Cross-Sectional Analysis of U.S. Health Insurance Payer Policies for Pharmacogenomic and Pharmacodynamic Testing for Psychiatric Therapies

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BACKGROUND

•Providers struggle to individualize psychiatric care for common conditions like depression, anxiety, and psychosis.
•For example, the response rate to first-line pharmacological treatment for depression is only 40–60% in adult populations, and up to 40% of individuals on antidepressants experience adverse drug reactions.
•The current trial and error approach to prescribing psychotropic medications delays symptom resolution, increases healthcare spending because of higher incidences of adverse events, and poor treatment adherence .

PGx Testing

•Genes encoding oxidative and conjugative metabolizing enzymes, can impact enzymatic activity.
•Genetic variations in drug transporters in the gut, liver, and blood-brain barrier can also influence drug distribution and pharmacokinetics.
•Pharmacogenomic (PGx) testing can improve drug selection and dosing strategies to reduce adverse treatment effects, improve drug efficacy, and reduce time from drug implementation to response.

METHODS

•Adapted prior methods to analyze public vs. private insurance coverage for PGx testing in psychiatry (medication selection/dosing).
•Identified publicly available coverage policies across various payers and plans using a commercial database.
•Plans pertaining to PGx testing for psychiatric conditions up to (January 2023) were extracted.
•Reviewed and coded key details from plans including payer type, covered biomarkers & codes, coverage decisions, and how test results might impact treatment.
•Examined evidence sources cited within policies to assess alignment with current literature and guidance from the Food and Drug Administration (FDA).

Results

Coverage Landscape

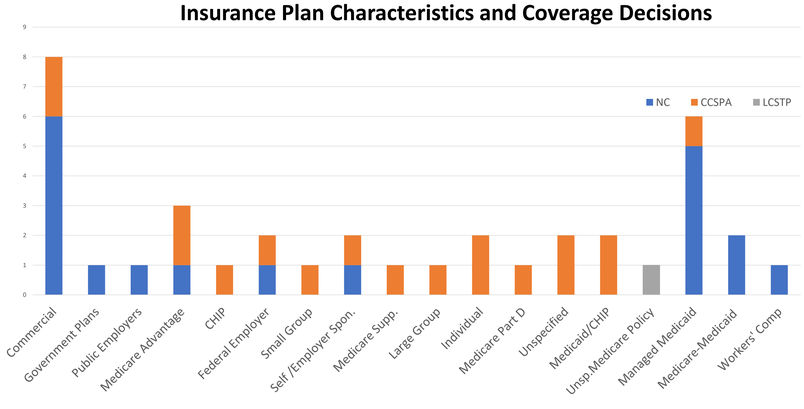
•There were a total of 38 coverage policies from 8 payers (and multiple subsidiaries) that were classified within the database across a diverse range of domains (e.g., employer-sponsored, self-funded).
•Across the 8 payers, 4 (50%) offered multiple plan types (e.g., Medicare, commercial, employee-sponsored).
• Results revealed a mixed landscape and half (50%) of the policies in our sample issuing a blanket denial for PGx testing for the purposes of psychiatric medication formula and/or dosage selection.

Pharmacogenomic Biomarkers with FDA Labels

•We identified 63 biomarkers across all coverage policies.
•Only 3 of these biomarkers are currently associated with FDA labeling guidelines for PGx testing including (*CYP2D6*, *CYP2C19*, & *SLCO1B1*).
•There are 45 psychiatric medications currently associated with these 3 biomarkers with FDA PGx labels.

Coverage Decisions	Count	Percentage
NC (No coverage)	19	50%
CCSPA (Coverage for specific patient populations and specific tests/panels)	18	47%
LCSTP (Coverage for specific tests/panels)	1	3%
Total	38	100%

Insurance Plan Characteristics and Coverage Decisions



Common Justifications for Refusing Coverage

1. Limited independent research on clinical utility, efficacy, and cost-effectiveness of PGx tests and panels.
2. Insufficient evidence of the analytical validity of commercially available PGx tests.
3. Inconsistent empirical evidence on the impact of PGx testing on clinical outcomes.
4. Inadequate clinical guidelines for many biomarkers.
5. Lack of consensus on the most clinically relevant genetic markers.
6. Unclear guidelines on the optimal use of PGx testing within psychiatry.

Implications

Ethical Implications

1.Access to PGx Testing: Currently, insurance coverage for PGx testing in psychiatry is inconsistent, but there's a trend toward wider adoption. To ensure it is implemented beneficially there is a need for high-quality, long-term studies across diverse patient groups to building a robust evidence base for PGx testing.
2.Precision Medicine for All: Expanding PGx testing coverage, coupled with real-world data, has the potential to personalize treatment for populations with limited representation in research, leading to better long-term outcomes.

Legal Implications

1.Regulatory Gaps: Limited regulations and oversight of PGx testing create uncertainty for payers, patients, and clinicians.
2.Limited Guidance: Limited number of biomarkers associated with FDA labels for PGx testing creates regulatory gaps. Only 3 biomarkers we identified across policies had FDA labels.

Social Implications

1.Healthcare Disparities: The uneven access to PGx testing can exacerbate existing healthcare disparities, particularly among underrepresented and economically disadvantaged communities.
2.Public Awareness: There is a need for increased public awareness and education about PGx testing to ensure that patients and healthcare providers can make informed decisions, potentially reducing stigma and misconceptions about genetic testing.