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Tufts Center for the Study of Drug Development
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Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

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.