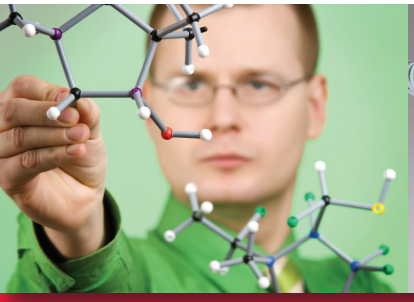
WhitePaper

A CEO's Guide to Molecular Diagnostic Reimbursement:

Navigating the Many Challenges of Reimbursement and Commercialization

By: Rina Wolf
Vice President of Commercialization Strategies,
Consulting and Industry Affairs, XIFIN Inc

Editor: Karen Appold

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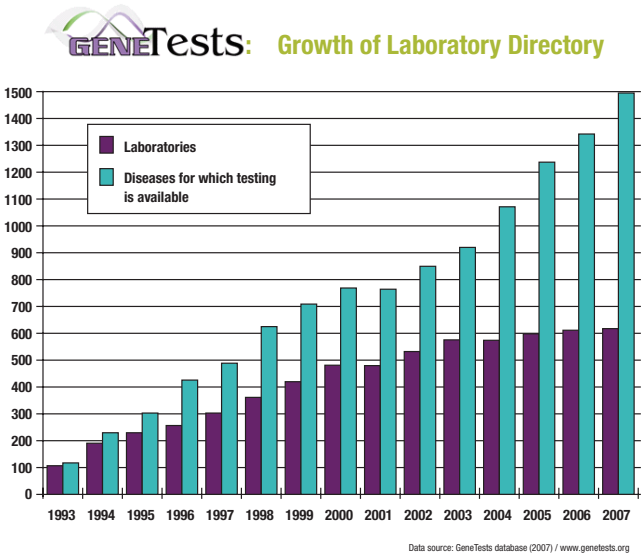
Preface

Reimbursement and commercialization are significant challenges in this era of personalized medicine and comparative effectiveness. Many traditional clinical laboratories and early stage startup companies are trying to enter this space and are struggling to evaluate both the market and its offerings. According to Gene Tests, a publicly funded medical genetics information resource, the availability of new diagnostic tests increases 10% annually. However, there is a 20% increase in the utilization of genetic tests per year versus a 1% to 3% increase in non-genetic diagnostic tests per year.

Figure 1



In 2007, for example, genetic tests cost Aetna 70 cents per member per month as an aggregate. These numbers are increasing. In 2005/2006 genetic testing comprised 17% of Aetna's testing dollars; in 2006/2007 it was 21%.

Figure 2

Rank	Cause of Death – known genetics factor	Number of Deaths in 2000
1	Heart disease	709,894
2	Cancer	551,833
3	Stroke	166,028
4	Chronic lower respiratory disease	123,550
6	Diabetes mellitus	68,662
7	Pneumonia and influenza	67,024
8	Alzheimer's disease	49,044
9	Kidney disease	37,672
11	Suicide	28,332
12	Chronic liver disease	26,219
13	Hypertension	17,964

Some view genetic testing technologies as disruptive to traditional physician practice patterns as well as to pharmaceutical companies, who may now have patient criteria limitations on their next potential blockbuster. Depending upon the source, it is believed that only between 9% and 21% of physicians use genetic tests. Many physicians say they don't understand genetic tests well enough to use them effectively. It is imperative, therefore, that the molecular diagnostic industry

improves its messaging and ability to educate physicians. There are many misperceptions regarding the capabilities of well validated genetic tests. Because genetic testing has proven to be valuable for the prognosis, diagnosis and management of many diseases, the commercial potential is quite significant.

1.

Considerations for Commercialization and Reimbursement of a New Molecular Diagnostic

Although many good ideas exist, competition for funding is significant. Investors will ultimately choose, and invest in, the most compelling business plans.

Test researchers/developers must contemplate a number of questions during early strategic planning in order to successfully execute a viable commercial launch. Long before a launch is even visible on the horizon, they must raise funds to finance continued research and development, as well as for commercial development activities for their tests. Venture capitalists and other investors want to ensure that in addition to solid validation of the science behind the test, a developer has thought through the entire commercialization process, understands the market for their test, understands all of the relevant commercial considerations and has a plan to address these considerations. Although many good ideas exist, competition for funding is significant. Investors will ultimately choose, and invest in, the most compelling business plans.

The following are some of the questions to consider when creating a business plan for commercialization of a genetic test.

How can clinical utility be established prior to launch?

This is problematic because clinical utility is the key to a molecular diagnostic test's value from the payer's perspective and the most difficult to truly define. A payer will want to know:

- How will the test be used in a clinical setting?

- Why did the physician order this test for a particular patient and, most importantly, will the information be used in making or changing a patient management decision?
- If the information was used, what are the outcomes of using the test as a component in the management decision and was that decision the correct one?
- What was the patient outcome and is there both a health and economic value of the test? This can be difficult to determine. If a test hasn't been commercially available or utilized in sufficient volume, gathering meaningful data will be challenging.
- Did you obtain this information by collaborating with a major health center in your disease space?
- Did you perform ongoing field tests, registries and repurposing existing studies?

Price must be carefully considered. Do less expensive diagnostic laboratory tests provide the same quality of answers as your tests and provide information that is as actionable?

All of these expensive options need to be factored in to determine what makes the most sense for your specific situation.

Technology assessments often conclude with rulings of "insufficient evidence," and unfortunately a clear definition of what "sufficient" evidence would be is rarely provided.

What is the current environment in your targeted diagnostic area?

Price must be carefully considered. Do less expensive diagnostic laboratory tests provide the same quality of answers as your tests and provide information that is as actionable? The cancer antigen levels in cancer diagnostic screening are a good example. They're relatively inexpensive, however there's a general acknowledgement that they may not provide actionable answers. Nonetheless, they're used millions of times a year because nothing else is available. If you offer a cancer test that competes with those cancer markers and you need to

charge more for it, will you be able to prove its worthiness? Will you get a better answer that in the long run will be cost effective?

When determining your price, be sure to account for all of your costs including test development, sales and marketing. Don't forget about the costs of getting paid.

What is the fully loaded cost of goods?

When determining your price, be sure to account for all of your costs including test development, sales and marketing. Don't forget about the costs of getting paid. Although a competitive price is ideal, be sure to include the costs and complexities of actually getting paid. Payment delays can result from a lack of favorable coverage policies, a high percentage of appeals and/or simply the labor costs of billing and accounts receivable management. Be sure to factor them into the price.

What will your billing capabilities be?

The selection of a billing vendor becomes more critical when you consider the difficulty of a billing conversion at the time you want to bring the function in-house…

Do you want to build capabilities in-house by developing these competencies internally or does it make more sense to outsource them? It's common for fairly new diagnostic testing companies to outsource their billing due to higher business priorities and little or no experience in building and managing a billing department. However, outsourced billing for laboratory testing is always more costly than in-house billing operations on a percentage of revenue basis and customer and payer service is not under a laboratory's direct management control. Accordingly, almost all laboratories eventually bring the billing function in house.

The selection of a billing vendor becomes more critical when you consider the difficulty of a billing conversion at the time you want to bring the function in-house and the selection of a system that can accommodate a high growth rate. When evaluating a potential billing partner, choose a flexible company such as XIFIN that will allow you to fully outsource your billing function and then bring all or part of

your billing services in-house over time without having to move your accounts receivable onto a new system.

While the number of laboratory tests performed, your adoption rate and list price are all important components of a successful business strategy, it is critical to establish an equitable reimbursement rate with a coverage policy that provides the payer with a value-based service that can be economically and medically justified. The primary attributes to consider when selecting a vendor is its expertise and experience in establishing coverage for new assays through strong payer relations and effective appeals management coupled with an ability to develop a comprehensive patient advocacy program during this process.

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If you decide to develop such programs, will your billing vendor or partner manage them or will you do that in house?

What will your billing policies and rules include?

When establishing billing policies, factor in regulatory requirements as well as rules that support your business philosophies. Regardless of whether you're building your capability in-house or outsourcing it, you must develop a set of rules that govern how your billing plan will be managed. If there is a concern, a government or regulatory agency must be able to view this policy. Additionally, it's imperative to understand the regulatory and legislative environment which constantly changes at local, state and federal levels. Be aware of regulations that are unique to Medicare and Medicaid patients. Compliance is not limited to HIPAA or Sarbanes-Oxley Compliance; it also includes Office of Inspector General guidelines that provide protection from the broad net of health care fraud and abuse.

Diagnostic Kit or Laboratory Developed Test?

Tests that are developed to be sold as diagnostic kits will require FDA clearance—a long, expensive process. Presently, the FDA does not regulate laboratory developed tests (LDTs) but the FDA has stated that it has the right to do so. Your ability to follow the FDA's potential movement in this direction, plan accordingly and be able to adjust your plan as appropriate will be critically important.

Tests that are developed to be sold as diagnostic kits will require FDA clearance—a long, expensive process. Presently, the FDA does not regulate laboratory developed tests (LDTs) but the FDA has stated that it has the right to do so.

FDA regulation may come first for tests that are considered *in vitro* diagnostic multivariate assays (IVDMIAs). Draft guidance on this issue was published in 2007, but it has not yet been finalized. However, there is tremendous pressure from both within and outside of the agency to also regulate all LDTs. Presently, there is speculation that if such regulation comes, it would be on a tiered basis based on perceived risk, but nothing is final. The FDA has also stated its intention to release an updated Draft Guidance for companion diagnostics in the near future. Although FDA clearance has not historically been shown to be a competitive advantage for LDTs, should FDA clearance become mandatory for a given test no payer would be able to develop or maintain a positive coverage policy until that test had become compliant with clearance.

2.

The Road to Coverage

After answering these questions and putting the appropriate policies and systems into place, the next step is to launch the molecular test and to get health insurance companies to provide reimbursement and coverage.

… the underlying purpose of a diagnostic service is to provide information to the physician that facilitates a determination of a medical course of action or therapy versus the outcome of that therapy.

Blue Cross Blue Shield Tec, a well-known tech assessment group, can be used as a benchmark for coverage readiness. However, if you look at its published criteria for evaluating any new modality, it's obvious that the criteria is not designed for clinical diagnostic services that do not require FDA clearance. This makes it extremely difficult for a clinical laboratory test, especially a proprietary clinical laboratory test, to fulfill the criteria.

When a drug is launched, it already has FDA approval, clinical trials performed and peer review publications readily available. Rarely is this the case when a clinical laboratory test is introduced, however, because the underlying purpose of a diagnostic service is to provide information to the physician that facilitates a determination of a medical course of action or therapy versus the outcome of that therapy.

This is compounded by the fact that Tec can only review 20 to 25 new modalities of any kind per year, including all non-laboratory diagnostics such as PET scans, MRIs, new drugs and medical devices. Therefore, when a tech assessment is triggered, whether it's at your company's request, the request of another payer or something that has hit the payer's radar screen, to the best of your ability make sure that assessment isn't conducted prematurely and that you are ready to demonstrate that you have met tech assessment criteria. To

increase your chances of success, you must establish analytical and clinical validity, have a sufficient amount of analysis of data appear in peer reviewed publications and demonstrate that this test has become an accepted standard of care. This can be established initially by soliciting physician testimonials and substantiating your claims volumes. Eventually, it will be important to have an appropriate organization for your specialty such as American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN) or American Congress of Obstetricians and Gynecologists (ACOG) provide testimony attesting to the assay as a standard of care or include it in their guidelines.

One of the biggest challenges is setting appropriate expectations regarding the length of the coverage and approval process with both your board of directors and senior management team.

If you get an equivocal or negative evaluation, you may not get the chance to present your case again for several years. One of the biggest challenges is setting appropriate expectations regarding the length of the coverage and approval process with both your board of directors and senior management team. Although some opportunistic early successes occur, it takes a long time and a lot of claims to achieve this.

Another hurdle occurs when a tech assessment group concludes there's insufficient evidence, but they don't specify what sufficient evidence is.

Economic arguments do not lead to payer coverage of a molecular test

Coverage by payers must be consistent. It must be aligned with your indicated uses, be objective and comprehensive, and most importantly be unbiased to cost. A good evaluation is based upon scientific evidence and clinical utility evidence, not cost. Cost should be considered only after a payer has decided to cover a test--whether it's on an individual patient-specific basis or a coverage policy is created. The contracting department will evaluate the cost to perform

the test, related charges and how they will pay for it. This becomes an actuarial exercise for the payer.

Many molecular diagnostics companies beginning this process maintain that if they can create a strong economic argument, then they will get coverage. However, currently in the United States, if you lead with economic arguments as opposed to scientific evidence and clinical utility evidence, you will lose because the tests have to be actionable and improve the currently available information for clinicians. The role of economic evidence is subject to change and will likely play a greater role in the future. For now, if resources only allow for a study that will demonstrate clinical utility or an economic model, always choose clinical utility first.

Only in the last few years have organizations started to add diagnostic modalities to guidelines. Before then, their guidelines were mostly limited to drugs and therapeutic protocols.

Proving Clinical Utility

Because clinical utility is critical to reimbursement, how do you demonstrate it if you don't have utilization? Establishing a new diagnostic assay as the "standard of care" can be difficult. How do you get appropriate organizations, such as ASCO or NCCN, to add your molecular tests to their guidelines?

Only in the last few years have organizations started to add diagnostic modalities to guidelines. Before then, their guidelines were mostly limited to drugs and therapeutic protocols.

HER2 and Onco*typeDX* were the first diagnostics to be added in the oncology arena. Although randomized clinical trials (RCTs) are the gold standard, they may not be applicable to these kinds of tests. In the time it takes to do a RCT, a laboratory test could become obsolete because the next generation assays are already available. Additionally, most independent entrepreneurial laboratories don't have the funds to perform RCTs. There is beginning to be acknowledgement by

appropriate bodies, such as congress, The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) and the FDA, as well as innovative private payers, that some alternatives to RCTs may be more appropriate for the laboratory industry.

Laboratory testing is often undervalued as far as payer resource allocation, even though diagnostics are used in greater than 70% of all health care decisions.

Recently, the FDA acknowledged that it may have to view things differently and propose ways to validate new diagnostic test technologies, given that some of these previously considered gold standards may be inappropriate. An added complexity for outside agencies conducting evaluations is the fact that many molecular diagnostics companies are privately held and much information is proprietary. Be cautious about what information you share in order to get an appropriate positive assessment and realize that it could be used by a competitor.

The Catch 22s of Molecular Reimbursement

A number of complex paths to coverage need to be navigated:

1. Payers will not devote resources to evaluate new molecular tests if demand hasn't been demonstrated. Demand is thwarted by reimbursement and coverage concerns.
2. Laboratory testing is often undervalued as far as payer resource allocation, even though diagnostics are used in greater than 70% of all health care decisions. If you're offered a contract by a payer, the template you'll receive will probably be designed for physicians and hospital providers. That's because smaller payers often don't view diagnostics as important enough to warrant a separate contract. This creates its own set of challenges.

It's critically important to set appropriate expectations for physicians who are willing to try a new molecular test early on because payers will require them to prove why they need a test…

3. Technology is moving faster than coverage criteria is revised to reflect existing technologies. A good example is Thin Prep, a companion diagnostic test for the human papilloma virus vaccine. When Thin Prep was introduced, doctors adopted it relatively quickly. However, it took many years before payer coverage policies would make a differentiation between payment and coverage. While scientists work quickly to bring new and better laboratory testing tools to the market, payers work slowly.
4. Blue Cross and Blue Shield tec criteria are difficult for molecular diagnostic tests to meet. Tremendous burdens are placed on early-adopter physicians. It's critically important to set appropriate expectations for physicians who are willing to try a new molecular test early on because payers will require them to prove why they need a test and hope that they will give up and stop using it. Documentation must be made regarding why a test was ordered, how the information was used, letters of medical necessity, copies of medical records, etc. Many requests are made of physicians to justify why they have ordered a test. As a result of this burden, some physicians opt to wait to order a test until reimbursement has been established.

3.

Reimbursement Options for Molecular Tests

The simplest approach to reimbursement is the stacked code, which requires looking at the various steps in the technology and methodology of a particular laboratory test and seeing if a code currently exists that is representative in its definition of that particular step.

Despite challenges and obstacles, molecular diagnostic tests do get reimbursed. There are two main approaches to obtaining reimbursement. Both have advantages and disadvantages.

Stacked Codes

The simplest approach to reimbursement is the stacked code, which requires looking at the various steps in the technology and methodology of a particular laboratory test and seeing if a code currently exists that is representative in its definition of that particular step. If that's the case, then you would literally create a stack or list of codes that you are performing. Sometimes they may be multiples if you're looking at various gene sets, for example. Pricing is determined by simply adding up the clinical laboratory fee schedule amounts that are assigned to those codes, calculating a sum and determining if that sum is sufficient to make your test commercially viable.

An advantage of stacked codes is that they hinder the ability of payers to analyze specific laboratory test activity. Consider this example using a polymerase chain reaction (PCR)-based test. A payer may receive millions of claims a day for the various steps in the PCR process. When the payer reviews the line items on the claim, it sees a stack of codes normally used together and most likely won't question the claim. Most payers' systems lack the sophistication to uncover a new technology that has been submitted. They will just crosswalk the codes in their system, which will assign a dollar amount based on the

sum of the codes that are pre-loaded. If you decide that the payment is unacceptable, as a non-contracted provider you can appeal the payment amount. The disadvantage of stacked codes is that the sum of the codes may not amount to a reimbursement level that's sufficient for a viable business model and it is not a permanent answer. When utilization begins to increase, the payer may realize that something is new and pursue further investigation.

The disadvantage of stacked codes is that the sum of the codes may not amount to a reimbursement level that's sufficient for a viable business model and it is not a permanent answer.

The process of getting a new current procedural terminology (CPT) code is difficult and can take 18 months to two years. To begin the process, you must prove a need by demonstrating national acceptance of the test. Ultimately, the result could be a dollar amount that is inappropriate. And, due to the lengthy process, you may enhance the test at the same time and render your own code obsolete by the time it's issued.

Miscellaneous Codes

Another approach, sometimes called a miscellaneous code or a Not Otherwise Classified (NOC) code, are codes that typically end in "99" and don't have pricing associated with them on the clinical laboratory fee schedule. The advantage of this option is that you can assign a price that is commensurate with a test's value. As a result, you can potentially get reimbursement that reflects your technology's sophistication and therefore capture some value for your intellectual property. The diagnostics industry doesn't have the same abilities as drug or medical devices, where a price for a drug going to market reflects the value of that drug and its many years of research and development. Additionally, pharmaceutical companies can recoup the costs of investigations that never led to a viable drug.

The disadvantages of miscellaneous or NOC codes is that every claim raises a red flag with the payer because they must be manually

processed. Little opportunity for electronic billing exists until you're in the contractual stage and the payer has set up a code to identify you in their system. Therefore, getting reimbursed can take a long time and you often have to negotiate with every payer for every claim. It's not uncommon to get a remittance advisory (RA) or an Explanation of Benefits (EOB) from a payer that might list five or six different encounters and have every one of them paid at a different level. One can be paid at full price and another at mid-price, and still another denied outright. In some cases, a payer has agreed to pay only a penny. Using this method, reimbursement can run the gamut and managing this process can be extremely expensive and resource demanding. Under CPT coding instructions, you cannot choose an NOC or miscellaneous code simply because the sum of a stack code is less than desired. Coding must reflect the methodology and technology or analyte that you're looking at.

… getting reimbursed can take a long time and you often have to negotiate with every payer for every claim.

4.

Coverage and Contracting for Molecular Tests

A crosswalk scenario occurs when it's determined that the new service is comparable to something that's already been coded and priced.

Medicare Coverage

Unlisted services are usually covered and priced by your local Medicare Administrative Contractor (MAC). If you are only performing the test in one MAC region, that is the one to convince. In essence, if your MAC implements a coverage policy (either positive or negative), it becomes a national coverage determination because all claims will go through your local MAC. When payment levels are determined, one of two methodologies is typically used. A crosswalk scenario occurs when it's determined that the new service is comparable to something that's already been coded and priced. Gap fill methodology is used when nothing is close to the methodology you're using and as a result, they create a new price to fill in the gap. Gap fills can take into consideration various costs and resources associated with performing a test, as well as amounts allowed by third party payers.

Private payers typically match their fee schedules to Medicare's clinical laboratory fee schedule (CLFS). At times it's a crosswalk. Sometimes it might be 10% or 15% higher, while other times it might be 10% or 15% lower. When you're doing projections, the CLFS is a reasonable place to start. If you think that your test is eligible for value-based pricing or a "not otherwise classified" or unlisted code, create a document that lists the CPT code that a certified coder agrees comes closest to representing your testing. Then, as

exemplified as CPT code 83908 in figure 3, describe why what you're doing is significantly beyond the definition of 83908. If you have various components in your test and only some of them match existing codes, then you might have justification for an unlisted code. Some companies are beginning to try a hybrid between stacked and miscellaneous methodologies with private payers. While, with limited experience, they are beginning to see some payment on the codes that are mapped, they still are getting denials or inappropriate payments for the NOC component, which can often be the most expensive part of their test.

Some companies are beginning to try a hybrid between stacked and miscellaneous methodologies with private payers.

Figure 3

CPT Code	Code Description	What we do
83097	Lysis of cells prior to nucleic acid extraction (e.g., stool specimens, paraffin embedded tissue)	
83890 83891 83892	Molecular Isolation or Extraction Isolation or extraction of highly purified nucleic acid Molecular diagnostics; enzymatic digestion	
83898	Amplification of nucleic acid, each nucleic acid sequence	
83908	Signal amplification of patient nucleic acid, each nucleic acid sequence	Specific reagents are added in a manner that does not interfere with subsequent amplification. Multiple serial technical steps More rigorous quality control oversight than for established procedures. Designed for the small amount and chemically treated nature of the DNA.

Negative Coverage Determinations

As more claims are submitted, the visibility rises which may result in a negative coverage policy. A negative or no coverage policy can make it more difficult to be paid, however you might still get paid on the appeals process through the Qualified Independent Contractor and the Administrative Law Judge process on the Medicare side. The appeals process on the private payer's side, especially up to the external appeal level, is another tool that clinical laboratories have to convince

payers that they need to cover a test because it's medically necessary, reasonable and contributes to improved patient care. The appeals process can take 12 to 18 months, and it can be costly and labor intensive. However, it's important to go through that process because sometimes payers will agree that coverage makes sense even though they still do not believe that you have supplied sufficient levels of evidence. It is very costly for them to defend these appeals, especially on the external level, and they may realize that continued denials do not make economic sense or effective use of their resources.

The reimbursement sandwich is the pressure created by the combination of the demand by the appropriate ordering physician providers for access to your test and the pressure of the appeals that drive a payer's willingness to reluctantly reimburse the test.

The Reimbursement Sandwich

The reimbursement sandwich is the pressure created by the combination of the demand by the appropriate ordering physician providers for access to your test and the pressure of the appeals that drive a payer's willingness to reluctantly reimburse the test. Both sides of the equation are necessary because even if you have a favorable bibliography of peer reviewed publications and a compelling economic analysis, if you are unable to demonstrate physician adoption you will not be considered for coverage because the payer will not see the need to expend their resources for an assessment.

Contracted vs. Non-Contracted

The goal for most clinical laboratories is to get coverage with a payer and have them sign a contract. But beware, sometimes you have more flexibility as a non-contracted provider. For example, if you can't get an agreement to price a test fairly, entering a contract might not be advantageous. Ultimately, if a non-contracted provider offers or pays an amount that's unacceptable, you have the right to a low payment appeal and can oftentimes win.

It's important to keep your allowable as high as possible when you're going through the early process of submitting claims and getting paid on an individual patient basis and appealing that payment amount. If you have a proprietary test that no one else is doing, it doesn't make sense to offer large discounts if the payer views that the test is medically necessary, it's a covered service and they'll pay your price. If you accept low offers in order to get paid quickly, then you will establish that you will accept a low price level when you get to the contracting table.

Most laboratories doing proprietary testing don't have direct patient encounters in a patient service center so you are dependent upon whoever forwards that test to you to provide accurate billable information.

Other Contracting Considerations

It's ideal to make all of your contracts win-win, which of course includes pricing, but also terms such as the timeliness of claim submission and payment. Most laboratories doing proprietary testing don't have direct patient encounters in a patient service center so you are dependent upon whoever forwards that test to you to provide accurate billable information. Sometimes it can take awhile to discover inaccurate information and have it corrected. It's recommended to contract for no less than 120 days, if not longer, to submit a clean claim. Some payers will give you a year to submit a clean claim; a lot of payers will propose 30, 60 or 90 days. That's unacceptable when there isn't direct access to the patient.

You will also need to have timeliness on the payer's side. Some states have laws that require a clean claim to be adjudicated within 30 or 60 days. Be sure to have contract language that reflects this. What is the definition of a medical necessity? Ideally, a test that is ordered by an appropriate physician will be viewed as medically necessary. Also try to eliminate onerous prior authorization requirements. This can be accomplished by providing meaningful education on how your test should be used and by possibly creating a decision tree for physicians so they can order tests only when appropriate for a specific patient.

Requiring certain information to justify the order in advance from the physician can be negotiated in lieu of a pre-authorization.

Sometimes you can be creative when contracting. When the payer is pressured into contracting by the appeals process, create a risk sharing agreement in which you'll start out with a certain level of discount. If the payer has the means to determine that the test was used appropriately and that management decisions were influenced, then the discount can fluctuate depending on the degree of actionability of the test information. The worst case scenario for a payer is to pay for an expensive test and then have physicians ignore the results.

If the payer has the means to determine that the test was used appropriately and that management decisions were influenced, then the discount can fluctuate depending on the degree of actionability of the test information.

5.

Conclusions

Given the infancy of molecular diagnostics, few CEOs have the prior experience to guide their companies to market while navigating these many challenges.

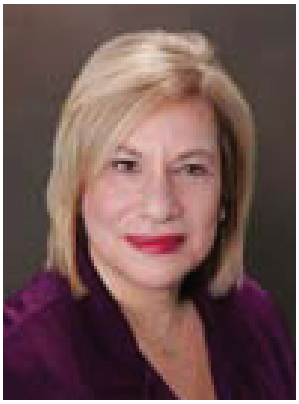
In the molecular diagnostics industry, unfortunately, too often great science and technological innovation does not automatically translate into great commercial success. Almost as much science and innovation needs to be applied to commercialization and reimbursement as to the diagnostic itself. There is no "one size fits all" solution in this industry and there are many potential paths to take, each with its own set of challenges.

Given the infancy of molecular diagnostics, few CEOs have the prior experience to guide their companies to market while navigating these many challenges. With all of the challenges associated with running an early stage technology company, issues that involve future reimbursement seem distant and oftentimes not a priority. Some of the decisions that have to be made include balancing ease of market penetration, with leaving money and future revenue on the table; outsourced or in-house billing; contracted or non-contracted claims submission; client advocacy programs; and FDA clearance or laboratory developed test (CLIA). The good news is that a number of molecular diagnostic companies have perfected the formula and have turned into hyper-growth success stories that are shaping the future of diagnostics and health care.

Appendices

A-1
About Rina Wolf

XIFIN Inc., Vice President of Commercialization
Strategies, Consulting and Industry Affairs



Ms. Wolf is a nationally recognized expert in the field of laboratory commercialization and reimbursement, with more than 20 years of experience in the diagnostic laboratory industry, specializing in molecular diagnostic laboratories. She lectures extensively on these topics and has consulted for major laboratories and laboratory associations throughout the United States. She is a former president and board member of the California Clinical Laboratory Association and is an active participant with the American Clinical Laboratory Association and the Personalized Medicine Coalition. Prior to joining XIFIN, Inc., Ms. Wolf held executive positions in the area of commercialization and reimbursement at RedPath Integrated Pathology, Inc., and Genomic Health, Inc., where she was responsible for creating and implementing reimbursement policies and programs that set the stage for value-based pricing on new molecular diagnostics. She was also at Esoterix (now LabCorp) and most recently, prior to joining XIFIN, held the position of vice president of reimbursement and regulatory affairs at Axial Biotech, Inc., where she was responsible for creating and implementing its successful reimbursement strategies. Ms. Wolf has a BA from UCLA and a Masters of Health Care Administration from the University of La Verne.

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About XIFIN Inc.

XIFIN® delivers a powerful combination of technology and services enabling laboratories to optimize revenue cycle management while building value in their financial operations that enable diagnostic service providers to drive out costs while maximizing value. XIFIN develops financial management software that helps health care providers and laboratories automate their billing systems, manage medical claims filing and reduce the costs associated with the complexity and regulatory compliance requirements of medical billing processes. XIFIN offers a hybrid of traditional billing solutions that fills an important gap between on premise software and outsourcing options. It consists of a highly automated, Web-based application with embedded infrastructure and managed services designed to support laboratory revenue cycle management. This integrated approach uniquely positions XIFIN to provide laboratories with the most sophisticated and up-to-date processing capabilities supporting their revenue cycle process.

Visit http://www.xifin.com/ for more information.

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About DARK Daily

"Dark Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession.

DARK Daily is a concise e-news/management briefing on timely topics in clinical laboratory and anatomic pathology group management. It is a solution to the dilemma facing anyone in the laboratory profession. New developments, new technology, and changing healthcare trends make it imperative to stay informed to be successful. At the same time, the Internet, cell phones, blackberries, laptop computers and wireless devices are overwhelming any one individual's ability to absorb this crushing Tsunami of data.

DARK Daily is a quick-to-read, easy-to-understand alert on some key development in laboratory medicine and laboratory management. It has no counterpart in the lab world. Why? Because it is produced and written by the experts at THE DARK REPORT and The Dark Intelligence Group, who know your world, understand your needs and provide you with concise, processed intelligence on only those topics that are most important to you!

You will find DARK Daily to also be an exceptionally valuable resource in laboratory and pathology management. Some of the lab industry's keenest minds and most effective experts will be offering their knowledge, their insights and their recommendations on winning strategies and management methods. Many of these experts are unknown to most lab directors. As has proven true with THE DARK REPORT for more than a decade, DARK Daily will be your invaluable— and unmatched—resource, giving you access to the knowledge and experience of these accomplished lab industry professionals.

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About The Dark Intelligence Group, Inc. and THE DARK REPORT

"Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner.

The Dark Intelligence Group, Inc., is a unique intelligence service, dedicated to providing high-level business, management and market trend analysis to laboratory CEOs, COOs, CFOs, pathologists and senior-level lab industry executives. Membership is highly-prized by the lab industry's leaders and early adopters. It allows them to share innovations and new knowledge in a confidential, non-competitive manner. This gives them first access to new knowledge, along with the expertise they can tap to keep their laboratory or pathology organization at the razor's edge of top performance.

It offers qualified lab executives, pathologists and industry vendors a rich store of knowledge, expertise and resources that are unavailable elsewhere. Since its founding in 1996, The Dark Intelligence Group and THE DARK REPORT have played in instrumental roles in supporting the success of some of the nation's best-performing, most profitable laboratory organizations.

The Dark Intelligence Group (TDIG) is headquartered in Austin, Texas. This location makes it very accessible for any laboratory organization seeking input, insight and support in developing their business operations, creating effective business strategies and crafting effective sales and marketing programs that consistently generate new volumes of specimens and increasing new profits. The Dark Intelligence Group, Inc. owns and operates two Web sites in the TDIG Website network:

THE DARK REPORT

http://www.DarkReport.com

DARK Daily
Clinical Laboratory and Pathology News/Trends

http://www.DarkDaily.com

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About the *Executive War College on Laboratory and Pathology Management*

Every spring since 1996, the lab industry's best and brightest gather at the *Executive War College on Laboratory and Pathology Management* to learn, to share and to network. Many consider it to be the premier source of innovation and excellence in laboratory and pathology management.

Each year, a carefully selected line-up of laboratory leaders and innovators tell the story of how their laboratories are solving problems, tackling the toughest challenges in lab medicine and seizing opportunities to improve clinical care and boost financial performance. The *Executive War College* is the place to get practical advice and solutions for the toughest lab management challenges. A unique case study format brings participants face-to-face with their most successful peers. They tell, first hand, how their laboratory solved intractable problems and successfully used new technology.

Many lab management secrets are shared, along with specific "what-not-to-do's" gained from hard-won experience! It's not pie-in-the-sky theory, but useful knowledge that can be put to use in any lab. The *Executive War College* offers superlative networking, with lab administrators and pathologists attending from countries as far away as the United Kingdom, Germany, Brazil and Australia. It makes the *Executive War College* a melting pot for all the best ideas, new lab technologies and management strategies now reshaping the laboratory industry. It's also become a recruiting ground used by headhunters and major lab organizations.

In the United Kingdom, The Dark Intelligence Group and the Association of Clinical Biochemists (ACB) have co-produced a meeting every February since 2003. Known at *Frontiers in Laboratory Medicine* (FiLM), it attracts laboratory leaders and innovators in the United Kingdom. Also featuring a case study format, this meeting pioneered the international laboratory side-by-side case study, where a North American laboratory and a United Kingdom laboratory prepare a comparison of best practices and an operational assessment of their two organizations.

In September 2005, a laboratory management meeting called *Executive Edge* was conducted in Toronto, Ontario, Canada, by The Dark Intelligence Group and QSE Consulting. It provided pathologists and lab directors in Canada with a customized meeting devoted to the strategic and operational issues of laboratory management in Canada.

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About Karen Appold

Karen Appold is the owner of Write Now Services, which offers professional writing and editing services. She has extensive experience working for clinical laboratory organizations and publishers. In addition to The Dark Intelligence Group, Inc., she is an editorial consultant to COLA, American Medical Technologists, American Association for Clinical Chemistry, American Society of Clinical Pathology and ADVANCE Newsmagazine's clinical laboratory publications. She is a former staff writer for Clinical Laboratory Management Association and also wrote for Clinical Laboratory Standards Institute.

Ms. Appold is also published in many other health/medical publications, such as Joint Commission Resources' newsletter. She authored a bi-monthly column on practice management and was a correspondent for an international health care journal based in the United Kingdom. She has a BA in English (writing) from Pennsylvania State University and resides in Limerick, PA.

Contact: KarenAppold@comcast.net or 610-948-1961

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Contact Information

The Dark Intelligence Group, Inc.
Customer Service
800-560-6363
21806 Briarcliff Drive
Spicewood, Texas 78669

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