

Impact of Payer Coverage and Reimbursement Policies on Off-Label Use of Anticancer Therapies

A report from the Association of Community Cancer Centers (ACCC) and Covance Market Access Services, Inc.

In 2008, ACCC and Covance Market Access Services, Inc., with assistance from the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO), sent survey invitations to nearly 3,500 office-based oncology practices. The goal: to see how payer coverage and reimbursement policies are affecting how physicians prescribe off-label.

Nearly half of the respondents report that their practice's frequency of off-label use of anticancer therapies has decreased over the past five years. Coverage and reimbursement challenges were the overwhelming reasons cited by oncology practices for their decreased use of anticancer therapies for off-label uses. Those oncology practices that reported an increase in off-label use attribute their increased utilization to the availability of more drugs that have been shown to be effective in uses that are not yet FDA-approved.

Other key study findings involved the importance of off-label drug use, drug compendia and peer-reviewed medical literature, and payer policies.

About Off-label Drug Use...

- Off-label use is extremely important to 50 percent of oncology practices surveyed,

and is at least somewhat important to 79 percent of oncology practices.

- Approximately 87 percent of oncology practices have prescribed at least one anticancer drug for an off-label use.
- Oncology practices rely on a variety of sources of information to make off-label treatment decisions for anticancer therapies.

About Drug Compendia and Peer-reviewed Medical Literature...

- More than half of oncology practices surveyed consider drug compendia extremely important to their practice's use of off-label anticancer therapies; 81 percent consider drug compendia at least somewhat important.
- Drug compendia are the primary sources of information that Medicare contractors use to support coverage and reimbursement for off-

label uses of anticancer drugs.

- For nearly 40 percent of oncology practices, 25 percent or less of off-label use is supported by drug compendia.
- Although they rely on drug compendia, private payers place almost equal emphasis on clinical guidelines and peer-reviewed medical literature to support coverage and reimbursement for off-label uses of anticancer drugs. For nearly 60 percent of respondents, peer-reviewed medical literature is extremely important to their practice's use of off-label anticancer therapies.

About Public and Private Payers...

- More than half of respondents report that local Medicare contractors' coverage and reimbursement policies frequently or very frequently restrict their practices' off-label use of anticancer therapies; 40 percent

report that private payers restrict off-label use.

- Claims denials are the primary method Medicare contractors have used to become more restrictive with coverage and reimbursement for off-label uses of anticancer drugs.

Prior authorizations, claims denials, and requests for medical records are the primary methods private payers have used to become more restrictive with coverage and reimbursement for off-label uses of anticancer drugs.

- Oncology practices report that more than 60 percent of off-label uses are at least occasionally denied, despite being supported by compendia listings or peer-reviewed medical literature.

Off-label coverage and reimbursement policies at least occasionally result in treatment delays for 74 percent of oncology practices, and frequently or very frequently result in treatment delays for 27 percent of practices.

Figure 1. Oncology Patients (Not Patient Visits) Seen by Oncology Practices Surveyed (per Month)

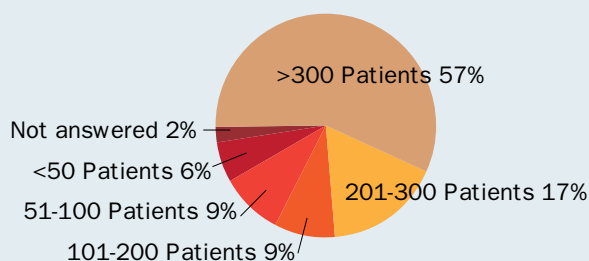


Figure 2. Number of Physicians Per Oncology Practice Surveyed

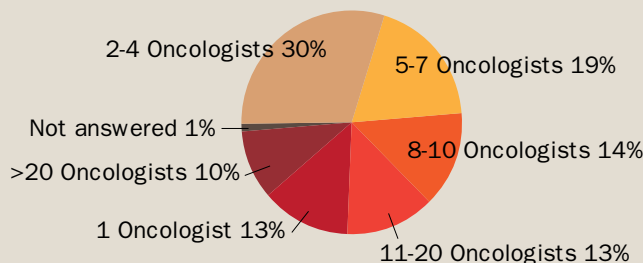


Figure 3. Distribution of Oncology Practices by Urban/Suburban/Rural Status

