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A Conversation with Natalie Carfora, Director of Market Access at Scipher Medicine, Discussing Strategic Market Access Considerations for Laboratory Developed Tests

Natalie, why did you want to discuss this topic?

A colleague recently said to me that attaining coverage and reimbursement for diagnostic testing is as difficult, if not more, than the R&D process to develop the test. While I can't speak to the challenges around developing a laboratory-developed test, I can reflect on the challenges associated with successfully attaining positive medical policy and contracting for reimbursement for said test and the resulting considerations to develop a market access strategy. While every payer agrees on the benefits of precision medicine in improving patient outcomes and decreasing wasted/total healthcare spending, there isn't consensus on the evidentiary requirements that would lead to universal coverage. As such, many laboratories have found themselves in the predicament that they have developed and commercialized a test for which they cannot get coverage or payment.

What are factors to consider when developing the market access strategy for a laboratory-developed test (LDT)?

I group strategy into three categories:

1. Coding
2. Positive Medical Policy
3. Contracting

With coding, it is important to consider if there is already established coding/pricing for which your test can utilize. It isn't always the best strategy to seek a unique PLA code.

With positive medical policy, there are multiple influencing stakeholders (each requiring its own strategy) including lab benefit management companies, technology assessors, societal guidelines, and provider advocacy. All these stakeholders ultimately are assessing the three buckets of evidence: analytical

validity, clinical validity, and clinical utility. Clinically, utility means improved patient outcomes and provider action. I understand health plans wanting to know that whatever tests are being run and paid for are impacting a provider's decision-making.

With contracting, you need to ensure all accreditations (CLIA, CAP) and state licenses are secured (i.e., NY, CA, RI, PA, and MD have specific individualized state requirements/paperwork/processes). Resolving these contracting dependencies takes time, and your ability to contract regionally/nationally is limited without them.

What are a few key points you think teams starting down this path should keep in mind?

1. The more innovative the technology, the more scrutiny there will be in evaluating its evidence.
2. This is a long process that needs to be collaborative with payers. Understand the endpoints/requirements from payers for positive policy and build them into your evidence generation pathway. Many have built the infrastructure internally to evaluate testing and explore the opportunity to collaborate on internal validations within a payers membership that would inform a positive policy decision.
3. Medicare coverage is not a guarantee for commercial coverage.