
Jacqueline Huang
Senior Associate
Reimbursement Policy and Government Affairs
Objectives

Learn how payers are developing standardized evidence requirements for molecular diagnostic tests

Understand the rationale behind trends in payer coverage for next generation sequencing oncology testing

Identify how to develop opportunities to create an evidence development plan to support payer coverage of new diagnostic tests
Standardization of Payer Evidence Requirements for Coverage
Payers are Working to Establish Coverage Criteria for Molecular Diagnostics

- Nearly 60% of payers with established criteria said they use standards set by external third party or advisory organizations including ACCE, DNA Direct, and Interqual
There is Consensus that Clinical Utility is Critical in Establishing Coverage Decisions

Evidence Most likely to Inform Coverage Policy Decisions on Molecular Diagnostics

- Clinical utility
- Test use changes patient management/care pathway
- Clinical validity
- Cost-effectiveness of test vs. SOC
- Absolute test performance
- Incremental test performance
- Analytical validity

Top 3 answers selected, proportion of all survey respondents
While clinical utility has been traditionally defined as a change in patient management that leads to improved patient outcomes, payers are also becoming interested in the health economic impact.

**Definitions of Clinical Utility**

- **Clinical Utility**: Does a test change and improve patient management leading to improved outcomes?

- **Decision Impact**: Changes in provider decision-making regarding patient management
- **Clinical Impact**: Improvements in healthcare outcomes
- **Economic Impact**: Improvements in health economic outcomes
- **Comparative Impact**: Comparative clinical effectiveness and cost effectiveness to standard-of-care
Simply qualifying for the Palmetto MolDX technical assessment process requires at least one prospective, observational clinical utility study.

**Randomized, Prospective, Controlled Trials**
Directly demonstrates that test use leads to improvement in patient outcomes as compared to a currently accepted standard of care. Endpoints must be clinically accepted and appropriately powered.

**Prospective-Retrospective Trials**
Uses archived samples from a previous prospective controlled trial to demonstrate that test use results in improved health outcomes. The chosen samples and study design must be sufficiently characterized and powered to permit definition of the indications for use and the intended use population.

**Prospective Observational Trials**
Involves prospective enrollment of patients in registry, where patients are treating according to a defined pathway using the molecular test. Test use must result in improvements in health outcomes, as compared to accepted historical controls.

 increasing level of evidence

Payer Next Generation Sequencing (NGS) Oncology Testing Coverage Trends
The GPC recommends coverage of multiplex panels of up to 50 genes when a subset of 5+ genes are considered standard-of-care with a given diagnosis.

- The GPC recommends coverage of panels greater than 50 genes only for limited indications, but further discussion is necessary to reach a consensus.
- The GPC does not recommend coverage of whole exome and genome sequencing, as they are considered investigational.

The GPC supports coverage of off-label usage of drugs and biologics when an individual patient has shown benefit after 3 months of treatment with the agent, which may necessitate asking drug makers to provide the agent free-of-charge during the initial three month trial.

- Substantial discussion is needed to develop a feasible framework for this arrangement.

The GPC recommends that payers develop program to promote high-quality evidence generation, which may include:

- Payment incentives to clinicians who refer patients to high-quality studies
- Payment incentives to laboratories for data sharing
- Payer participation in collaborative initiatives for enrolling patients into high-quality registries and clinical trials for biomarker evaluation (TAPUR, MED-C)
Top Commercial Payers Beginning to Cover NGS Oncology Panels

- Existing coverage landscape among top 10 commercial payers is broadly mixed
- Four of the largest commercial payers are currently providing limited positive coverage for NGS oncology panels that are in line with CMTP recommendations

<table>
<thead>
<tr>
<th>Payer</th>
<th>NGS Panels</th>
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<tbody>
<tr>
<td>Anthem</td>
<td>Covered</td>
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<tr>
<td>UHC</td>
<td>Covered</td>
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<tr>
<td>Aetna</td>
<td>Covered</td>
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<td>HCSC</td>
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<td>Cigna</td>
<td>Not Covered</td>
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<td>Kaiser Permanente</td>
<td>Silent</td>
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<td>Health Net</td>
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<tr>
<td>Highmark</td>
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<tr>
<td>CareFirst BCBS</td>
<td>Silent</td>
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<tr>
<td>BS CA</td>
<td>Not Covered</td>
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**Covered Indications:**
Metastatic Stage IV NSCLC

**Coverage Criteria:**
- NGS technology is only used to test for EGFR mutations, HER2 mutations, RET rearrangements, and ALK rearrangements, **AND**
- Laboratory providing services must be approved by the New York State Department of Health
Independence Blue Cross Coverage of Next-Generation Whole Genome Sequencing

- Independence Blue Cross recently entered into an agreement with NantHealth to cover next-generation whole genome sequencing for a variety of cancers

"The intent of this policy is to communicate the coverage position for the proprietary test only by NantHealth called GPS Cancer™ due to this test’s very specific and complex features related to the clinical investigation of specific types of cancer and the potential for improvements in objective health outcomes."

- The unlisted Code 81479 must be reported with the following narrative: "GPS Cancer™"
- Providers must not bill other procedure codes to represent GPS Cancer™ testing by NantHealth

**Covered Indications:**

- Cancer of unknown primary
- Rare cancers
- Metastatic cancer that has progressed after treatment with a regimen of chemotherapy and for which additional chemotherapy is indicated
- Primary brain cancer
- Pediatric cancers
- Triple negative breast cancer
- Virally infected tumors
- Metastatic NSCLC that has progressed after treatment with two different regimens of chemotherapy and for which additional chemotherapy is indicated
- Individuals eligible for cancer immunotherapy
# Medicare Administrative Contractors with LCDs for NGS Oncology Testing

<table>
<thead>
<tr>
<th>Medicare Administrative Contractor</th>
<th>Palmetto GBA, CGS, Noridian</th>
<th>Cahaba GBA</th>
<th>National Government Services</th>
<th>Novitas</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCD Title (ID#)</td>
<td>NSCLC, Comprehensive Genomic Profile Testing (L36143, L36174, L36194)</td>
<td>Partial Genome Profiling in Non-Small Cell Lung Cancer (L36446)</td>
<td>Genomic Sequence Analysis Panels in the Treatment of Non-Small Cell Lung Cancer (L36376)</td>
<td>Biomarkers for Oncology (L35396)</td>
</tr>
<tr>
<td>Covered Indications</td>
<td>Patient has been diagnosed with advanced (Stage IIIB or IV) NSCLC; and Patient is a lifetime nonsmoker or former light smoker with ≤ 15 pack year history of smoking; and Patient previously tested negative for EGFR mutations, ALK rearrangements, and ROS1 rearrangements through non-CGP methods; and Testing is performed by a lab that satisfies the CMS MolDX Contractor’s published AV criteria.</td>
<td>Patient has been diagnosed with advanced (Stage IIIB or IV) NSCLC; and Has had previous CDx or LDT specific gene testing on a prior pathology specimen. Generic (not disease specific) genomic sequence panels (NGS comprehensive definitive cancer testing panel/s) of 51 or greater genes are non-covered at this time (certain disease specific 51+ gene tests, e.g. Prosigna breast cancer assay, can be medically necessary).</td>
<td>Newly diagnosed patients with advanced (stage IIIB or IV) NSCLC, who are not treatable by resection or radiation with curative intent. Previously diagnosed patients with advanced NSCLC, who have: 1. Not responded to at least one systemic therapy, or who have progressed following resection; OR 2. Been resistant to at least one targeted therapy and are able to undergo tumor tissue biopsy for testing</td>
<td>Indications may be considered for coverage, pending adequate quality control (e.g., CLIA certification), if the NGS panel provides more “intermediate” range information (e.g., in the 5-50 mutation range). Novitas does not cover NGS panels that generate an “extensive” amount of genomic information.</td>
</tr>
<tr>
<td>Covered CPT Codes</td>
<td>81445, 81455, 81479</td>
<td>81445</td>
<td>81445</td>
<td>Coding and billing should be based on “one-at-a-time” biomarker approach</td>
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Adapted from Quorum Consulting’s Diagnostics Reimbursement Quarterly. Vol 5, Issue 1. [http://us3.campaign-archive1.com/?u=37401aafef1e83151c373f3e9&id=5912ff8d8a](http://us3.campaign-archive1.com/?u=37401aafef1e83151c373f3e9&id=5912ff8d8a)
In the past year, we have seen a clear growth in positive coverage policies for next generation sequencing oncology tests.

**Pros**
- Overall there is more acceptance in the payer community on NGS testing
- FDA-approved and/or proprietary panels can be recognized through limited positive coverage

**Cons**
- Coverage criteria amongst payers are clearly inconsistent
- Some payers are using more unsophisticated methodologies to establish coverage to force NGS oncology tests to a lower price point
How to Support Payer Acceptance of New Moldx Tests
Tips on How to Develop a Successful Evidence Plan to Support Payer Coverage

1. Effectively develop a targeted list of payers. Considerations:
   1. Volume of claims
   2. Alignment with regional KOL support

2. Profile the targeted payers early on
   1. Conduct payer medical director interviews to validate evidence plans (existing literature and study protocols)
   2. Assess payer interest in coverage with evidence development arrangements. E.g., Palmetto MolDX Program

3. Apply a top-down/bottom-up approach
   1. Utilize quick claim wins AND published evidence to support reimbursement success for your test

Coverage with Data Development (CDD)

- Test characteristics
  - Areas of high clinical impact or significant unmet need
  - Strong analytical (AV) and clinical validity (CV)
  - Strong indication of clinical utility (CU) from early studies
- Policy offers coverage within the scope of the study and requires the collection and reporting of certain data to Palmetto GBA with clear, statistically significant clinical utility endpoints.
Key Takeaways

1. Payers are developing more structured criteria around evidence requirements for coverage.

2. We will continue to see a trend in payer coverage policy development, with some payers using it as a mechanism to restrict payment on next generation sequencing and other advance molecular diagnostic tests.

3. To support payer acceptance, labs must be prepared to coordinate with payers to align on evidence requirements and invest in generating high quality clinical utility evidence.
Contact Information:

Jacqueline Huang
Jacqueline.Huang@quorumconsulting.com
415-835-0190 x131