The Evolution of Outpatient Laboratory Benefit Management: Sound Science & Medicine With Appropriate Oversight

By Jeffrey M. Petrizzi, President, Kentmere Healthcare Consulting Corporation

Before 2000, the category of outpatient lab benefit management did not exist. Both concept and category were established by Kentmere Healthcare Consulting Corporation to assist health insurers manage outpatient laboratory testing costs and use as well as improve laboratory service quality and access for members and physicians. As Kentmere continued to define the category, lab benefit management now includes providing effective and ongoing evaluation of new laboratory testing, including genetics, for clinical validity and utility with medical policy guidelines. It also includes measuring performance standards to include member and physician service levels access and turn-around times.

Prior to this initiative, health insurers managed lab benefits and evaluated necessity of testing with guidance from professional societies and evidence-based reports to determine clinical validity. Contracting staff with limited understanding of laboratory processes and management and less on clinical care were responsible for negotiating contracts with labs on behalf of plans. The piecemeal approach prevented a comprehensive overview of benefits management.

With medical and scientific advancement, new testing options grew. From 1950-1974, the number of lab tests performed grew 10-15 percent per year. In the decade following, the use of lab testing doubled. At the time, lab testing was relatively inexpensive. Financial incentives encouraged physicians to order testing. Hospital testing increased nearly 70 percent from 1972-1979. With the increase of available testing, the volume of testing claims increased and reimbursement requests grew rapidly. In addition to the volume of tests, insurers began questioning whether some tests were medically necessary to improve a patient's outcome or whether the tests were experimental or investigative. Further challenging insurers was the difference in state mandates to cover testing, regardless of evidenced value.

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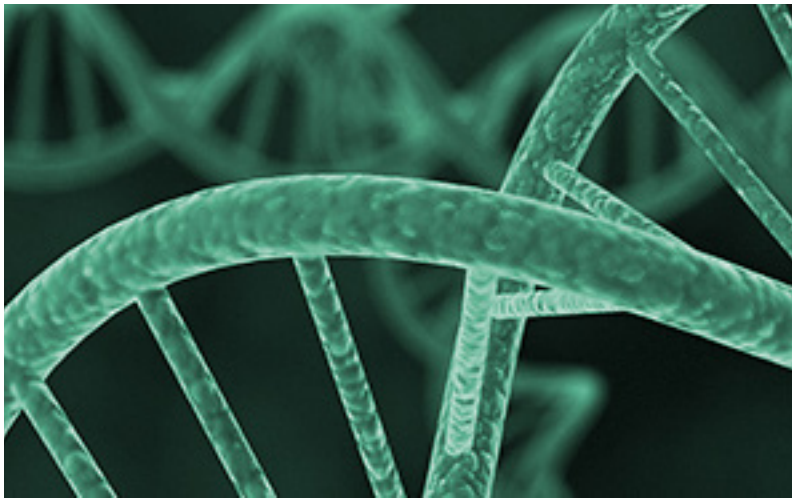
Consumers lack incentive to decline additional testing over concern for health (more information is better) and also because costs seem remote as they are covered by the third party insurer. About $30 billion per year is spent by pharmaceutical companies to advertise their products. Of that, 32 percent is aimed at direct-to-consumer advertising; 68 percent to health care providers. Google reports 70,000 medical searches per minute with one billion searches reported each day.

With an eye toward longevity, consumers are actively collaborating with their healthcare providers to learn more, do more, prevent more to acquire long life. Many times this collaboration involves expanded testing to determine current health and projections on what issues may arise and eventually cause a decline in health. Pew Research reports there are currently 500,000 people living today at or over age 100 and projects 3.7 million over age 100 by 2050.



The advent of innumerable test options for an apparent infinite number of risk factors, diseases, preventions, and treatments as well as human desire to live as long as possible have all added to the complicated benefits administration for health plans. With 7 billion tests performed annually and 66 percent of those tests influencing clinical decisions, wading through historical, current, and prospective protocols has become challenging territory for health plans. Payers have become overwhelmed by the booming diagnostic testing market. There are some 75,000 genomics tests alone with 10 new ones developed each day.

While testing can detect disease, genomic or genetic testing can test for the predisposition to get a disease. Developing through the 1980s, it is now possible to sequence the entire genome – some three billion base pairs of human DNA. Further, it is possible to sequence all three billion in less than 24 hours, simultaneously multiplexing 50-100 genes. Done with a specific purpose, genetics testing can be helpful.

However, physicians advise caution with self-testing and the do-it-yourself home kits such as 23 & Me and Ancestry, among others. These test results present possibilities for disease, not probabilities. The results also present, in many cases, needless worry because they make no distinction in a remote possibility and an infinitesimal probability. So while one may learn of a possibility of developing Alzheimer's or breast and colorectal cancer, or other diseases – something that was a possibility known before such a test – one will not learn how probable or likely it is that the disease will actually develop. These tests are not comprehensive, looking only for limited factors of disease. Indicators from these tests – either as a predictor or an all clear for disease are likely to mean only more laboratory tests conducted in collaboration with a health care provider.

Like any business, health plans operate on a simple model. Insurance profitability is based on premiums collected minus claims and expenses. Estimates of claims liability are anything but simple with insurance companies investing deeply in projecting the health and likely long term health and claims of a beneficiary. The Affordable Care Act limits plans' restrictions such as pre-existing conditions on coverage and increases plans' potential claims liability.

This year, 2020, is unprecedented. COVID-19 has upended everything and created a near perfect storm for outpatient labs as volume was reduced significantly with patients postponing and cancelling doctor visits. Doctors, those who order tests, weren't seeing patients and as a result wrote many fewer test orders. With elective surgeries postponed or cancelled, there has been no need for pre-surgical testing. COVID-19 testing filled the void and then some. With most tests costing $100 per test and 100 percent government reimbursement guidelines, laboratories did well.

Next year, 2021 will be different. The risk of visiting a doctor may no longer be outweighed by potential COVID-19 exposure. Postponing a surgical procedure may no longer outweigh the risk of COVID-19 exposure. Doctors will be back to writing test orders and labs will be back to running them along with ongoing COVID-19 testing. Another difference anticipated for 2021 is COVID-19 testing is likely to be restricted to those with symptoms.

Emerging from this combination of events has been a need for plans to enhance the quality of patient care while keeping costs as low as reasonably achievable. Kentmere was the first to recognize the need for deeply experienced laboratory management professionals to support health plans in navigating the complicated lab benefits management.

By providing the most sophisticated proprietary analytics, database, benchmarking, medical and reimbursement policy guidelines, new test technology evaluation, contracting and network development, its partners recognized initial savings of more than 20 percent per year in actual lab costs. When including trend reduction, cost avoidance or downstream costs, savings were even more.

Kentmere is the only lab benefits management partner that doesn't require major disruptions to health plans, members or providers by forcing health plans to use or integrate outside IT or claim systems. It does not impose medical policies, or require the health plan to give up control of their lab network, or create confusion for physician and members by instituting cumbersome test ordering or prior authorization requirements.

Since the model was established and best in class practices defined, others attempted to offer various segments of lab test management and national laboratories began to generally offer physicians genetic testing options.

Some imaging companies entered the market as an add-on to their existing imaging prior-authorization IT systems. CareCore (now Evicore), an imaging management company, began offering existing clients prior authorization and information on the genetic testing sector. Their subsequent acquisitions of DNA-Direct and MedSolutions added to their genetic testing expertise.

NIA an imaging company owned by Magellan tried to enter the genetic testing market as an add-on service. It was ultimately unsuccessful. At the same time, some of the large consulting firms and other health care consulting companies such as McKinsey and McKesson, among others tried to enter the market. Their offerings were limited in health plan laboratory cost analytics or new test registry.

Following these was another round of efforts to enter the lab benefit management sphere. Beginning with Beacon Lab Systems, a subsidiary of LabCorp, most were heavily funded with massive overhead offering concepts only for certain segments of the category.

In the case of Beacon, it is owned and subsidized by LabCorp, and was modeled as a lab network manager where physicians would order through Beacon and only labs in the Beacon network would be considered. By excluding Quest and remaining exclusive to LabCorp, Beacon was limited to one client – United Healthcare, a customer of LabCorp. Only offered in Florida, Beacon later attempted to install a program in Texas for United Healthcare. However, physicians objected and the initiative was dropped.

Beacon has since been redesigned and recently relaunched as a modified version of the McKesson/Palmetto model. This version requires laboratories to register each test under a unique test code as

McKesson previously did with their proprietary Z codes. Re-launched as a national network that includes LabCorp and Quest and some other regional and specialty labs, it has not yet shown that it will work based on initial push back by some labs and other related groups.

Within a few years after that, Avalon Lab Solutions was formed. Originally conceived and funded by the venture capitalists, Avalon's concept was to use the pharmacy benefit management (PBM) model, owning the lab network and negotiate prices directly with the laboratories.

Pharmacy Benefit Management and Laboratory Benefit Management are apples and oranges different. The margins on pharmaceuticals is considerable with costs largely spent on research, development, testing, and marketing – long before a script is ever written. Once in production the drug cost is miniscule in comparison.

In the lab space, a vendor may differ but the test remains virtually the same. Each test is as individual as is the patient for whom the test was ordered. The costs are recognized in the people who administer and process the test, service, pick-up and delivery, the paperwork associated with processing it. There is only a small percentage of total lab cost in the actual cost of doing the test. For these reasons, efforts to model a LBM as a PBM are not successful.

In the initial concept, Avalon would contract with the health plans and try to control the laboratory network and manage utilization through medical policy and claims edits. Some health plan clients are stockholders of Avalon. The model was based on giving the first health plan or plans equity in Avalon to use them as a beta site. They have since changed their model and product offering by processing claims as a third party administrator and requesting plans to use Avalon's medical polices. Delegating ownership of the network has not proven to be well accepted by many health plans since the health plans remains ultimately responsible for physician and member quality, access and service, and other liabilities. Further, the business model of contracting directly with the labs has resulted in costly flaws in execution. While deep in academic and managed care experience, labs recognize the lack of understanding in commercial lab management. As a result, some labs are declining to participate directly with Avalon, and as a result, have negotiated directly with the health plans. This eliminates some of the lab benefit management third party relationship for which the health plans are paying.

AIM, an imaging company owned by Anthem Blue Cross Blue Shield offered an add-on program for Genetic testing prior-authorization program to its clients like Evicore's.

Other attempts in entering the lab benefit management space have been mostly unsuccessful, had limited impact or done with limited services. These have included genetic counseling companies, utilization management companies, research/database providers and hospital and electronic lab test ordering IT based companies. Those with a heavy leaning in the IT category and a lighter leaning in the commercial lab management have faced technical challenges. Connectivity problems have created workflow disruptions for health plans, labs, and physicians, and is creating operational chaos across the industry.

A lab benefit management company should provide education, designate streamlined cost effective lab networks, review prior authorization requirements, test formularies, coverage policies, conduct utilization reviews and determine medical necessity and conduct claims reviews. The benefits include efficient health plan claim processing, reducing inappropriate test ordering, greater transparency in billing practices, and provide cost savings from using preferred labs. There should be more; Health plans should demand more.

Unlike others, Kentmere goes well beyond preauthorization by forming lab networks that meet cost criteria as well as access and quality. The objective is to focus on clinical cost utility, monitor lab testing quality and improve service to health plans by redirecting business to in-network labs, and manage the lab relationship including monitoring performance standards.

In the last 20 years, the category of laboratory benefits management has evolved. There have been many changes and entry and exit of many different vendors with differing models and distinct results in performance or lack of performance. The space can be confusing but there are several conclusions Kentmere can provide.

First, is that the large overhead, heavily staffed and with expensive IT infrastructure, many lab benefit manager programs are not cost efficient. Much of their fees are derived from savings they allege to provide – much of which could be recognized by a plan using a proper outside laboratory SME consulting help. It is essentially low hanging fruit which does not require a lab benefit manager to obtain.

Companies with years of outside investors are expected to provide a significant return to those investors either through profits from high fees or keeping much of their clients' savings for themselves, and in all likelihood, eventually selling the company. Investors are in the investing business, not lab benefit management. They look for a large return in as short a time as possible or they get out and invest in something else. Their years of going through the learning curve at their clients' and investors' expense is a burden of sunk costs that eventually need to be recovered.

A second conclusion is that the third party administrator and pharmacy benefit manager models are not cost efficient. There are not equal margins in lab tests prices as there are in the drug industry. Also, the lab industry is a service business with at-the-moment costs of a test including processing and performing the test, pickup and delivery, and billing with a very low average cost per patient encounter basis.

Finally, some lab mangers have a very high cost overhead structure with many salaried experts providing information and conclusions of clinical validity and utility of new tests. While accomplished in academic and university settings and managed care, there is a notable lack of experience in the commercial lab industry – a profound knowledge gap. This information is readily available in timely-published literature by many other organizations. The same issues and options are available for medical policy and claim edits for which most health plans are already paying. And claims editing systems when modified at significant cost gain only a small incremental savings.

A partner in the lab benefit management space is more and more a necessity for health plans. Testing is complex and there are more being done every day. While the pendulum seems to be swinging slightly away from consumers demanding tests to predict their future health and treatment for diseases that may be in the pre- stages, it is a category difficult to navigate in a way that is responsible to the plan and those within their responsibility. It is high stakes for all involved. Based on two decades leading the category, here are Kentmere's Conclusions on how health plans should engage with a laboratory benefits management partner.

Kentmere Conclusions

K1: Before looking at a third party administrator or a claims-based editing lab manger, before overhauling medical polices and creating physician and member disruption, bring in a full-service lab subject matter expert with a lab benefit management program. Assure their use of correct lab industry analytics, plan benchmarks, and to have analyzed the lab network, medical, and reimbursement policies. Once you have determined where you are and where you should be in the future, implement the LBMP customized specifically for your plan not an off the rack one size fits all offering.

K2: Before meeting with a LBM call their independent references. Independent references have no stock, company options, or any direct or indirect relationship with the ownership of the LBM company. Ask the independent references to validate actual savings and ROI, not trend reduction cost avoidance.

K3: Ask the lab manager vendor to show you what laboratory performance standards and guarantees they have in actual contracts they have previously negotiated.

K4: Define what the lab manager promised ROI is expected to be and how soon will you see it?

K5: And while everything is fine until it isn't, create an exit clause so you may exit without penalty in the event commitments are not met.

There have been some health plans disappointed in the poor results from trying various iterations of lab management programs that didn't work or have been modified numerous times by choosing the wrong plan. Some are even stuck with costly programs for years to come that cost more than they save. There is a reason Kentmere created the category, defined a best in practice model, and has acquired 20 years of independent experience in lab benefit management. https://www.kentmerehealth.com/