Lack of clinically useful diagnostics hinder growth in personalized medicines

Less than 1% of currently marketed drugs in U.S. have a companion diagnostic

- Lack of evidence linking diagnostic tests to health outcomes has caused payers to be skeptical about the clinical usefulness of those tests.
- Lack of clinical usefulness of many companion diagnostics has led payers to deny or restrict reimbursement of tests.
- A minority of U.S. payers require documentation that a diagnostic test has been conducted prior to prescribing personalized drugs – even when the diagnostic is included on the label.
- U.S. payers impose reimbursement restrictions on self-administered personalized drugs, such as high cost sharing, prior authorization, and quantity limits.
- Pharmacogenomic experts foresee moderate growth over the next five years in post hoc development of companion diagnostics to personalize already approved drugs, co-development of companion diagnostics, and personalized drugs.

The number of personalized medicines and companion diagnostics in use in the United States has gradually increased over the past decade—from a handful of medicines and tests in 2001 to several dozen as of 2011. The numbers, however, haven’t reached the potential hoped for when the human genome project was completed in 2001. Based on surveys conducted by Tufts CSDD, it appears that lack of evidence concerning the clinical usefulness of many current companion diagnostics is a major factor limiting the potential of personalized medicine.

Despite a few success stories, pharmacogenomics—research that explores ways in which genetic variations can be used to predict whether and how an individual patient may respond to a drug—has had limited impact to date on clinical practice. Scientifically, the process of biomarker discovery and validation in general, and parallel development of drugs and companion diagnostics in particular, has been slow. Additionally, regulatory and reimbursement issues have limited uptake in clinical practice, particularly with respect to companion diagnostics, but also for drugs lacking effective diagnostics. Without clinically useful diagnostics, development of personalized medicine is likely to continue at a relatively slow pace.