

Study Shows Critical Misalignment Between Health Plan Utilization Management & Clinical Guidelines for Specialty Drugs

Data from NPC and CEVR reveal utilization management is common even when clinical guidelines do not support its use.

WASHINGTON, DC, UNITED STATES, July 8, 2025 /EINPresswire.com/ -- New research by the National Pharmaceutical Council ([NPC](#)) and the Center for the Evaluation of Value and Risk in Health ([CEVR](#)) at Tufts University in Health Affairs explores the relationship between clinical guideline recommendations for specialty drugs and utilization management criteria by U.S. health plans. The analysis found that health plans' deployment of utilization management (UM) criteria is common and often misaligned with available clinical guidelines that do not recommend UM, potentially leading to limited patient access and adverse clinical outcomes.

"Drug Coverage Policies and Clinical Guidelines Alignment: Most Coverage Decisions Include Additional Restrictions" is authored by Julia A. Rucker, MSW, MPH, Molly T. Beinfeld, MPH, Katherine A. Clifford, MPH, and James D. Chambers, PhD, of CEVR and Jon D. Campbell, PhD, and James Motyka, PharmD, of NPC.

In an analysis of nearly 6,000 policies covering 389 drug-indication pairs from 18 large commercial health plans, researchers found that alignment with clinical guidelines is often weak. Specifically:

1. Most plans — 61 percent — imposed UM criteria regardless of clinical guideline availability.
2. Health plans were more likely to align with guidelines that recommended UM versus those that did not recommend UM (67 percent vs. 37 percent).
3. In other words, 63 percent of plan decisions included UM when guidelines did not support UM.

The paper provides evidence that health plans do not consistently follow existing clinical guidelines when considering UM for patients, especially for specialty drugs. Notably, about half of the specialty drugs in the research sample — particularly orphan drugs — lacked an associated clinical guideline, thus making it more difficult for plans to seek clinical direction.

"The data shows that health plans' implementation of utilization management criteria does not align with clinical guideline recommendations, leading to inconsistent coverage decisions across the healthcare system," said Dr. Campbell, NPC Chief Science Officer. "Our research signals an urgent need to publish and standardize clinical guidelines for specialty drugs and for health plans to consider clinical guidelines prior to making stringent utilization management policies that could harm patient access and outcomes — especially for rare disease patients with high levels of unmet need."

As the use of utilization management by plans is increasing, likely driven by rising financial pressures, it is important for:

1. Clinical guideline development to consider and involve the payer community;
2. Clinical guidelines to be updated frequently; and
3. Payers to increase transparency and explanation around how utilization management policies are formulated.

"Collaboration between the experts making clinical decisions, the patients who rely on access to medicines, and the payers who determine utilization management requirements is critical to create a well-oiled machine that ultimately benefits patients," emphasized James Motyka, study co-author and NPC Research Manager. "We must collectively ensure patients can reliably and affordably access the treatments they need."

About the National Pharmaceutical Council

NPC serves patients and society with policy-relevant research on the value of patient access to innovative medicines and the importance of scientific advancement. We envision a world where advances in medicine are accessible to patients, valued by society, and sustainably reimbursed by payers to ensure continued innovation. For more information, visit www.npcnow.org and follow NPC on LinkedIn.

About the Center for the Evaluation of Value and Risk in Health (CEVR) at Tufts University
CEVR is a leader on issues pertaining to value, cost-effectiveness, and risk tradeoffs in health care decisions. We inform national clinical and public health policy issues through our analysis of the benefits, risks and costs of strategies to improve health and health care. Our organization is a member of the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, Boston. We undertake scientific research projects, advance methods development for the field, train the next generation of practitioners and users, and work with policymakers worldwide to develop reasoned policy solutions.

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