The Regulatory & Reimbursement Policy Landscape in Personalized Medicine: A (Payer’s) Perspective

Girish Putcha, MD, PhD
Director of Laboratory Science
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Please note that the opinions expressed herein are my own.
Disclaimer

• Any opinions expressed are my own and not necessarily those of MolDX, Palmetto, or CMS.

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A vicious cycle for diagnostics

LDT and IVD
“parallel universes”

- Poor and inconsistent coverage and reimbursement
- Highly variable and non-transparent evidence development
- Weak and inappropriate clinical adoption

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A case study in dysfunction: BRACAnalysis CDx

Insurance Plans Dropping Coverage of FDA-approved BRCA Diagnostic Test

- Insurers in New Jersey, North Carolina, and Tennessee stopped covering the CDx in favor of less expensive LDTs
- Indications for use: “as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with Lynparza™ (olaparib)”
- Variant classification according to “a defined classification process by an in-house committee” so will the efficacy and safety of Lynparza be the same in patients identified by the LDTs? Do we know or care? Should we?

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Regulatory Challenges

- Almost all commercially available genomic tests are laboratory-developed tests (LDTs).
  - Of 5921 tests registered with MolDX from inception to 9/25/2015, >93% (5512) are LDTs.
- Many have similar, if not identical, intended use(s) as FDA-cleared or approved tests
- Limited to no oversight of marketing claims
- Limited to no transparency for providers, patients, or payers into their “quality”
- Evidentiary standards for commercialization are almost entirely self-determined with limited, generally non-transparent independent 3rd party review (e.g., CAP, NYSDOH, health technology assessment (HTA) groups, payers)
- Is this situation in the best interest of patients? Of innovation? Of healthcare in the US?
- Why is this appropriate for diagnostics but not for medical devices, drugs, etc?

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Reimbursement Challenges

• Coding
  • CPT codes for genomic tests can be over-simplified, failing to recognize clinically important differences among these tests, resulting in their commoditization and undervaluation
  • Obscure unambiguous identification of a test/service by allowing code stacking v2.0 (i.e., by analyte vs methodology)

• Coverage
  • Idiosyncratically variable despite presumably asking similar if not identical questions based on the same evidence
  • Appropriately focused on clinical utility while inappropriately ignoring analytical and (to a lesser extent) clinical validity, generally deferring to “regulatory approval”
Reimbursement Challenges

• Payment

  • Unlike some other areas of healthcare, pricing continues to be based on cost instead of market, let alone on value
  
  • “Market-based” pricing imminent under PAMA though gaps may remain (e.g., 81479)
    • Core underlying assumption in PAMA is that commercial payers are “better” (i.e., cheaper) at pricing tests than CMS

  • Impact of “value-based” models is unclear

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God, grant me the serenity to accept the things I cannot change, the courage to change the things I can, and the wisdom to know the difference.
A virtuous cycle for diagnostics

LDTs and IVDs complement, not duplicate, each other

Robust and consistent coverage and reimbursement

Robust, consistent and transparent evidence development

Strong and appropriate clinical adoption

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Solutions: Regulatory Principles

- Develop a unified regulatory “system” in which LDTs and IVDs complement, not duplicate, each other in the marketplace
  - For example, once test with a given intended use is cleared or approved by the FDA, the sales and marketing of LDTs with the same intended use ceases (likely with a “sunset period” and exceptions for public health, low risk, rare diseases, etc)
  - At an absolute minimum, 3rd party-assessed AV and CV performance characteristics should be publicly available BEFORE commercial availability

- Accordingly, CMS (and its approved accreditation organizations and exempt states) continue to focus on process and personnel; FDA on the product, manufacturing, and marketing

- “System” should be risk-based, both for the purposes of enforcement discretion and prioritization of reviews during the transitional period

- Improved transparency of AV and CV performance data (i.e., publicly available and independently assessed), and of ongoing proficiency testing

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Lessons from the EU’s IVDR?
Exemptions (i.e., LDTs)

- Devices manufactured and used only within “health institutions” if following also met:
  - Not transferred to another legal entity
  - Under appropriate quality management systems
  - Laboratory compliant with EN ISO 15189
  - The target patient group’s specific needs cannot be met or cannot be met at an appropriate level of performance by an equivalent device available on the market.

- Provisions do not apply to devices manufactured “on an industrial scale”.

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Solutions: Coding

• Develop “better” codes that recognize clinically important differences among tests that impact their cost and value (because you cannot pay for “value” or “quality” if you cannot identify it)
  • PAMA: Advanced diagnostic laboratory test (ADLT) codes and codes that distinguish FDA-cleared/approved tests from LDTs
  • AMA: Proprietary laboratory assay (PLA) codes

• Clarify appropriate use of codes (e.g., MoIDX M00127 and M00130 billing and coding guidelines for NGS panels)

• Ensure internal consistency of reimbursement (e.g., 81432 at $622.53 and 81162 at $2485.86 on CLFS) and/or eliminate “vestigial” codes more quickly

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Solutions: Coverage

• Transparently define and consistently apply criteria for coverage
  • Apply same CU metrics (e.g., improvement in “net health outcomes”) for all healthcare interventions (i.e., diagnostics, therapeutics, physician services, hospital services, etc) so value-based trade-offs designed to optimize both the cost and effectiveness of care are possible

• Require and specify appropriate comparators: “Best practice” or “real world”?

• Consider risk-sharing approaches (e.g., coverage with evidence development)
Solutions: Payment

- Price all healthcare activities (i.e., diagnostics, therapeutics, physician services, hospital services, etc) transparently using similar value-based (or at least market-based) metrics
  - FFS-based systems misalign incentives for all stakeholders, but especially for patients, providers and payers
  - In a FFS world, reimburse activities commensurate with their “value”, taking into account the strength and quality of their evidence

- Stop “silo-ing” money for different activities so value-based trade-offs designed to optimize both the cost and effectiveness of care are possible

- Consider value-based risk-sharing approaches (e.g., “reimbursement with evidence development”)

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Thank you.

Questions and comments are always welcome.

gputchapmdx@gmail.com