Bridging the Gap Between Clinical Utility and Coverage: Real-World Impact of Unreimbursed NGS Testing

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Background

Genomic testing is the cornerstone of precision oncology, revealing rare yet clinically actionable alterations that define diagnosis, risk stratification, and treatment choice. Despite its proven clinical utility, inconsistent coverage and inadequate reimbursement constrain routine use, reflecting a persistent misalignment between clinical value and payer policy. Evaluating real-world utilization and clinical impact of unreimbursed testing can highlight critical gaps in standard oncology care.

Methods

Molecular profiles of 7,271 patients with unreimbursed testing were analyzed by integrating NeoGenomics sequencing data (09/2025 – 12/2025) with standardized clinical data (cancer diagnoses, ICD-10 codes, medication records, molecular testing results) extracted from comprehensive electronic medical records using the xCures Platform.

Results

In a broad cohort (n=7,271), testing was performed in patients covered by commercial (58%; n=4,200), managed (22%; n=1,634), and government (20%; n=1,434) plans, with orders primarily from hospitals (49%) and physician groups (42%). Testing predominantly targeted hematologic malignancies (>90%), with solid tumors representing 8%. Among patients with available medical records (n = 3,409), hematologic panels remained most common (67%), led by Neo Comprehensive® - Myeloid Disorders (n=1,064), NeoTYPE® MDS/CMML Profile (n=485), Neo Comprehensive - Heme Cancers (n=385), NeoTYPE CLL Profile (n=299) and NeoTYPE Lymphoid Disorders Profile (n=211). Abnormal molecular findings were identified in 1,056 patients, including 470 patients with pathogenic or likely pathogenic variants (SNVs, deletions, insertions, fusions, and substitutions), with 23% (104/470) of alterations (i.e, ABL1, ERBB3, KDR, MAP2K1, TOP1, TSC1, TSC2) not identified by previous methods. Of 66 patients receiving targeted therapy, 4 (6%) were treated within 60 days for pathogenic alterations (EZH2, JAK2, KIT, BCR-ABL1) identified by NeoGenomics. Eleven (17%), initially with unspecified diagnoses, received therapies (venetoclax, obinutuzumab, lenalidomide) for newly defined indications, and 2 (3%) were treated (venetoclax, lenalidomide) based on relevant biomarkers (NPM1, SF3B1) of sensitivity, all guided by test results within 60 days. Among 386 patients with initially unspecified conditions, EMR for 137 patients (36%) confirmed diagnoses within 60 days.

Conclusion

Genomic testing delivers substantial clinical value by enabling rapid, definitive diagnoses and informing timely, targeted treatment decisions. Despite inconsistent payer coverage, these data show that comprehensive NGS testing frequently identifies actionable alterations and biomarkers not previously detected by single gene testing or small targeted panels, which directly impact patient management. Aligning reimbursement policies with anticipated clinical utility is critical to closing gaps in standard care and expanding equitable access to precision oncology.

Real-World Landscape of Unreimbursed Testing

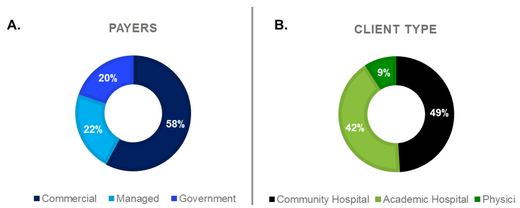

Figure 1. Unreimbursed testing across a large, payer-diverse cohort. (A) All 7,271 patients in this cohort underwent testing that was not reimbursed, despite coverage spanning commercial (58%), managed (22%), and government (20%) plans. (B) Orders were driven primarily by hospitals and physician groups.

Unreimbursed Testing Pattern

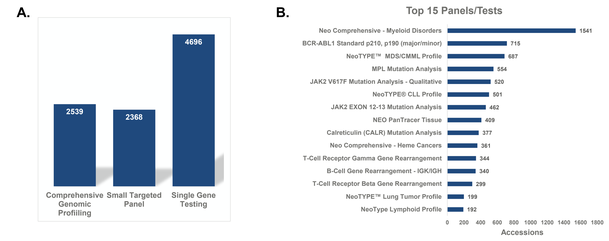

Figure 2. Distribution of Unreimbursed Molecular Tests by Type, Panel, and Clinical Indication. Unreimbursed testing categorized by: (A) test/panel type, including single-gene assays, small targeted panels, and comprehensive genomic profiling (CGP); (B) the most frequently ordered assays (top 15 tests/panels); and (C) clinical indication.

Medical Record Review of a Subset of Patients with Unreimbursed Testing

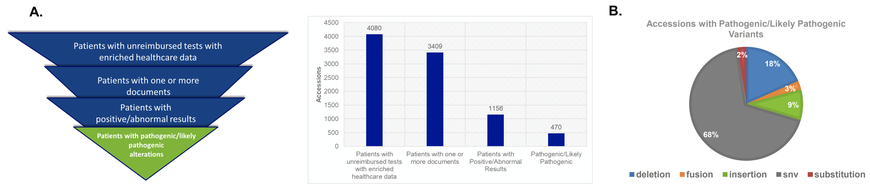

Figure 3. Cohort overview of patients with available medical records and distribution of pathogenic genomic alterations. A) Integrated molecular and clinical review of 3,409 patients, including availability of medical records, proportion with abnormal/positive results, and cases harboring pathogenic or likely pathogenic variants. B) Distribution of pathogenic or likely pathogenic variant types, including single-nucleotide variants (SNVs), deletions, insertions, fusions, and substitutions.

Patterns of Unreimbursed Testing: Biomarkers with 5 or More Accessions

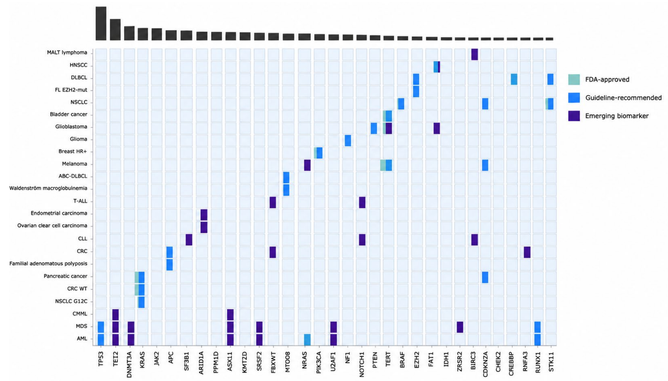

Figure 4. Distribution of biomarkers identified through unreimbursed testing. Clinical actionability of biomarkers with pathogenic or likely pathogenic variants identified in ≥5 accessions, stratified as FDA-approved, guideline-recommended, or emerging biomarkers.

Clinical Impact of Unreimbursed Testing on Diagnosis and Treatment Within 60 Days

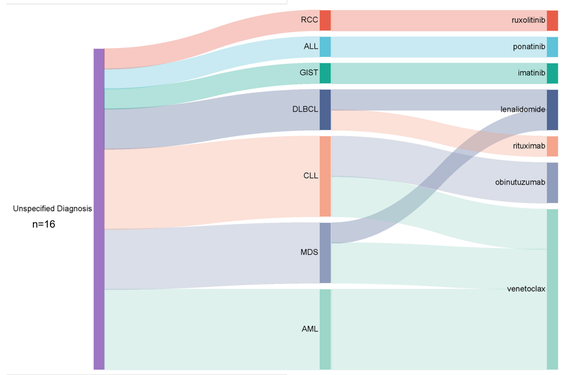

Figure 5. Transition from Unspecified to Defined Diagnoses Drives Therapy Selection. Genomic testing enabled transition from unspecified to defined diagnoses, informing treatment selection in 17 patients

Patient Journey

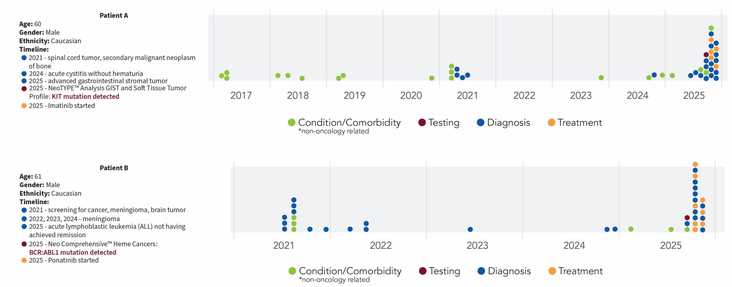

Figure 6. Patient journeys highlighting timely diagnosis and treatment through testing at NeoGenomics. Note, only selective details relevant to oncology have been shown on the left panel.

Key Insights

- Net new pathogenic/likely pathogenic alterations were detected in 23% (104/470) of patients with unreimbursed testing.
- Seventeen percent of treated patients with initially unspecified diagnoses received indication-specific therapies following molecular characterization.
- Testing supported rapid diagnostic clarification, with 36% of patients with initially unspecified conditions receiving confirmed diagnoses within 60 days.
- Results highlight a persistent gap between demonstrated clinical utility and payer reimbursement policies, underscoring the need for broader coverage to improve equitable access to precision oncology.