The Challenges of Access and Reimbursement

Insights into Diagnostic Testing

Diaceutics GROUP

Contents

Introduction

The cost of personalized medicine therapies and tests will always be an issue affecting all stakeholders, and access to the right diagnostics is closely linked to efficient reimbursement. Each test and each market is likely to have its own specific barriers and it is critical to understand these early in the planning stages as anything that blocks access and reimbursement is a barrier to test adoption. Pharma needs to be aware of the global differences concerning diagnostic access and consider ways to comply with current and future reimbursement criteria in this fast evolving space.

This Ebook has been created from a selection of our Expert Insights. We hope it will be a useful tool for initiating discussions, creating awareness within your team about diagnostic planning and getting you ready for a future in personalized medicine.

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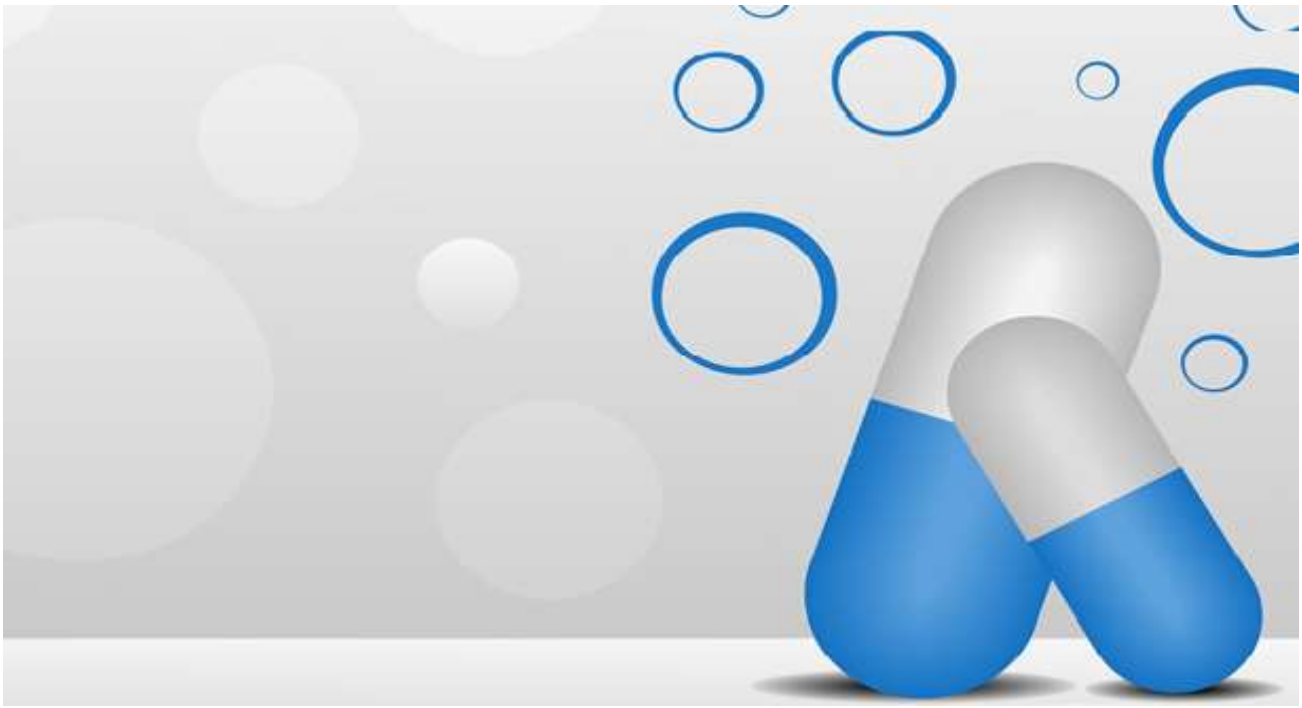
Dx Reimbursement: Not Broken, Just Fragmented



The murky world of companion diagnostic reimbursement and access around the world is not easy to navigate and for pharma and companion diagnostic partners, these complexities will not go away anytime soon. However, as a starting point, reimbursement for new and expensive companion diagnostics needs to be perceived as part of the personalized medicine package. **Margery Rothenberg** points us in the right direction.

Companion diagnostic reimbursement is complex for three reasons:

- All reimbursement systems have evolved to be local to the health care and cost management infrastructure. Europe and the US do not reimburse diagnostics at the same rate or speed.
- Payer management of the new companion diagnostic costs is still in flux, with Australia and Germany reaching towards streamlined decisions and clarity over HTA requirements and other countries, e.g., Italy and Brazil, simply without guidelines.
- Some pharmaceutical companies have stepped in to subsidize companion testing costs to 'accelerate' access to their targeted therapies in certain markets. However, there are long-term financing implications for such market subsidies.

For pharma and companion diagnostic partners these complexities will not go away anytime soon. However, as a starting point, reimbursement for new, expensive companion diagnostics needs to be perceived as part of the personalized medicine package. An 'expensive' test up front can save tens of thousands of dollars of unnecessary treatment down the road and can speed delivery of the best available treatment for all patients. This

'hybrid' approach couples the value of a diagnostic test and personalized medicine so that they are considered together. Some countries (US, UK, Australia, Germany, France, Canada…) are striving to review Dx and Tx together and are reaching towards streamlined reviews and reimbursement decisions, but far more countries are still struggling to put the cart and the horse together. To complicate matters further, in the US the reimbursement decision will migrate into the hands of provider organizations (e.g., ACOs) upon whom payers will rely for review of expert treatment pathways. Clinical laboratory tests (versus imaging tests) have traditionally been reimbursed by Medicare and other payers in the US but are now being questioned. Outside the US, tests are usually covered by DRG-like payments or hospital budgets.

The big money question is 'what is the clinical utility of the test?' The more expensive the test, the bigger the question! It's one thing if the test stratifies patients in order to identify which patients would most likely respond to a drug, but it's quite another thing if the test only provides prognostic information or if it reveals a genetic abnormality for which a treatment does not exist. But some payers will pay for a prognostic test that can help a patient and his/her physician understand—and prepare for—what the likely course of the disease may be.

Congratulations to Martina Garau, Adrian Towse, Louis Garrison, Laura Housman and Diego Ossa for their excellent white paper entitled 'Can and Should Value Based Pricing Be Applied to Molecular Diagnostics?'[1]. We commend it as important reading. Their paper contends that current [2012] pricing and reimbursement systems for diagnostics are not efficient and provide poor incentives for new diagnostic approaches and that a value-based pricing (VBP) framework for efficient use and pricing of medicines also might be applied to diagnostics.

For those of you just now diving into the murky world of diagnostic reimbursement and access and perhaps commissioning research on reimbursement practices for companion diagnostics, take a moment to consider that in fact you are observing two parallel worlds. The first world is one where chronic underinvestment in diagnostic cost-effectiveness studies has resulted in an imperfect market for diagnostic coverage across the globe. From the US, where a coding system has been tortured to provide sufficient reimbursement to laboratories for high volume multi-component testing procedures, over to Europe, where you have a smorgasbord of coverage of novel diagnostics ranging from full reimbursement (Spain) to little or no reimbursement (Italy), all the way to China where the patient predominantly pays.

The second parallel world (albeit more hidden from view) is the increasing trend for pharmaceutical companies to have to pay for companion diagnostic testing, most obviously at work in the UK and in France, where a number of pharma companies have formed partnerships with INCa, the national cancer association, which has enabled testing for important new targeted therapies. For example, Pfizer formed a partnership with INCa through a scientific collaboration signed in June 2010. INCa's €3 million program will provide additional support for 28 hospital-based molecular genetics platforms to routinely detect a panel of biomarkers that will determine access to the targeted therapies soon to be available to patients.

While this extended access to companion diagnostics is understandable given the infrastructure gaps in diagnostic reimbursement policies, procedures and budgets, it is an interim 'fix' in most instances and not sustainable as a model to enable a global personalized medicine marketplace. It is this dilemma which led Garau *et al* to author their white paper exploring a VBP model which may help us leapfrog over these parallel worlds.

But there is a barrier we need to overcome before we can make this leap and one which requires a collaborative dialogue between pharma, payers and laboratorians. We need to develop models where a targeted therapy and companion diagnostic investment returns and the cost benefit of patient targeting are joined up. This is not easy since, to date, value-based pricing solutions, like that put in place between NICE and J&J for Velcade, tend to be a last resort for pharma-payer negotiations after initial coverage rejections.

Perhaps we can all agree that personalized medicine has the potential to remove wasted cost and poor clinical outcomes and focus payer dollars on the right patients at the right time. It is our view that, in the short term, such VBP models will need to be developed on a personalized medicine therapy-by-personalized medicine therapy basis, unfortunately putting the onus back on pharma's project and access teams to pioneer new VBP models. More simply put, there is no shortcut to a better VBP model.

So as you commission that diagnostic reimbursement research make sure you structure your RFPs to:

- Help understand the CURRENT situation with regards to companion diagnostic reimbursement in your therapy area
- Address the local/regional geographic infrastructures and practices
- Illuminate the various national schemes being applied by pharma to provide extended access to companion testing
- Develop win-win models which articulate the cost benefit of targeted therapy in a manner which ensures that both testing and treatment access is aligned from launch.

Almost ten years after the mapping of the human genome, the trickle-down effect has delivered scores of genetic and genomic tests that are expensive at this point in time, although costs are decreasing as technology accelerates. The underlying problem with 'all companion test reimbursement is local' is that the patchwork of approaches will proliferate, not decrease. While complexity is here to stay, a common starting point is a well-articulated, joined-up economic benefit of test and treatment. Back to the data, I'm afraid!

**This Expert Insight was originally published in 2012.*

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Personalized Medicine Can Help Reshape the Pharma Financial Business Model

When long-awaited Zelboraf was finally launched in Europe it was met not only with excitement and hope but with fear arising from its likely price tag. **Dr Christof Koelsch** asks if personalized medicine is doomed because it is simply too expensive, or if there is still a way to reach the brilliant future it has for so long promised.

When the long-awaited new melanoma treatment Zelboraf (vemurafenib) was finally launched in Europe a few months ago [2012] it was met by a lot of excitement and hope. But there was also one big fear, which had nothing to do with the adverse events or other clinical considerations: Zelboraf's likely price tag. In the Cancer Research Science Update blog, Henry Snowcroft wrote an entry under the headline 'New melanoma drug goes on sale – but will it be affordable?'[1]. He reviews the promise and the limitations of the new drug, finishing with a stern reminder that its price tag may well become the 'be all or end all' factor deciding this great new drug's impact: "We recognise that everyone – even pharma giants – are feeling the effects of the recession. We do understand that the price of a drug reflects not just the cost of the trials to develop it, but the cost of failed trials of other drugs (…). And we recognise the vital role the pharmaceutical industry plays in shouldering the costs – and the risks – of large clinical trials. But too often in recent years, price has been a stumbling block in getting effective drugs to patients that need them. It would be deeply frustrating – for patients, for researchers, and for supporters who donate to charities like ours – to see this unhappy story being told yet again."

And, indeed, it took six more months until at last Roche and the UK authorities reached an agreement that would see Roche offer an undisclosed, but likely substantial, rebate on the price of the drug charged to the NHS, in exchange for an official approval of the drug being used in melanoma patients in England (note that as of this writing [2013] the drug is still not covered in Scotland, Wales and Northern Ireland!).

So, where does that leave the great promise of personalized medicine? Zelboraf is a drug that, arguably, is a considerable step forward in the treatment of melanoma, if only in a specific patient population. If Roche with such a drug, offering substantial clinical superiority over existing treatments, faced major hurdles to reimbursement, for no other reason than the sheer inability of payers to afford providing access to the drug, how will its many peers and competitors waiting to launch more and more such high priced targeted therapies address such an increasingly difficult access and reimbursement environment? Are the golden days of personalized medicine over before they really started? Will personalized medicine be doomed in the end, not because of insurmountable scientific challenges, but because of it simply being too expensive to afford? Or is there a way out of this looming disaster that yesterday still looked like a brilliant future?

Diaceutics discusses these developments in our article, 'Towards a Balanced Value Business Model for Personalized Medicine – An Outlook' in the January 2013 issue of the journal *Pharmacogenomics*[2]. In this article, we revisit the basic value drivers in the

pharmaceuticals business, consider the shift from the traditional volume-driven, 'one size fits all' blockbuster model towards the low volume/high price model followed by most personalized medicine launches over the past decade. We outline the challenges to the sustainability of this recent model, and propose a new Balanced Value business model for personalized medicine, leveraging the emerging opportunities to reduce drug development cost and time for targeted therapies, as illustrated in principle by the more recent launches of Xalkori and Zelboraf. We also outline the changes required within the pharmaceutical industry and, more broadly the environment in which this industry operates, and illustrate critical success factors in implementing such a new model.

We strongly believe that our Balanced Value business model has a fundamental ability to not only contribute substantially to the continued success of the pharmaceutical industry in an increasingly challenging environment, but also offer a new and more sustainable equilibrium between the various stakeholders in health care.

**This Expert Insight was originally published in 2013.*

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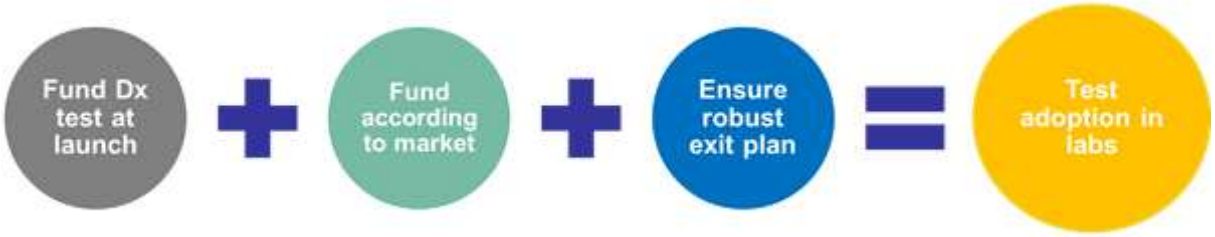
Funding a Diagnostic Test at Launch to Ensure Test Adoption

As part of the series 'Personalized Medicine: What Pharma should do to get Ready', **Tessa Sandberg** discusses why pharma should consider funding a diagnostic test at launch to ensure adoption.

Uber is a young company that, as you probably know, offers taxi services through a smartphone application linked to the customer's credit card. Traditional taxi services consider Uber as a competitive threat due to its low fares and special customer services, which range from offering a bottle of water and mints to easy-to-use payment through the app. The most interesting thing about Uber is its implementation strategy. It all started in San Francisco, USA, and the company quickly expanded to other American cities. The founders were not scared to think big and challenged themselves to establish Uber worldwide. To achieve their goal, Uber invests in friend-to-friend commercialization to acquire new customers. Each time an Uber user invites a non-user to sign up and use the app for a ride, the Uber customer gets free credit on their account and the new customer gets the first ride for free. And this is happening worldwide… What a huge financial investment!



In the field of personalized medicine, a drug is launched together with a diagnostic test and the main challenge to ensure test adoption is consistently reimbursement. So, getting back to the Uber implementation strategy, how does this example relate to the pharmaceutical industry and, in particular, to the field of personalized medicine? In order to drive test adoption, pharma must first 'socialize' laboratories by offering the new test for free at launch for a certain period of time, in the same way that Uber connects with potential customers by offering them their first Uber ride for free, thereby driving product adoption. Diaceutics has noticed that an increasing number of pharma companies fund the diagnostic test at launch in conjunction with three best practices:

- **Fund the diagnostic test at launch where possible**
  Funding a new diagnostic test is a great way to drive test adoption in the market. Pharma should plan and adapt for each country as they all differ in terms of their regulatory process. For instance, in Germany, funding a diagnostic test at launch is not allowed.

- **Fund the diagnostic test according to market requirements**
  Reimbursement of a diagnostic test varies across countries, particularly in Europe, where every country has a different way of covering the costs. Due to the complexity, pharmaceutical companies need to understand the individual European markets. For

instance, Italy's reimbursement system is based on local catalogues and therefore some variation is seen between regions, whereas France has a national system for oncology which is controlled by the French National Cancer Institute (INCa).

- **Ensure careful exit of diagnostic test funding**
  While subsidizing a diagnostic test at launch is a good strategy, pharma should also carefully plan the exit by developing a robust strategy. In fact, if pharma suddenly stops subsidizing testing when no alternative reimbursement is in place, laboratories are likely to stop using the test.

Finally, Diaceutics believes that funding a diagnostic test at launch is a great solution to drive adoption because it addresses the time gap that exists before test reimbursement is implemented. In addition, this opens up a way to educate and communicate to laboratories on the availability of the newest test. Uber offering a free ride to a new customer is like pharma subsidizing a new diagnostic test at launch. While Uber wants to gain more customers, what is at the end of pharma's journey? Driving drug adoption to deliver personalized medicine!

**This Expert Insight was originally published in 2015.*

Economics of Genomic Testing for Women with Breast Cancer

Jordan Clark of Labceutics comments on the *American Journal of Managed Care* article 'Economics of Genomic Testing for Women with Breast Cancer' and highlights that personalized medicine is being held back by the unwillingness of payers to reimburse genomic testing

Robert D Lieberthal, PhD, from the Jefferson Population Health Continuing Professional Education Collaborative, describes in the *American Journal of Managed Care*[1] what he believes to be the first structured review of the economics of breast cancer care. The NIH estimates that the annual financial burden of breast cancer is around $14 billion. Lieberthal's excellent review highlights what is generally agreed, namely that genomic testing and personalized medicine can reduce costs but that there is still inadequate reimbursement for genomic studies.

We wholeheartedly agree with the recommendation from Dr Lieberthal that more studies into the health economics of personalized medicine are urgently needed. In addition, the move towards inclusion of direct clinical trial data as the backbone of such studies would be an improvement on the current modeling algorithm approach. He eloquently visualizes the direct and indirect cost of breast cancer care and it is a stark reminder that genomic testing is only a small, but essential, gear in the patient care pathway.

Elsewhere in the Expert Insight section titled PM2.0 we discuss that in order for personalized medicine to fulfil its potential, we must start taking the long-term holistic view of health economics, rather than a short-term detrimental view, that will not fund genomic testing in the order of $100s. The cost of genomic testing pales into insignificance when compared to the potential direct and indirect cost savings of treating cancer using precision medicine.

Of course, we recognize that the fragmentation of stakeholders and inefficiencies of reimbursement systems currently supporting personalized medicine, and companion diagnostics in particular, are holding back a shift to PM2.0. However, it all starts with the data and this paper should ring alarm bells for us all given that even in breast cancer, where we now have some of the most advanced biomarker and risk assessment tools, we do not have the business model sorted out. Pity.

**This Expert Insight was originally published in 2014.*

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Diagnostics Ignored in Targeted Therapy Pricing, Access and Value

Peter Keeling provides insight on the role personalized medicine can play, specifically the diagnostic, in adding value to a therapy and why pricing models need to be reviewed to reflect the value that complementary and companion diagnostics can have on the overall targeted therapy value.

There is a rising storm of debate around 'excessive' therapy prices on one side and, on the other, the exploration of 'new models' to articulate the positive impact which the pharma industry's 10 per cent of the health cost pie has on the other 90 per cent of healthcare spend.

At one end of the spectrum, payers are seeking and getting steep discounts from launch onwards for new therapies[1]. (This combative approach is surely equivalent of Tesla launching its new people's car with 30 per cent off from day one!) Payers' empowerment comes from the arrival in the US of cost-effectiveness groups like the non-profit Institute for Clinical and Economic Review (ICER), whose methods closely resemble those of NICE, the successful gatekeeper to therapy pricing in the UK[2]. Whether we agree with the methods deployed by ICER in terms of their inclusiveness or not, they are getting the ear of Medicare and presidential hopefuls[3] and will serve to intensify the pricing debate.

Does personalized medicine help or hinder the debate?

Of course, not all of the therapies under pricing scrutiny are personalized with the use of biomarkers. It does seem as if the pharma industry has, by implication, leveraged its existing Health Economic Assessment (HEA) models to consistently cross the $100,000 per patient barrier in return for dramatically improved outcomes in smaller patient segments targeted

with the use of biomarkers. It is a pity then that the diagnostics at the heart of this segmentation are so ignored.

Our observation here is a simple one. Current HEA models which focus on therapy pricing generally ignore the value of the diagnostic in two ways:

1. Diagnostic value is seldom expressed in its own right despite its huge impact on improving therapy value. As recently reported in GenomeWeb from the American Society of Clinical Oncology's annual meeting, “researchers presented data from a cost-effectiveness analysis of Opdivo and Keytruda when administered with PD-L1 testing and without. In studies of patients who had non-squamous cell tumors with PD-L1 expression in 1 per cent or more of cells, the cost per QALY gained decreased from $176,000 to $105,000. For Keytruda, when patients had PD-L1 expression in 50 percent of more cells, the cost per QALY gained dipped from $163,000 to $138,000”[4].

2. The financial and clinical promise of personalized medicine is NOT optimally delivered in the premium pricing of late stage therapies (despite their clinical impact on outcomes), but rather in integrating diagnostics and therapy ever earlier into the treatment pathway. Diaceutics has already published on the opportunity to harness personalized medicine to strike a more balanced value for all stakeholders5. Indeed to give this balanced value model a chance to breathe, we, along with a group of physician, pharma, laboratory and diagnostic stakeholders, have established a unique not-for-profit initiative (pmconnective.org) to get specific with the value equation at a disease level. This pre-competitive initiative has already started to identify the barriers to a balanced value approach with the goal of developing a collaborative (versus combative) model.

We are conflating access with value

We will be the first to decry the lack of reimbursement infrastructure which dogs new companion and complementary diagnostic launches across the leading healthcare markets. We continue to encourage our clients to invest time to navigate this neglected field[6].

However, we must not confuse the access barriers to optimal testing (a pain to manage though they are) with the need to articulate the profound impact which diagnostics can have on the value of targeted therapy. We laud the three year journey which EPEMED and the Office of Health Economics (OHE) have been on to argue for a new evaluation framework dedicated to diagnostics. EPEMED and OHE have proposed “a broader framework for considering the value contribution of complementary diagnostics and provides policy recommendations to support the implementation of this comprehensive framework for assessing their potential value contribution.”[7]

Frankly, the inclusion and articulation of diagnostic value needs to be elevated alongside the articulation of the targeted therapy and it is no more acceptable to talk about personalized medicine value only for therapies, than it is to describe the value of a new car without tyres.

As we all search for new models which collaborate to unlock value rather than battle to protect historic turf, we encourage access and reimbursement experts everywhere to better understand the heroic power of diagnostics to reshape the debate.

**This Expert Insight was originally published in 2016*

Visit PM Connective at http://www.pmconnective.org/

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Drug Pricing Models

In the wake of numerous articles on the high cost of new drugs, several organizations have developed drug pricing models. With a number of these scorecards arriving at the same time to raise the profile of cost versus value, could they pose a major threat to pharma? **Jeff Waldron** examines three recent models and attempts to find out.

The drug pricing models published recently come from organizations that have their own entirely self-specific reasons for doing so, and transparency and accuracy are not the only key attributes—as with everything, “where you stand depends on where you sit!”

So, providers want to explain why they prescribe such expensive medications, hence the educational aspect of the Memorial Sloan Kettering model. Pharma companies, on the other hand, are loathe to discuss pricing due to the negative press they’ve been receiving.

Pharmacy Benefit Managers (PBMs), are caught in a classic ‘double edged sword’ situation. They want to control Rx costs for plan sponsors but, at the same time, set drug sales revenue as a goal. Express Scripts, the largest US PBM, tell us they are deploying a unique pay-for-performance drug pricing model based on a combination of the Memorial Sloan Kettering and ICER models. This plan will price the same drug differently for different diseases and applications.

In the US, private payers have by far the largest market share of medical and pharmacy plan members and they protect their corporate pricing acidulously. Their pricing structures vary widely and are determined by clinical, business-related and geographical factors, as well as plan sponsor category and plan type. Prices fluctuate over time as well. The major government payer, CMS (Medicare and Medicaid) has somewhat more transparent pricing, but it also varies.

Thus, drug pricing models offer educational value, defence of high costs and, in some cases, specific comparative pricing to guide policy and buying decisions. How is a provider, payer or patient supposed to judge cost against value?

DrugAbacus from Memorial Sloan Kettering

This model helps us to ask what is the ‘right price’ for a new drug? It takes 54 new cancer drugs approved since 2001 and lets you compare the company’s price to one based on value - the ‘Abacus Price.’ How does DrugAbacus find the value of a drug? It doesn’t. You do. It stores everything about these drugs that might be relevant to their value (based on the data sent to the FDA to get the first approval). It uses the idea that a drug’s value can be broken up into its parts, leaving you to decide which parts should matter and with what weighting. The results are then compared to the drug’s actual price.

The DrugAbacus tool is quite informative as an educational model. It depicts the key attributes to be evaluated in determining a drug price. You can select a particular disease, and it shows quite handily all of the drugs used to treat that disease and their relative pricing.

You can even alter the embedded variables used to calculate the drug price, such as dollars per life-year or cost of development. By way of example, Iressa (AZ) returns an actual price of $2,069 and a DrugAbacus price of $454. One major limitation of the model is that it only prices the drug at initial launch in 2014 adjusted US dollars. Nonetheless, the model is an interesting and useful tool for general understanding of the determinants of drug pricing.

Value Framework from the Institute of Clinical and Economic Review (ICER)

The Value Framework is intended to address 'problems' such as poor reliability and consistency of value determinations by payers, finding a transparent way to analyse and judge value and the tension between long- and short-term perspectives. Its goal is to find a common language and descriptive model of the components of value for all stakeholders. With a grant of $5.2m, ICER expects to provide benchmark prices for up to 20 drugs over two years, beginning with the new category of potent cholesterol-lowering drugs developed by Sanofi and Regeneron.

The framework considers the following aspects that lead to an assessment of care value:

- **Comparative Clinical Effectiveness:** the comparative net health benefit and the level of certainty in the evidence on net health benefit. ICER uses its Evidence-Based Medicine (EBM) matrix to describe the judgement of the scientific staff.
- **Incremental Cost per Outcomes Achieved:** the cost per aggregated health measure (QALY).
- **Other Benefits or Disadvantages**: information about the intervention to caregivers, the delivery system or other patients not captured in the available 'clinical' evidence.
- **Contextual Considerations:** can include ethical, legal or other issues (but not cost) that influence the relative priority of illnesses and interventions.
- **Potential Budget Impact:** estimations of net changes in total health care payer costs over an initial two year timeframe and alternative measurements of the net budget impact of all known eligible patients switching to or beginning a new care option.
- **Provisional Health System Value:** an early judgement based on the care value, potential budget impact and affordability of a new drug.
- **Managing Affordability:** an action step, ideally supported by enhanced early dialogue among stakeholders to firstly determine the extent to which real-world constraints in uptake will limit the actual budget impact of the new service, and secondly to decide if this expected budget impact is manageable in the current health care landscape.

Overall, the ICER model is a rigorous, research-based analysis customized to the particular therapy and disease and the components are more academically derived than DrugAbacus. The ICER approach may not be as user-friendly, but that's because it's not a tool—it's a scientific, quantified, organized and well thought out research methodology that is consistently applied.

The American Society of Cancer Oncology (ASCO) has recently released a Scorecard, or conceptual framework, for assessing the value of new cancer therapies based on treatment

benefits, toxicities and costs. Developed by the ASCO Value in Cancer Care Task Force, the framework will ultimately serve as a user-friendly, standardized tool that physicians can use with their patients to discuss the relative value of new cancer therapies compared with established treatments. It is currently [2015] a discussion draft with ASCO inviting input on the proposed framework.

ASCO's framework seems to add complexity beyond the ICER model. It uses many of the same considerations and variables, but it relies on extensive explanations and justification along with a visually complex structure.

My overall assessment of these models is that they are the first steps in the transition to a much more transparent health care system that allows all stakeholders to make effective decisions that yield improved health outcomes and better economic value. Advanced new personalized therapies, combined with state-of-the-art diagnostics, are poised to offer dramatic improvements in treating many major diseases, but the value tools are not in my view sufficiently explicit about the value of integrating one or more diagnostics alongside these therapies. Since the pricing of recent personalized medicine therapies (targeted by specific biomarkers) is triggering much of the development of these tools, it will be important that the diagnostic and therapy values are equally clear. In the long run, this will help both payer and pharma negotiate the right price for the right drug at the right time.

**This Expert Insight was originally published in 2015.*

Further information

- Memorial Sloan Kettering Cancer Institute DrugAbacus - http://www.drugabacus.org
- Institute of Clinical and Economic Review (ICER) Drug Research - http://www.icer-review.org/icer-ljaf-drug-assessment-announcement
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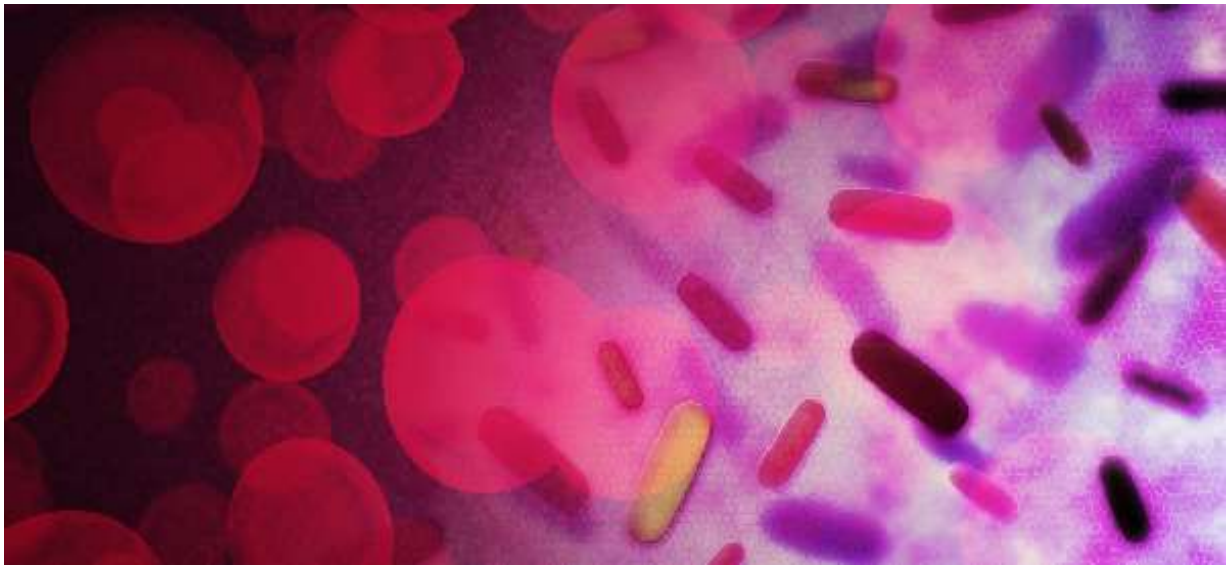
Will the CMS Proposal to Adjust Laboratory Reimbursement Through Data Collection Disproportionately Hurt Small Labs?



Eloise Aita, PhD, writes that on the surface CMS proposals for laboratory reimbursement could simplify a complex process but is concerned that smaller labs, particularly those offering fast test turnaround for critically ill patients, will struggle to compete with the big players.

As part of the Protecting Access to Medicare Act of 2014 (PAMA), the Centers for Medicare and Medicaid Services (CMS) proposed a rule to determine reimbursement rates for laboratory tests that seems to favor larger labs due to their size, high volume operations and lower associated costs. Basing reimbursement rates on deeply discounted negotiated contract fees typical of the large national laboratory networks means that small labs, physician office laboratories (POLs) and hospital facilities, which shoulder higher costs due to their size and lower testing volumes, will be at a disadvantage.

For the past 30 years, CMS has used a clinical laboratory fee schedule (CLFS) to reimburse patient testing. In the past, adjustments were made to CLFS based on the cost of living index, but in recent years laboratories have seen significant reductions to these fees as a result of federal budget cuts, including sequestration. Due to advances in automation and improved testing methods, overall laboratory costs have come down. As part of PAMA, CMS plans to base future CLFS fees on actual provider payments. There will be a requirement for labs of a certain size to report what they are being paid for testing.

Although CMS proposes to base reimbursement rates on private payor rates, only labs earning more than $50,000 in CMS fees will be required to submit payment data for inclusion in the weighted median calculation (the method that will be used to establish the new CMS fees). Payments to hospitals for laboratory services are reimbursed under the Hospital Inpatient Prospective Payment System or Outpatient Prospective Payment System, so hospitals will not be asked to provide payor data to CMS. This exclusion, however, will likely have a negative effect for labs overall as those higher hospital payment rates will not be taken into account when setting the new CMS rates.

By excluding hospitals, academic labs and POLs from the data collection, CMS is essentially saying reimbursement will be based on data collected from large independent labs performing the highest percentage of testing. In addition, payors can negotiate concessions with the large independent labs based on volume discounts, prompt payment schedules, exclusive contracts and a number of other circumstances which could in turn affect the data on payment rates.

> "With regard to price concessions, section 1834A of the Act is clear that the private payor rate is meant to reflect the amount paid by a private payor less any price concessions that were applied to a CDLT."[1]

What data will be collected for tests that are not reimbursed or denied coverage by payors? And when an applicable lab performs a test and the insurance company decides there is no clinical evidence for it, will a zero dollar figure be entered into the CMS data, further driving down the median payment?

All this means that future reimbursement for the non-applicable labs (those not required to submit data to CMS) will be dictated by the larger, cost-efficient, volume-driven, highly automated and contracted independent labs, even though the non-applicable labs typically do not enjoy such efficiencies and are performing the same testing at a higher internal cost. This will negatively impact hospital and academic laboratories in particular, where acutely ill patients require timely testing results that impact treatment using personalized medicine or companion diagnostics. Insufficient reimbursement for these relatively low volume lab tests may well force these laboratories to discontinue such testing, possibly leading to delayed or suboptimal treatment decisions for the most seriously ill patients.

When we look at the different levels of services offered by laboratories it's not hard to see why this new approach to data collection could affect the reimbursement claims for so many smaller labs. Academic centers and hospitals may offer fairly large test menus, designed to produce quick results that support the best patient care. The needs of acutely ill patients demand that testing be performed in-house and not sent out to reference labs. Lower testing volumes create higher costs on a per test basis.

> "Accordingly, under our proposal, only one laboratory may design, market, perform, and sell the test. If more than the one laboratory engages in any of one of those activities, the test would not meet the criteria to be an ADLT. If our proposal is finalized, we would not expect to see more than one applicable laboratory report applicable information for an ADLT."[1]

In many instances when a laboratory sends testing to a reference lab, the sending lab will bill payors for the testing and the performing lab will 'client bill' the sending lab. The CMS proposal for this situation would not accurately reflect the payor rates as each sending lab might have different fee schedules with multiple payors and, in the case of a hospital lab or non-applicable lab, no payment information for the advanced developed laboratory test (ADLT) may be submitted to CMS at all.

Given the fast pace of advances in laboratory medicine, particularly in molecular testing, an ADLT may be developed with technology that might be replaced by newer, better and possibly less expensive technology in a fairly short time. Additionally, once a novel test has been developed it is critical for patient care that the test be vetted and improved upon by other labs to ensure that the test result is accurate, reproducible and reliable.

The reimbursement strategy for ADLTs outlined in the proposed rule may:

- Curtail innovation and might actually remove the incentive to improve novel tests if only the originating lab can expect to be reimbursed;
- Hinder payors' ability to negotiate lower rates with laboratories as other labs will be unlikely to develop competing tests for an ADLT;
- Incentivize labs to set high list prices for ADLTs resulting in more out of pocket costs for uninsured patients or patients with co-pays.

The CMS proposal may look like a simplification of the test reimbursement process but will it produce an accurate reflection of the value of tests performed? And will the labs that have no voice in contributing to the data be adequately reimbursed under the proposed new payment schedules? Only time will allow us to answer these important questions but until then we run the risk of negatively impacting patient care and undervaluing critical laboratory testing.

**This Expert Insight was originally published in 2016.*

References

1. Department of Health and Human Services Centers for Medicare & Medicaid Services, Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, Proposed rule, January 2015.