results, the drug compendia are still an important tool for payers and providers alike. Additionally, the 2013 survey clearly showed that providers continue to wrestle with issues related to off-label therapy; 80 percent of respondents report that payers have denied coverage for medicines that are listed in compendia. Other challenges include:

- **Prior authorizations.** A little more than 90 percent of respondents report that private payers are using prior

authorizations to restrict coverage and reimbursement for off-label uses of anticancer drugs.

- **Post-payment audits.** Respondents in this year's survey report increased use of post-payment audits by Medicare (40 percent in 2013, up from 27 percent in 2008) and private payers (47 percent in 2013, up from 25 percent in 2008.)

One of the new survey questions asked in 2013 had to do with the use of guidelines and pathways. Pathway utilization has grown significantly in the last five years, and these treatment parameters may have had an effect on off-label drug use, including how people are using drug compendia. For example, if the off-label indication is on the approved pathway, then the practitioner may no longer be responsible for providing compendia or journal evidence with the claim. In the 2013 survey, 27 percent of respondents report having some type of partnership with payers regarding clinical pathways.

The bottom line remains: a compendia listing does not guarantee coverage or payment, and coverage policies of public and private payers continue to have a major impact on treatment decisions. In fact, 95 percent of survey respondents report that coverage and reimbursement policies cause clinicians to alter their clinical decision-making. Further, the increasing utilization of pathways and guidelines may continue to alter the oncology landscape, and ACCC will continue to monitor these changes to determine how off-label therapy impacts its membership. 