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**Expected Growth in PBM Exclusion Lists Poses a Challenge to Drug Developers**

BOSTON – May 10, 2016 – Rising drug prices in the United States will lead payers and pharmaceutical benefit managers (PBMs) to increase the number of drugs ineligible for reimbursement, which will challenge drug developers to provide more concrete evidence of clinical superiority and cost-effectiveness of their products, according to a newly completed analysis by the Tufts Center for the Study of Drug Development.

"Payers are responding to rising drug costs with new, more restrictive formulary management policies," said Joshua Cohen, associate professor at Tufts CSDD. "With prescription drug spending in the U.S. having grown more than 8.5% in 2015, and projected to continue rising, PBMs are likely to expand their exclusion lists."

Exclusion lists, which are intended to reflect clinical and cost-effectiveness, contain drugs that are ineligible for reimbursement, along with covered recommended alternatives in the same therapeutic class. Excluded drugs are those that purportedly offer no additional benefit over alternative treatments in the same therapeutic class.

Cohen noted that PBMs and payers also will respond to rising drug costs by increasing use of traditional approaches to formulary management, including tiered formularies, prior authorization, step therapy, and off- and on-label indication restrictions. These actions, he said, will challenge the biopharmaceutical industry to provide more evidence-based assessments of the value of their products.

Among key findings from the analysis, reported in the May/June Tufts CSDD Impact Report, released today, are the following:

- The number of drugs on the exclusion lists of the two largest PBMs in the U.S. grew approximately 65% from 2014 to 2016.
- Drug manufacturer rebates to PBMs appear to play a key role in determining exclusion decisions, as do coupon or co-pay offset provisions offered by drug manufacturers to patients.
- Cost-effectiveness does not appear to correlate with exclusion or recommended (covered) status.
- More cost-effective brand name (single source) drugs are not always recommended over other less cost-effective brand name drugs in the same therapeutic class.

The analysis was based on data maintained by the Center for the Evaluation of Value and Risk in Health, as well as peer-reviewed literature comparing the cost-effectiveness of excluded and recommended products.
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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development 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 Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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