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Three-Quarters of U.S. Health Plans Reimburse for Off-Label Uses of Prescription Drugs, According to Tufts Center for the Study of Drug Development

BOSTON – March 10, 2009 – Reflecting recent rapid growth of off-label prescribing of prescription drugs, 75 percent of all health plans in the United States now reimburse patients for such treatments, according to a study recently completed by the Tufts Center for the Study of Drug Development.

Of health plans that reimburse for off-label uses, over half impose conditions, including step therapy, indication restrictions, prior authorization, and quantity limits, and nearly 90% rely on pharmaceutical compendia to inform their off-label use reimbursement decisions, the study found.

The findings were based on a Tufts CSDD survey of 179 third-party payers in the U.S. that administer Medicare and Medicaid pharmacy benefits.

“Since patients do not pay directly for most off-label uses, third-party payers have become crucial for market access,” said Joshua Cohen, a senior research fellow at Tufts CSDD and lead investigator on the study. “While reimbursement decisions with respect to on-label indications are relatively well understood in terms of evidence requirements, off-label use reimbursement until now has been less transparent.”

The practice of off-label use involves prescribing medicines for a purpose outside the scope of a drug's intended purpose, as indicated on its label. Once a drug is approved in the U.S., the Food and Drug Administration does not regulate its use, and doctors may prescribe the drug for an off-label use.

Cohen noted that with off-label prescribing likely to increase, “health plans will need to balance the value of rapid patient access to the best pharmaceutical care possible, sometimes through the off-label use of a drug, with the need for comprehensive data on the benefits and risks of such care.”

The Tufts CSDD study, reported in the March/April *Tufts CSDD Impact Report*, released today, found that:

- * Sixty percent of the health plans surveyed require that off-label uses must be referenced in one or more pharmaceutical compendia to be reimbursed.
- * More than three-quarters of health plans ascribed a “very important” role to peer-reviewed literature as a factor in determining off-label use reimbursement decisions.
- * Almost four-fifths of plans ascribed a role to cost-effectiveness in off-label use reimbursement decisions; almost one-fifth said cost-effectiveness data play a “very important” role.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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