Overcoming Barriers to Biomarker Testing

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Overcoming Barriers to Biomarker Testing

- Previous Limited Genomic Testing outside Academic Center
- Time between Ordering the Next Generation Panel and Results
- Reimbursement for Next Generation Panels
Previous Limited Genomic Testing outside Academic Center

- Initial Evaluation after Diagnosis of Nonsquamous NSCLC is Limited to Small Panel of Genes (EGFR, ALK, ROS1, PD-L1)
- No information on FDA Approved Targeted Therapies (V600E BRAF, and NTRK rearrangements)
- No information on Targeted Therapies Likely to be Approved within 1-2 Years (RET and KRAS G12C and Tumor Mutation Burden)
- Problems with Subsequent Reimbursement for Next Generation Panels
Time between Ordering the Next Generation Panel and Results

- Foundation Medicine States <2 weeks
- Caris Molecular Intelligence 8-14 days
- DF/BWH is 12 Calendar Days (if tumor is at BWH Pathology)

https://www.foundationmedicine.com/
https://www.carislifesciences.com/
Oncopanels Ordered (2015-2019)
“FDA Approves Foundation Medicine's FoundationOne CDx™, the First and Only Comprehensive Genomic Profiling Test for All Solid Tumors Incorporating Multiple Companion Diagnostic” Press Announcement November 2017

“MSK-IMPACT™ Is the First Tumor-Profiling Multiplex Panel Authorized by the FDA, Setting a New Pathway to Market for Future Oncopanels” Press Announcement November 2017

“Foundation Medicine, Inc. today announced that the Centers for Medicare & Medicaid Services (CMS) issued a final National Coverage Determination (NCD) for patients who receive next generation sequencing (NGS) testing with an assay that meets the coverage criteria.” Press Announcement May 2018
NSCLC: 2019 Payer Mix and Payments

- **Private Payer #1**: 41% (99% Paid)
- **Private Payer #2**: 8% (57% Paid)
- **Private Payer #3**: 3% (52% Paid)
- **Government Funded**: 12% (86% Paid)
- **All Other**: 35% (52% Paid)

(Payer Mix (Major Payers))
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