The Ongoing Revolution in Oncology Care

Results of *The Precision Oncology Annual Trend Report, Second Edition*, sponsored by Novartis Oncology, reveal the growing impact and importance that predictive biomarker tests have on treatment decision making.

Impact of Positive Basket Trials

The American Society of Clinical Oncology and the National Cancer Institute are conducting basket studies that are enrolling patients regardless of tumor type and defining treatment according to biomarker status (TAPUR and MATCH, respectively). Another study by the Memorial Sloan Kettering Cancer Center was recently completed.¹⁻³

**TAPUR and MATCH Basket Clinical Trials**

Providers expect TAPUR and MATCH to **redefine the appropriate use** of targeted oncology therapeutics by relevant predictive biomarker test/companion diagnostic.

Providers and payers believe successful TAPUR and MATCH data will make **biomarker test results more important than a patient’s tumor type** when making coverage or treatment decisions.

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In August 2015, 125 respondents (n=50 oncologists, 25 pathologists, and 50 payers), completed an online survey with additional in-depth interviews conducted with 5 members of each group. Data were collected from payers representing more than 175 million covered lives.

TAPUR, Targeted Agent and Profiling Utilization Registry Study; MATCH, Molecular Analysis for Therapy Choice.
The development of next generation sequencing (NGS) technology will increase the opportunity to identify multiple cancer-related gene mutations in a single, rapid, low-cost test. While current coverage is low, this report supports an increase in coverage of genomic-sequence panel tests. Many providers and payers believe that NGS technology could change the face of cancer treatment and lead to greatly improved outcomes.

Payers surveyed indicated that a price threshold of just under $1000 would disrupt the market and potentially replace single-mutation tests.

The Potential of Biomarkers

Understanding the Role of Biomarkers Tests and Companion Diagnostics Is Essential to Helping Payers Continue to Improve Patient Care

We are trying to achieve the best outcomes possible for our members. Providing coverage for oncology predictive biomarkers is critical to reaching that goal.

— Medical director at a large-sized plan (<1 million lives managed)

Next Generation Sequencing

Broader Adoption of Next Generation Sequencing and Genomic-Sequence Panel Utilization/Coverage

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PD-L1 Biomarker Test May Define PD-1 Inhibitor Utilization

84% of oncologists and 70% of payers surveyed indicated they would prescribe and cover a PD-1/PD-L1 with a highly predictive biomarker test identifying responding patients. 64% of payers surveyed strongly agreed or agreed that a PD-1/PDL1 inhibitor with a predictive biomarker test would be more cost effective.

n=50 oncologists, 25 pathologists, and 50 payers

Immuno-Oncology Products Show Efficacy and Gain Approvals

- October 2015 – pembrolizumab approved by FDA for second-line treatment of non-small cell lung cancer (NSCLC) tumors that express high levels of the PD-L1 protein with a companion diagnostic to test PD-L1 levels. Recently approved treatments have demonstrated remarkable response rates in melanoma and NSCLC but at a significant price.

Everyone is interested in cost savings and you can make an argument for enriching the population of people who will benefit. I think ASCO and all decision-making groups will probably encourage this because you are sparing patients who are not going to benefit and you are also saving money.

— Oncologist

ASCO, American Society of Clinical Oncology.
Predictive Biomarker Tests: Making the Value Proposition

Key Insights from The Precision Oncology Annual Trend Report

- **Predictive biomarker tests**
  - Can improve quality and cost effectiveness of oncology patient care
  - Payer coverage lags behind provider intent to use
  - Utilization is being influenced by payer coverage management tools such as prior authorization and, increasingly, pathways
  - Require better outcomes data and/or third-party validation for payer coverage
  - May drive preference among PD-1 inhibitors
  - Next generation sequencing is on the brink of widespread adoption and enabling precision oncology

References: