Personal Medicine & Genomic Profiling Enter the Mainstream?

Direct-to-Physician Marketing

By Karen Gilden

While limited prognostic genomic testing is available for breast cancer, for most tumor sites, personalized medicine tests are still seen as "on the drawing board" or at best, experimental. However, beginning in 2008, three companies have entered the market with commercially available tests that provide genomic profiles of individual patients' tumors. Some front-line physicians, faced with patients for whom there exists no (or no untried) validated options available for their patients' disease, or advanced state of disease, are drawn to the opportunities offered by these emerging, commercially available genomic tests. In the January 19, 2011 issue of the Journal of the National Cancer Institute, science writer Ken Garber discusses direct-to-physician marketing efforts by three biotech companies. Information from this article, as well as a brief list of implications for cancer program administrators and hospital c-suite executives, are highlighted in this article.

Available Here & Now. While to date, fewer than 13,000 cancer patients have used these tests, they are being marketed directly to physicians. Since the laboratories performing these tests are CLIA certified, no FDA approval is needed to sell them. Clearly, the most important question about such testing is whether or not the tests work. And by implication, do they lead to better outcomes than are normally derived from treatment selection without genomic testing?

So What Are the Implications for Community Cancer Program Administrator?

- Know that your Cancer Center or Cancer Program physicians may be receiving targeted marketing about these genomic testing products/services directly;
- Be aware that genomic testing is no longer "in the future" but has advanced to the marketplace and access to, or use of these tests, may eventually be used by you or competitors as a point of differentiation in your local market;
- Some insurers, including Medicare, are reported to be reimbursing for these tests; and,
- There is some difference of opinion about the timing and role of clinical research related to the existing genomic testing products/services.

Some Scientists Urge Controlled Clinical Trials. Several physician scientists weigh in strongly that controlled trials should occur before any test is used guide physicians who select patient treatments. Further, physician researchers note that genomic tests should lead patients to clinical trials. Those who defend current use of genomic profile testing, prior to rigorous clinical trials, urge use of the emerging technologies that make such testing possible and point out that awaiting completion of Phase III trials will delay genomic testing use by decades – to the detriment of current patients with advanced disease.

Current Genomic Testing Value. The one research study, referred to as the Bisgrove trial, completed and published to date, indicated slightly more than ¼ (or 27%) of 66 patients whose treatments were based on test guidance using the Caris Life Sciences test (Target Now), had a progression-free survival (PFS) time lasting at least 30% longer than that achieved by previous treatments. Investigator and lead author Daniel Van Hoff called the study results' conclusions "promising." But randomized efficacy studies remain in early stages.

The three companies – Caris Life Sciences (Irving, TX), Intervention Insights (Grand Rapids, MI), and GeneKey (Boston, MA) — who currently offer these tests, position them as tools that assist oncologists to choose appropriate therapeutic drugs or drug combinations. One such test, Target Now (the Caris product), does not result in a specific treatment recommendation. Instead, the test results report provides the oncologist with a list of applicable drugs, accompanied by relevant literature citations, and an efficacy "weighting". The test report summary from OncInsights, sent to the treating oncologist, similarly provides a list of drugs, along with a scoring or efficacy "weighting" figure that incorporates test evidence and background material, rather than a specific treatment recommendation. One expert referred to the results as "hypotheses for discussion with the physician."[1]

What does Genomic Testing Cost & Do Insurers Pay? These two companies charge $3,400 - $3,900 for each test. According to a Caris Life Sciences executive, the test is fully reimbursable from Medicare and from several private insurers. OncInsights representatives note most insurance does not yet cover their test.

The GeneKey service costs considerably more ($30,000 - $35,000) per individual patient. To date, fewer than 20 patients have used the service. GeneKey representatives note they rolled out their genomic testing service slowly to ensure test procedure consistency and delivery capabilities. But they say they are now ready to launch the product more broadly. Following biospecimen submission and testing, GeneKey dispatches a scientific team to meet in person with the patient and his/her physician to discuss the results and test implications. GeneKey has published no research on its test; though the organization notes it is designing controlled studies.

[1] GeneKey company Chief Scientist Raphel Lehrer, Ph.D., quoted in JNCI, Vol. 103, Issue 2, January 19, 2011. " Ready or Not: Personal Tumor Profiling Tests Take Off". P. 85.