Of the many business, operational, legal, regulatory and clinical obstacles standing in the way of widespread delivery of personalized medicine, the single greatest challenge seems to lie in solving the reimbursement puzzle. Advocates of personalized medicine contend that it results in better care for the patient, as therapy is specific to an individual and his or her clinical condition, and that it should also result in cost savings, as treatment that is unlikely to work for that patient is avoided. So if personalized medicine results in better clinical care and reduced costs, why are payers seemingly so reticent to pay for it?

Given the lack of standardized reimbursement codes and definitions covering precision medicine treatments and services, particularly molecular genetic laboratory tests, combined with the fact that the industry hasn’t even settled on a standard definition of “personalized medicine”, it is particularly difficult for providers to detail the items or services they have provided, let alone get reimbursed, especially for new or innovative offerings. In order to secure payment from insurers, personalized medicine providers must be able to accurately describe the item or service provided and prove the clinical efficacy of their treatments or genetic testing. They must also establish the value they offer to payers. Doing so requires a deep understanding of health care economics in addition to clinical expertise.

That formidable landscape provided the backdrop for a panel discussion at the Business of Personalized Medicine Summit earlier this year. The discussion carried the title “Moving Targets,” an apt description of a market in the midst of dramatic structural and philosophical change. Even in light of the revising and challenged health care legislation in Congress, the health care market remains mired in uncertainty. The Affordable Care Act, and other government and payer initiatives, pushed the industry toward value-based reimbursement while the Obama administration provided vocal support for personalized medicine. Thus far the Trump administration has yet to signal whether it will support continued movement in those directions.

In that shifting environment, the imperative for personalized medicine providers is to recognize and fully understand, at the earliest possible stage, how they will make money. Every personalized medicine business strategy has to identify who the payer will be and how pricing and reimbursement will work. It also has to articulate the product differentiation – because payers may not pay for it advantageously unless it is better or cheaper than what they are already supporting.

The providers need to have a plan for demonstrating clinical utility in order to meet payers’ evidentiary requirements for coverage, said panelist Mark McCoy, Senior Director, Reimbursement at Guardant Health. In most cases that means building a body of clinical literature, since most payers want to see published data proving either cost savings or cost effectiveness of outcomes.

That has ramifications for sales and marketing, McCoy said. It’s vital to work with providers to set up clinical tests with appropriate utilization controls and other elements that payers will expect to see, including ensuring that customers [i.e., the physicians who
order and rely upon the test that is reimbursed by payers] have no financial incentive to use a particular test that would compromise their clinical judgment. That means, as the business and product evolve, changes must be carefully communicated to providers who cannot be expected to take pains to support use of the company’s product. “At a previous company we’d found you can get good early adoption, but if you change your ordering process a year or two in providers will get frustrated and just drop you,” he said.

Providers also require a lot of education on not only personalized medicine treatments or tests, but on how to apply new evidence to specific patients and how to articulate the results. Panelist Amber Trivedi, Chief Innovation Officer at InformedDNA, said payers want to see that providers are involved in explaining their clinical decisions, which puts the impetus on companies to ensure that providers understand how payers define clinical utility and that they document that utility in encounter notes.

Trivedi advised taking a very hands-on approach in dealing with physicians. “You might even have to teach them how payers define medical necessity and what clinical factors are relevant when trying to secure coverage,” she said. “There’s a lot of variation out there in understanding of even the most basic terms.”

Rigorous evidence-based review should be expected, said panelist Anita Chawla, Managing Principal at Analysis Group. The MoIDX Program for esoteric laboratory tests, developed and administered by Palmetto GBA, helps determine Medicare coverage and reimbursement across several states—making its determinations of clinical utility among the most influential in the industry.

Given that influence, it makes sense for personalized medicine providers to factor in MoIDX criteria for evaluating clinical utility when designing clinical studies. “It can save a lot of time downstream,” Chawla said. She pointed to the MoIDX Clinical Trial Designations – which identify randomized, prospectively controlled trials as the gold standard – as an important set of considerations for companies in the testing-design stage.