LAB TREND REPORT 2021

from Avalon Healthcare Solutions, 2021

avalon

CONTENTS

FROM THE DESK OF BILL KERR, MD 4

FROM THE DESK OF JASON E. BUSH, PH.D. 6

LESSONS LEARNED FROM THE COVID-19 PUBLIC HEALTH EMERGENCY 7

- Uncertainty Produced by the Federal Government 7
  - Different Types of COVID-19 Testing 7
  - Reimbursement of Testing 9
  - Changes in Response to the Market and Science 10
- Avalon's Immediate Responses to COVID-19 11
- A Call to Arms - Avalon's Continuing Response 12

IMPORTANT FORCES AFFECTING THE LAB INDUSTRY AND HEALTH PLANS 12

- Reimbursement 12
  - Trends by Place of Service 14
- Molecular Diagnostics (MDx) and Genetic Testing 16
- Hospital-based Outpatient Lab Testing 17

AVALON'S LBM SERVICES MANAGE VOLUME AND ACCESS 17

- Health Plan Adoption of Laboratory Policies 18
- Compliance Through Automated Policy Enforcement 18
- Compliance Through Prior Authorization 18
- New Policies Introduced in 2020 19
- Trend Management Experienced by Avalon's Clients 20
  - Aggregate Allowed and Unit Trends 20

IMPACT OF AVALON'S PROGRAMS 21

- Policy Enforcement and Prior Authorization – Avalon's Approach to Savings 21
- Utilization Management From Policy Enforcement 23
- Utilization Management From Prior Authorization 24

A LABORATORIAN'S PERSPECTIVE – A MESSAGE FROM AVALON'S CLINICAL ADVISORY BOARD 24

AVALON'S VALUE-BASED CARE FOCUSED EVOLUTION 26

- Early Identification 27
- Evaluation of Treating Physician Behavior 28
- Production of Decision Support Recommendations 30

FROM THE DESK OF BARRY DAVIS 32

CONTENTS (continued)

ACKNOWLEDGEMENTS 33

APPENDIX 33

Description of the Population 33

Glossary 33

ENDNOTES 34

FIGURES AND TABLES

Figure 1: Monthly Distribution of COVID-19 Tests, by Type* 8

Figure 2: Growth in COVID-19 Testing, Relative to Utilization in April 2020 9

Figure 3: Percentage Change in Paid Units PMPM by Place of Service, Relative to 2018 14

Figure 4: Percentage Difference in Average Allowed Payments From Independent Labs for 2020's Top 10 Procedure Codes by Unit Volume 15

Figure 5: Percentage Change in Average Cost per Unit by Test Type, Year, and Place of Service, Relative to Tests Rendered by Independent Labs 15

Figure 6: Percentage Change in Monthly Allowed Payments PMPM, Relative to January 2018 20

Figure 7: Percentage Change in Monthly Paid Units PMPM, Relative to January 2018 21

Figure 8: Units Per Patient by Month 21

Figure 9: Percentage Change From 2019 to 2020, Units of Utilization Decreased, Allowed PMPM Decreased, COVID-19 Increased Allowed PMPM 22

Figure 10: Percentage Change in Monthly Allowed Payments PMPM From January 2018, by Managed Code Status 23

Figure 11: Percentage Change in Monthly Units Without Clinical Utility Relative to January 2020, by Place of Service 23

Figure 12: % Change in Monthly Averted Costs Relative to January 2020, by Place of Service 23

Table 1: Top 5 Codes Determined to be Non-Compliant by Prior Authorization 24

Table 2: Top 5 Codes Approved by Prior Authorization 24

Figure 13: Distribution of Patients by Stage of Chronic Kidney Disease at Time of Diagnosis 28

Figure 14: The Role of Avalon, the Lab, and the Physician in Diagnosing Breast Cancer 29

Figure 15: Evaluating Provider Performance Using Process Versus Outcome Measures 30

From the desk of

BILL KERR, MD

CEO, AVALON

Lab test results guide approximately 70% of patient treatment decisions and have played a critical role in clinical decision-making for decades. Most people take lab testing for granted as it seems straightforward—the lab receives a specimen and then provides a yes or no answer. The COVID-19 pandemic publicly illuminated the complexity of lab testing, as lab-related issues were often headline news. People outside of the lab industry started to ask:

- What test provides accurate results?
- Who can perform the test?
- How is the specimen collected?
- How long should it take to get the result?
- How often should it be repeated?
- How much should it cost?
- What is a false negative/positive?

Never before has laboratory testing received attention like this. Every day false positives and negatives materially impact a patient's quality of life.

Over the past two decades, scientific developments have led to an explosion in our ability to measure components of the human body. While advances in our ability to measure DNA have received the most attention, additionally we can now measure more chemicals in body fluids, stain more tissues, attach more antibodies to cell surfaces, and break down components into more building blocks than ever before. Many of these developments are not yet relevant to patient care, but some new testing is profoundly relevant. Keeping up with what can be measured, when it is relevant, how to interpret the results, and how much the test should cost has proven to be too great a challenge for physicians, health plans, and certainly those of us looking to manage our own health.

Lab testing plays a key role in influencing the trajectory of patient care across medical specialties. While at the unit level, lab test prices are often lower than other health services, these unit prices represent only the direct costs associated with lab testing. Overall, lab tests drive 70% of medical treatment decisions, and have a disproportionate impact on spending throughout the care continuum.

Avalon was built to address the ever-growing complexity of the lab industry. Our true north is the science of lab testing. Our core competency is translating that science into the marketplace to identify: which tests make a difference under what circumstances; which lab should perform which test; what should be done with the result; and how much should that test cost.

please continue...

Our programs not only operate at the individual physician-patient-lab level, but also scale to operate at the population level. Thus, Avalon's offerings address the needs of health plans and health systems serving populations.

Each year, Avalon accrues additional specialized knowledge and data on how lab medicine impacts other areas of medicine. For just a few examples, analyzing data from our clients has provided us insights into the following: diabetes and chronic kidney disease management, a more nuanced understanding of how genetic variants impact the efficacy of specialty pharmaceuticals, and innovative means of measuring healthcare providers' compliance with best practices. Avalon has amassed a proprietary database of information from which insights can be extracted concerning laboratory behavior, insurance trends, and population health. This database works across health plans, in and out of network providers, contracted amounts, and laboratory values. No other company has as comprehensive a lab database as Avalon.

In response to the increased public attention to lab medicine, Avalon is leveraging its unique insights—derived from intelligent mining of this database—to publish the first Lab Trend Report. Due to its great breadth, Avalon can witness trends more comprehensively than is possible at any single lab or health plan. I am proud of the work Avalon has performed over the years, but never more so than over the last eighteen months; I am thrilled to share the findings we have made to date.

From the desk of

JASON E. BUSH, Ph.D.

CHIEF DATA OFFICER, AVALON

This inaugural Lab Trend Report reviews the recent past and market dynamics to identify emerging trends of importance to healthcare executives. Briefly, a review of lessons learned from the COVID-19 pandemic and changes in the factors facing laboratories provides a glimpse into changing market trends. The Chair of Avalon's Clinical Advisory Board shares insight into the challenges facing labs from a laboratorian perspective. Finally, a brief discussion follows of Avalon's observations of the trends in health plans' claims data, the impact of Avalon's programs, and a preview of the role of laboratory values in realizing the promise of patient-centric, value-based care. Overall, the following three trends are the most pertinent to healthcare executives.

Avalon's core products assist plans to manage overall outpatient spend.

Spend will increase. A combination of the mix of lab services utilized, the mix of sites in which lab services are performed, pricing, and utilization thereof all drive overall outpatient lab spend. The pandemic reduced overall utilization, yet the PMPM increased due to changes in the mix of services and increased fee schedules. Additionally, PAMA has materially decreased independent laboratories' appetite to offer unit price discounts while simultaneously increasing the unit prices of advanced genetic and esoteric tests. Furthermore, hospitals continue to purchase physician practices and direct office testing toward core laboratories at significantly higher fee schedules. The explosion of scientific capabilities continues to produce significant new genetic tests resulting in more options for treating physicians. As many of these tests have few substitutes, they garner premium prices. A post-pandemic rebound in demand for lab services combined with the above trends will likely increase PMPM and overall spend dramatically.

Recognizing the need to increase coordination among payers, the government, and laboratories. COVID-19 demonstrated that the current set of relationships between healthcare providers, legislators, regulatory agencies, and labs is inadequate to address a pandemic. Frequent and rapid changes in science, reimbursement, and regulations collectively produced confusion and uncertainty. There continue to be additional changes, as there are adjustments being made to federal regulations covering prior authorization.

Measuring outcomes. Evolving from ACOs, many health plans are increasing their focus on alternative payment models which tie payment to better health outcomes for patients. Some health plans are stating that over 50% of their membership is under an alternative payment model. In place of implementing process-based measures of quality using administrative claims data, health plans working with Avalon can access lab values to increase the efficacy of these programs by accurately representing patients' healthcare trajectories over time.

Avalon's access to lab data combined with lab experience provides a powerful platform for analytics and the realization of patient-centered, value-based care.

LESSONS LEARNED FROM THE COVID-19 PUBLIC HEALTH EMERGENCY

The COVID-19 public health emergency moved lab testing to the forefront of the minds of the public and government leaders. Federal, state, and local regulators set lab-test-related thresholds for allowing schools to offer in-person learning and for permitting various forms of businesses to operate. While lab testing took a more central role in public life, the regulatory environment surrounding COVID-19 created additional challenges, rather than clarity. The rapid evolution of the science further added to the dynamism of the situation. Avalon helped clients address these challenges through a series of immediate actions, while simultaneously coordinating a longer-term response to better address similar situations should they arise in the future. The challenges posed by developing and scaling testing for a novel pathogen, and the disjointed response, brought to light issues that have long plagued the lab industry. Labs need to pre-emptively coordinate with the government and health plans to ensure that they will be better able to address future pathogens or variants of COVID-19.

Uncertainty Produced by the Federal Government

Labs, health plans, and citizens alike sought guidance from the federal government in answering three questions:

- Which lab tests have the government authorized for the detection of COVID-19?
- Who will pay for the costs associated with the lab tests?
- How much will labs be reimbursed for performing the testing?

Various functions of the government are responsible for answering each of these questions. Labs, health plans, and diagnostics companies faced added adversity during the pandemic, as the answers to each of these questions changed repeatedly. Due to the evolution of the scientific evidence, the lab tests available, and the regulations surrounding those tests, labs made several pivots during the first year of the pandemic. While different bodies of the government each worked to increase physical and financial access to testing, changes were made in a rapid and often uncoordinated fashion.

Different Types of COVID-19 Testing

Initially, there were no tests on the market with regulatory approval that clinicians could use to detect COVID-19. On February 5th, 2020, the Centers for Disease Control and Prevention (CDC) sent out COVID-19 test kits that it had developed, which soon were determined to have faulty negative controls caused by contaminated reagents. The Food and Drug Administration (FDA) initially prevented commercial and state labs from developing their own COVID-19 diagnostics, requiring them to instead use the one developed by the CDC. After the problems with the CDC's diagnostic became apparent, the FDA reversed course on February 29th, 2020.[1]

> Missteps by the CDC and confusion on approval pathways for new tests combined to confuse providers and insurance companies.

Although not required by the FDA to do so, labs could seek Emergency Use Authorization (EUA) for their laboratory-developed tests (LDTs), as an EUA provides labs Public Readiness and Emergency Preparedness (PREP) Act coverage, which shields them from lawsuits related to tests that they have developed.[2] Further confusion was added to the marketplace when the FDA declared in October of 2020 that it would no longer review EUA submissions in order to improve the use of organizational resources.[3] A month later, the United States Department of Health & Human Services (HHS) directed the FDA to reverse course and to review EUAs in a timely manner. The degree of regulatory uncertainty highlighted the importance, going forward, of the government cooperating more closely with labs and health plans in addressing public health emergencies.

Changes in the types of testing were occurring as labs introduced new tests to the market. Initially, only one form of testing was available, but once labs developed additional tests and regulators approved them, three categories of COVID-related tests became available:

1. **Molecular tests**, such as those utilizing a Polymerase Chain Reaction (PCR), detect the presence of RNA from SARS-CoV-2, the virus causing COVID-19. These tests are the most accurate but take hours or days to produce findings.
2. **Antigen tests** detect the presence of surface protein fragments of the virus. These tests can yield results in under an hour but are more likely to produce false negatives than molecular tests.
3. **Antibody tests** detect the presence of immune response to a past COVID-19 infection. While these tests aid in determining the seroprevalence of an infection in a population, they are unsuitable for workplace safety initiatives, as they are unable to provide insights into whether a person has an active infection at the time of the test.[4]

In March of 2020, only PCR-based molecular tests were available for the detection of COVID-19 infections. The number of tests conducted grew thousands-fold within only a matter of weeks. Furthermore, the mix of the types of tests conducted changed dramatically from month to month. As Figure 1 depicts, antibody tests first occurred in significant volumes in May. Meanwhile, antigen tests became available in July and experienced growth in utilization throughout the remainder of the year. Nonetheless, some labs hesitated to adopt antigen tests due to concerns over their accuracy relative to molecular tests. Testing volume did not trend steadily upwards.

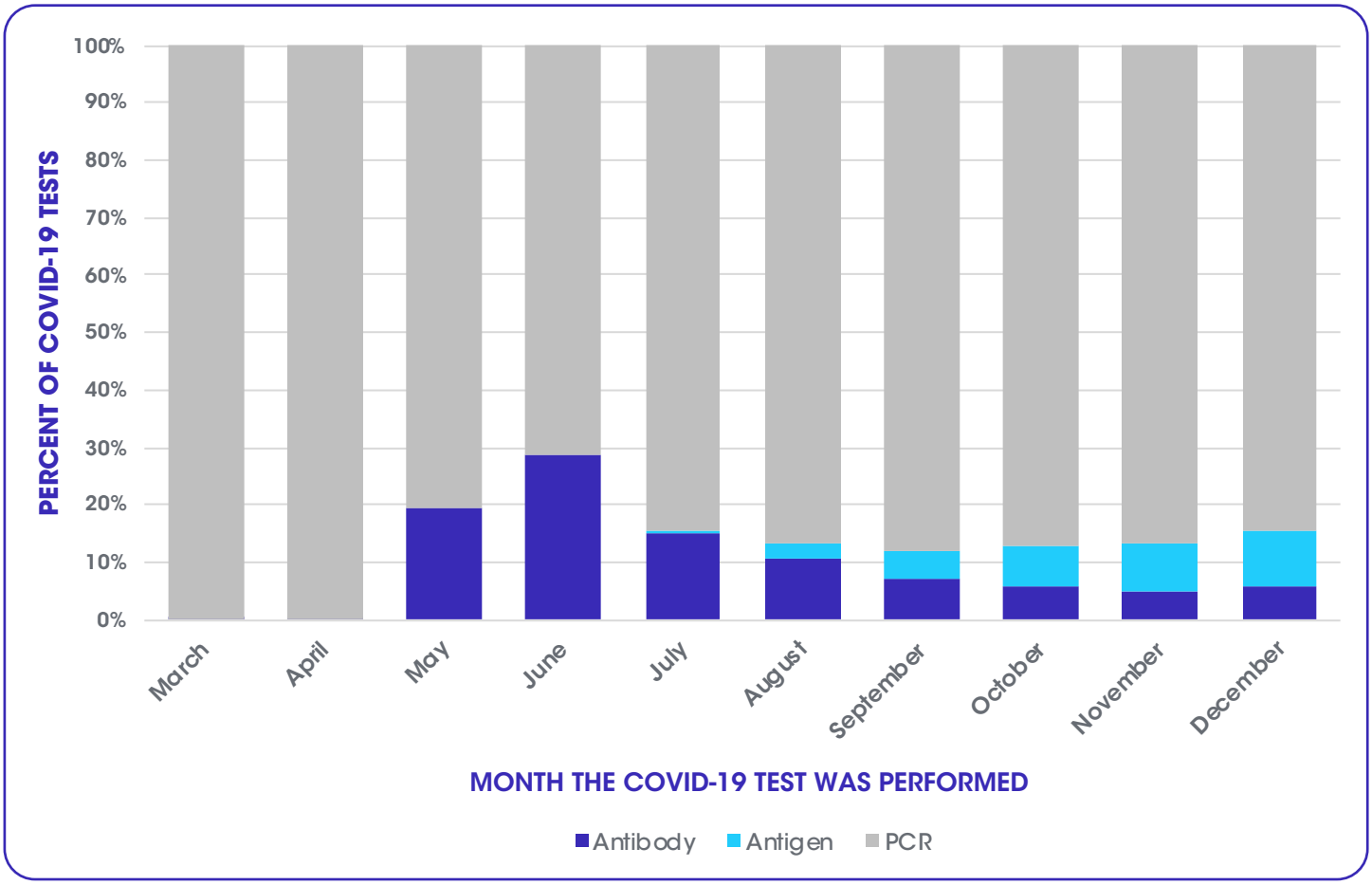

Figure 1: Monthly Distribution of COVID-19 Tests, by Type*

* The data shown reflect only testing billed through insurance companies that are Avalon clients. There was additional testing conducted at county and state testing sites which labs did not bill to insurance companies. Furthermore, some testing sites completely switched from PCR to antigen testing over the course of the year.

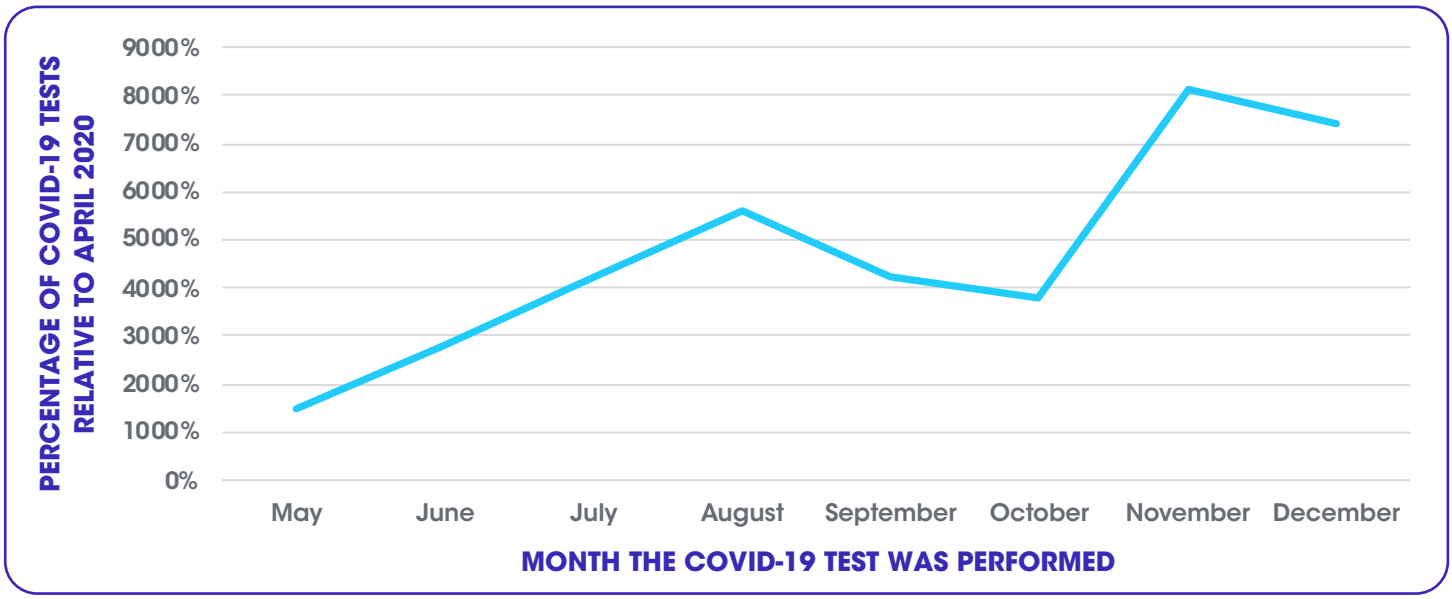

Figure 2: Growth in COVID-19 Testing, Relative to Utilization in April 2020

Figure 2 reveals that there was a dip in COVID-19 testing in the fall of 2020, as the decreased prevalence of COVID-19 during the early fall led to less testing.[5] Testing rebounded during the winter holidays as case counts grew.

Reimbursement of Testing

There was an unprecedented degree of political willingness to at least partially socialize the costs associated with COVID-19 testing and treatment. As a result, new legislation became law, and new regulations and sub-regulatory administrative guidance altered coverage and reimbursement policy surrounding lab testing. These dynamic and regulatory requirements were revised and refined as the pandemic progressed. Health plans had to rapidly modify their coverage policies in response to two new laws:

- **Families First Coronavirus Response Act (FFCRA)** (March 18, 2020): required health plans—public and private—to cover COVID-19 testing without any cost sharing. Sections 6001 through 6004 of the FFCRA stated that testing could not be subject to a deductible, coinsurance, or copayment. The act additionally required that health plans cover other items and services related to COVID-19 testing without cost sharing.[6] The government likewise prohibited health plans from imposing prior authorization requirements on COVID-19 testing.[7]

> Rapidly produced legislation designed to increase access to testing produced significant uncertainty regarding insurance coverage, i.e., which services were reimbursable and under what conditions.

- **Coronavirus Aid, Relief, and Economic Security (CARES) Act** (March 27, 2020): modified the FFCRA to broaden the range of diagnostics and services that the government required health plans to cover. The CARES Act also required health plans to reimburse labs performing COVID-19 diagnostics at either negotiated rates, or in the absence of such a rate, at the cash price for the diagnostic listed on the lab's website.[8]

These statutory changes were designed to increase access to COVID-19 testing. However, since the law provided favorable reimbursement for uninsured patients with a COVID-19 diagnosis and eliminated certain out-of-pocket expenditures for insured patients with a COVID-19 diagnosis, this resulted in the unfortunate side effect of incentivizing the inclusion of as much care as possible to COVID-19 diagnoses. The FFCRA and CARES Acts then created the Health Resources & Services Administration (HRSA) COVID-19 Uninsured Program, which offers

Statutory mandates on reimbursement and coverage provided incentives to increase the number of services bundled with COVID-19 claims.

New methods for detection and evaluation of potential abuse and waste were required.

healthcare providers Medicare-level reimbursement rates for delivering testing and treatment to individuals with COVID-19 listed as their primary diagnosis. Coverage under the program is wide-reaching, and includes everything from testing, to inpatient care, to long-term acute care.[9]

Mirroring the inconsistency that surrounded the approval of new tests, the Centers for Medicare & Medicaid Services (CMS) repeatedly modified the fee schedules associated with COVID-19 testing. For high throughput COVID-19 diagnostic tests, CMS increased Medicare payments to labs from approximately $51 to $100 per test in April of 2020. Since January of 2021, Medicare's base payment for high throughput COVID-19 diagnostic tests has been reduced to $75, with labs eligible to bill a $25 add-on payment code (U0005) if: one, they complete the test in two calendar days or less; and two, complete most of their COVID-19 diagnostic tests that use high throughput technology in two calendar days or less for all their patients (both Medicare and non-Medicare).[10]

Changes in Response to the Market and Science

The government's response to the COVID-19 pandemic highlighted the need for health plans to implement several changes going forward. Namely, health plans will increasingly need to: (a) offer broad networks, (b) have the capability to rapidly assimilate scientific developments, and (c) be able to quickly deploy evidence-based lab policies. Although COVID-19 highlighted the need for health plans to maintain these capabilities, the potential for government-led creation of additional mandatory benefits and the proliferation of new lab-developed tests will make these capabilities even more essential in the years ahead.

Limitations in COVID-19 capacity necessitated broad networks to increase access to testing for their members. Broad networks with corresponding effective management and oversight increase access to care and member satisfaction.

As previously discussed, the government—seeking to provide broad access—required health plans to offer COVID-19 testing as a covered benefit without member cost sharing. Furthermore, the government required health plans to provide coverage for tests performed at out-of-network labs at their advertised rates unless another rate was negotiated between the plan and the lab. In response to the opportunity for price gouging that the government's actions created, some labs offered COVID-19 testing at list prices with exceptionally high profit margins. Health plans with broad lab networks were at a strategic advantage, as they had more ability to contain the cost of the COVID-19 testing that their members received.

The new COVID-19 tests brought new science as well as new confusion on indications for use to the marketplace.

As diagnostics companies rapidly brought new innovations to market, health plans faced two challenges: one, determining how they should message these market developments to their members; and two, ascertaining which tests the government required them to cover. Coverage requirements rapidly evolved. For instance, on June 23rd, 2020, the U.S. Department(s) of Labor, Health and Human Services, and the Treasury jointly released guidance stating that health plans did not have to cover testing performed for back-

to-school or back-to-work purposes, eliminating the burden that health plans potentially faced from this repetitive testing.[11] However, a coding convention was not created to differentiate between testing for these uncovered screening purposes versus covered diagnostic purposes, further adding to health plans' difficulty in determining which claims they were obligated to pay.

Likewise, when antibody tests became available, it was not immediately clear whether they would play a key role in managing COVID-19. The American Medical Association released guidance that positive antibody tests do not indicate individuals' immunity to COVID-19, severely limiting their utility.[12] While the government initially indicated that health plans were required to cover antibody tests, the aforementioned June 23rd government guidance clarified that the law did not require health plans to cover antibody tests.[13]

In response to the proliferation of new tests, health plans had to adapt their coverage policies frequently. While health plans must cover diagnostic testing for COVID-19, the law does not require them to pay for any test that labs may bill, no matter how vaguely connected to COVID-19. As there were numerous tests introduced and many potential codes that labs could bill, Avalon created an evidence-based policy for coronavirus testing in the outpatient setting that health plans could potentially adopt to navigate the changes.

Avalon's Immediate Responses to COVID-19

To help clients manage the changes brought about by COVID-19, Avalon took a series of actions both internally and externally. Internal actions related to policy development, while external actions consisted of direct client education and indirect influencing of public policy. Avalon developed a 56-page, science-based policy—"Coronavirus Testing in the Outpatient Setting"—for health plans to consider for adoption. Consistent with the FFCRA which prohibits prior authorization in this context, the document describes which CPT and HCPCS codes that health plans do and do not cover.

To foster clients' understanding of policy issues, trends, and lab performance, since March of 2020

As a service to our clients and the larger community, from the early stages of the pandemic Avalon provided information on laboratory capacity, turnaround times, and challenges, as well as the impact of statutory and regulatory changes promulgated by the federal government.

Avalon produced and updated a COVID-19 policy throughout the year as science and understanding of the disease and testing changed.

Avalon has held COVID-related seminars and issued ongoing bulletins with the latest information on statutory and regulatory changes, coding, coverage requirements, science, and lab testing capacity. Lab turnaround time for both molecular and antibody testing has been a regular feature in the reports, enabling clients to gain a better understanding of the actionability of the results delivered to physicians by specific labs. The reports have additionally contained insights gleaned from Avalon's proprietary data, providing information not available from other sources.

Avalon's library of webinars and bulletins during the COVID-19 pandemic can be found online.

Avalon's COVID-19 efforts have helped inform the public and the government. In addition to providing clients with policy updates, Avalon has provided advice to federal legislators to better shape policy—both virtually and through written letters. In doing so, Avalon has worked to protect the interests of its clients which the government required to absorb costs associated with COVID-19 that their actuaries could never have anticipated when setting premiums.

A Call to Arms - Avalon's Continuing Response

There can be no question that Avalon took an immediate and aggressive series of actions to help clients navigate the concerns that they faced in 2020. But by the end of the year, it was clear that the industry needed new approaches to managing the uncertainty and lack of coordination between government, industry, and insurance companies surrounding COVID-19 related policies and practices. Both the variety of tests available and the science supporting testing are growing at an unprecedented rate, and health plans need systematic ways of addressing these rapid changes.

A new perspective consisting of representatives from the government, health plans, and labs would enable unprecedented communication and collaboration so that all stakeholders impacted by testing have a forum to discuss the implications, assess consequences of policy changes, and educate lawmakers before the government drafts legislation. By coordinating responses to technological and regulatory changes, the stakeholders in the industry will be able to operate with greater clarity and be able to reduce the frequency with which the government needs to revise policies. Using the lessons learned from helping clients manage the evolution of COVID-19 testing, Avalon is working towards enabling the industry to handle change in a more proactive fashion.

IMPORTANT FORCES AFFECTING THE LAB INDUSTRY AND HEALTH PLANS

Changes brought about by COVID-19 were but one component of the multitude of changes that labs underwent over the past several years. Regulatory change impacted how payers reimburse labs, which in turn has caused them to rethink pricing and contracting strategies. The proliferation of genetic testing increased costs associated with labs and instigated the growth in use of hard to manage miscellaneous procedure codes for billing purposes. With hospital labs costing 2x-3x that of independent labs has led to increased payer awareness of the role of place of service in determining costs, and in turn, has driven payers to direct members to lower-cost labs. The changes in how lab reimbursement occurs have collectively impacted the trends that Avalon's clients have recently experienced.

> Coding is unable to keep pace.
>
> In 2020, 68 new procedure codes were issued for genetic tests, while 4,781 new genetic tests were registered with the Genetic Testing Registry.

Reimbursement

The Protecting Access to Medicare Act (PAMA)[14] has had a complex impact on reimbursement in both intended and unintended ways. While the direct objective is to reduce reimbursement for some lab tests over time, strategic responses by laboratories to the law have in some instances resulted in increased reimbursements for laboratory tests. Likewise, strategic responses to PAMA have altered the landscape of the industry and have driven opportunistic merger and acquisition activity.

Under PAMA, the Clinical Laboratory Fee Schedule (CLFS) is set by using the weighted median private payer rate for each test as the fee schedule payment rate.[15] CMS periodically collects and uses payment data to update the fee schedule. Each year, CMS modifies reimbursement for each test by an amount up to a predesignated cap, taking market rates into consideration. The cap varies by year and has not been set to exceed 15% through 2024.[16]

Despite the reduction in reimbursement facilitated by PAMA, Medicare lab spending has continued to grow. Overall Medicare lab expenditures increased from $7.13 billion in 2017, before the per-unit reductions, to $7.59 billion in 2018 and $7.68 billion in 2019, after CMS implemented a 10% reduction cap.[17] Increased spending on genetic and other costly tests drove the growth in expenditures

those years, which more than offset reductions in expenditures on other testing. While overall Medicare lab expenditures increased by $550 million from 2017 to 2019, Medicare expenditures on genetic testing increased by $890 million during this period. Among the twenty-five most utilized tests in 2019, seventeen had payment reductions. In aggregate, these payment reductions led to savings of $175 million on these seventeen highly utilized tests. The $173 million increase in expenditures on molecular pathology procedure level 9 (81408) tests alone nearly entirely offset these savings.[17]

The unit prices and mix of services drive overall spend. Despite reductions in fee schedules, increases in availability and use of genetic tests nearly eliminated the impact of CMS price reductions.

Since 2018, Avalon's clients have seen a net reduction in genetic test spending.

Medicare data demonstrates the accelerated historical growth of genetic testing. Avalon's clients have witnessed relatively flat PMPM expenditures for genetic testing attributable to Avalon's utilization management programs. Effectively, health plans need to have a robust solution in place to address genetic and non-genetic outpatient spend.

A significant increase in 2020 Allowed PMPM is attributable to the unprecedented volume of COVID-19 tests.

In addition to directly impacting reimbursement of tests on the CLFS, PAMA has influenced the types of tests that laboratories offer. CMS provides Advanced Diagnostic Laboratory Tests (ADLTs)—tests only offered by a single laboratory and not sold for use by other laboratories—much greater latitude in their pricing than the Clinical Laboratory Diagnostic Tests (CLDTs).[18] Namely, CMS will pay laboratories their list charges when they bring ADLTs to market, and then will only recoup excess payments if the list charges are determined to be more than 130% of market-based rates for similar tests. After CMS has collected market-based pricing data, CMS uses the data to add the ADLT to the CLFS. The nature of this process provides a disincentive for labs to discount the pricing of their ADLTs when contracting with payers, as CMS will use their historic pricing as the basis for their CLFS payments. Further, setting above-market rates enables them to maximize revenue during the initial period when CMS will pay up to 130% of the market rate for similar tests.

PAMA produced less appetite for clinical labs to offer unit price discounts as well as unrestricted pricing of novel esoteric and genetic tests resulting in an overall increase in unmanaged lab spend.

Since PAMA indexes to market rates, if a lab achieves a high reimbursement and does not discount, PAMA rules will not reduce the test's price. For instance, CMS has not discounted Cologuard (81528) for colon cancer screening and Oncotype (81519) for breast cancer screening under PAMA. To the contrary, Oncotype received a price increase from CMS in 2019, and commercial health plans reimburse it at 105% of the CMS fee. Consequently, PAMA may influence lab discounting behavior, with the consequence being to increase prices for commercial plans. Facing these potential payment reductions, larger laboratories may become less willing to entertain unit pricing discounts. Therefore, two types of health plans will likely continue to receive discounts:

1. Plans from large, national managed care organizations with substantial market power
2. Plans in regions where independent labs are successful in leveraging price transparency to drive members toward lower cost providers

Redirecting members to lower-cost sites of service will likely play a key role in controlling expenditures

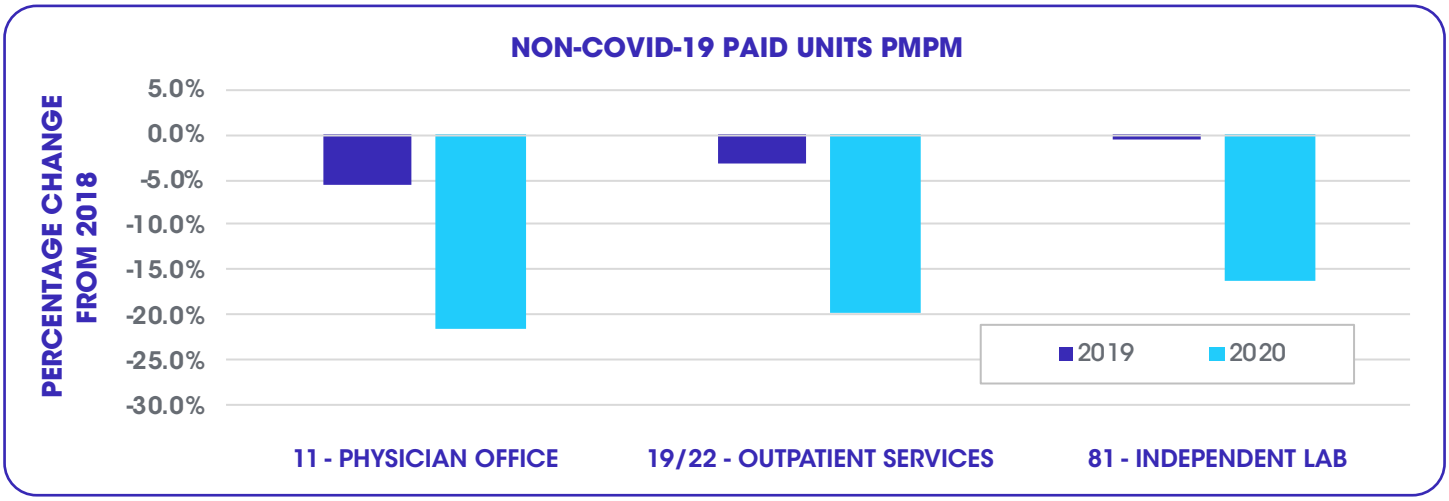

Figure 3: Percentage Change in Paid Units PMPM by Place of Service, Relative to 2018

in the years ahead. The second most common place of service for a laboratory test in 2017 was a hospital outpatient and outreach laboratory setting, which accounted for 36% of testing volume, while independent labs accounted for 48% and physician office labs accounted for 15%, and other sites of service accounted for the remainder.[19] As health plan members frequently receive their lab tests in hospital labs (that cost 2-3x more compared to independent labs), there remains great potential to reduce laboratory expenditures by redirecting members to lower-cost independent labs.

Trends by Place of Service

Avalon's trend charts examining claims by place of service help illustrate how PAMA, COVID-19, Avalon's programs, and payer policies have impacted where members receive labs. Compared to 2018, unit reduction in PMPM indicate that in 2019, testing migrated from physician and hospital settings toward independent laboratories. The number of paid units PMPM were not higher in any setting in 2020 than they were in 2018, primarily due to the overall reduction in testing attributable to COVID-19.

There has been a growing effort by payers to redirect members towards independent labs, and away from outpatient hospital labs. As shown in Figure 4, the cost of performing labs in an outpatient services setting is several times higher than doing so in an independent lab setting for several popular tests. The average unit cost of eight of the ten most ordered tests was also higher if the test happened in a hospital outpatient setting, rather than an independent laboratory or physician office setting.

> A lipid panel test at a hospital outpatient lab may cost 3000% of the price at an independent laboratory.

Similarly, when we examined the average cost per unit, by year and test type, the cost per unit for services performed in outpatient services settings were dramatically higher than those for services performed in independent lab settings (Figure 5). The unit cost of organ- or disease-oriented panels, as well as therapeutic drug/drug assays performed in outpatient services settings, markedly increased in 2020 relative to the unit cost of such tests performed in independent laboratory settings. While tests performed in an outpatient services setting were more expensive on a per-unit basis than tests performed in an independent laboratory setting in 2019 as well, the size of the difference became more marked over time.

Costs were markedly higher for tests rendered in an outpatient services setting. Incredibly, lipid panels (80061) on a per-unit basis had an outpatient services price in 2019 that were over 3,000% of the price for lipid panels performed in independent labs. These stark cost differences are a concern for payers, and are a key factor driving payer policies to redirect patients toward more affordable places of service.

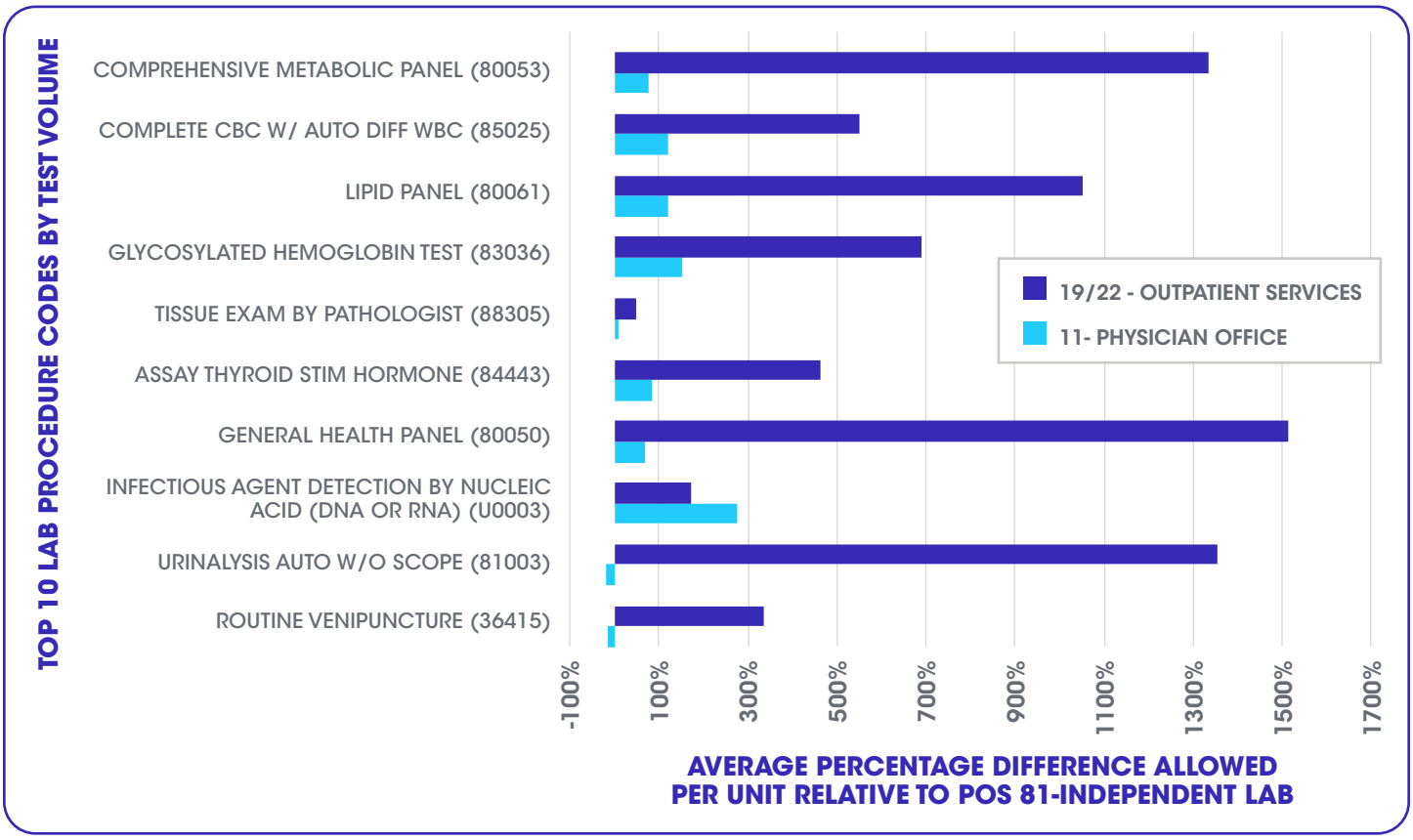

Figure 4: Percentage Difference in Average Allowed Payments From Independent Labs for 2020's Top 10 Procedure Codes by Unit Volume

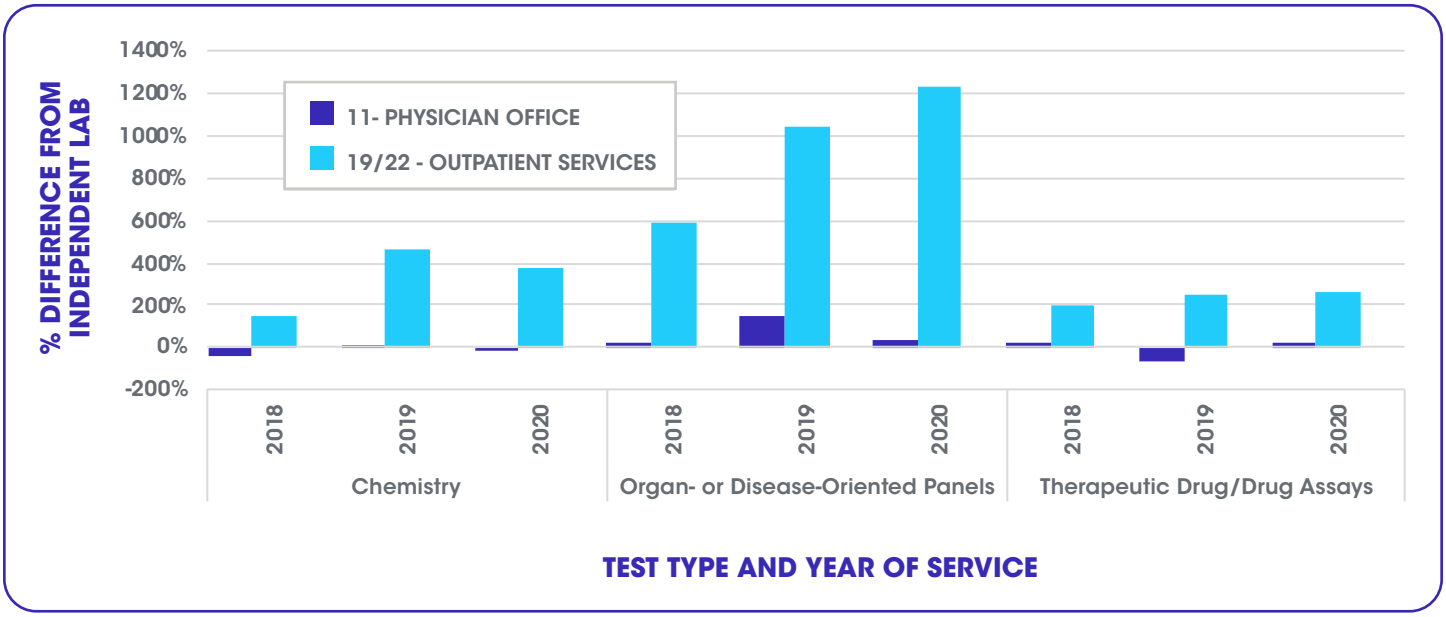

Figure 5: Percentage Change in Average Cost per Unit by Test Type, Year, and Place of Service, Relative to Tests Rendered by Independent Labs

Molecular Diagnostics (MDx) and Genetic Testing

Although they only accounted for 11% of Medicare laboratory testing expenditures in 2015, as a consequence of the substantial financial pressure placed upon CDLTs, the recent goldrush for laboratories has been in the molecular diagnostics (MDx) space.[20] National spending on molecular oncology testing increased from $708 million in 2010 to over $3 billion ($3,037 million, for comparison) in 2017—a compound annual growth rate of 23%.[21] Likewise, Medicare spending on genetic testing has nearly tripled from 2017 to 2019, going from $473 million to $1.36 billion during that span.[22] According to total 2017 allowed charges, the top three defined molecular pathology tests were Cologuard (CPT 81528), Oncotype (CPT 81519), and BRCA 1 & 2 full sequence analysis (CPT 81162). The top three molecular pathology tests in 2020 among Avalon's clients were fetal chromosomal aneuploidy (81420), Cologuard, and cystic fibrosis carrier screening (81220).

Molecular diagnostics are growing at a 23% compounded annual growth rate.

As many of the molecular oncology tests that labs bill to Medicare do not have dedicated CPT codes, the molecular oncology CPT code with the second highest allowed charges in 2017 ($116 million) was "unlisted molecular pathology procedure" (81479)—a CPT code that accounted for a mere $4M in allowed charges in 2013.[23] Since this single CPT code could describe hundreds of different tests, there are high administrative costs associated with processing it which health plans must absorb. As these tests are expensive, complex, and increasingly common, there is a need for an automated approach to pre-certifying them.

Procedure code 81479—unlisted molecular pathology procedure—grew from $4M to $116M in CMS spend in only four years. Many novel genetic tests utilize this procedure code.

Health plans face several challenges when paying for MDx and genetic tests, all of which relate to the complexity of the reimbursement process. As previously mentioned, CMS sets prices for new tests using the ADLT process, in which laboratories are paid list charges when they bring ADLTs to market. Further, they are still allowed to retain 130% of market rates if CMS retrospectively discovers that their initial pricing was too high. CMS adds tests to the CLFS as they become more established in the market. Upon doing so, CMS reimburses them based upon market rates. Current reference prices are based upon private payer data collected at the beginning of 2016. CMS will not update rates until 2023, at which point they will be based upon the weighted median of prior payer rates observed in the first half of 2019. These rates will then be in effect through the end of 2025.[24] Aware that their private payer rates will impact public payments for years to come, labs are hesitant to offer discounts to private payers.

Lack of code specificity makes it challenging to analyze the nature of the testing that is driving costs and to fight unnecessary utilization. Eight of the twenty-five lab and pathology tests, by fastest growth in 2019 Medicare payments, had non-specific codes. For instance, CPT 81407, which corresponds to "Molecular Pathology Procedure, Level 8," had the fastest growth.[25] Given that the nature of these tests cannot be determined by payers until adjudication, in the short-term, there is a need for more precertification to ensure that when providers order these, they are appropriate for the patient. The use of these miscellaneous CPT codes is particularly problematic, as the greater work required during the adjudication process can lead to more errors. Furthermore, the need for a larger amount of information from providers during the prior authorization process to determine the nature of the test and its appropriateness can lead to provider abrasion. In the long-term, these problems are addressable through greater code specificity. This in turn can help facilitate appropriate pricing for these labs when billed to traditional Medicare, Medicare Advantage plans, and commercial plans.

Eight of twenty-five lab and pathology tests, by fastest growth in 2019 Medicare payments, had non-specific codes. Greater code specificity is needed.

Hospital-based Outpatient Lab Testing

While independent labs negotiate solely for laboratory services, hospital labs typically receive the benefit of the overall negotiation for all services which, as shown in Figures 4 and 5, are significantly higher. Consequently, hospitals' outreach labs are moving back into the hospital and then billing with an outpatient place of service rather than with an independent place of service. Further, as hospitals acquire more and more independent physician practices, the resulting laboratory testing migrates to the higher-priced hospital labs.

As private payers and CMS work to decrease the costs associated with common labs, one open question is the extent to which federal transparency laws will cause hospital-based labs to reduce their prices. Since the start of 2021, the government has required that each hospital in the United States provide clear pricing information. Hospitals must present all items and services to the public in a machine-readable file.[26] Furthermore, hospitals must present shoppable services in a consumer-friendly format. The government also requires that hospitals list the prices of frequently provided ancillary services (such as labs) alongside listed shoppable services. Hospitals must explicitly share their highest and lowest negotiated rate for each service.[27] Given the greater price transparency that this policy brings to the market, hospitals may be willing to discount their prices. Thus, while PAMA exerts pricing pressure on independent labs, price transparency requirements exert pricing pressure on hospital-based labs.

Ultimately, the migration of lab testing from physician offices into hospital outreach labs will adversely affect overall spend by increasing unit cost for the same volume. Price transparency at hospitals may educate patients and result in member redirection toward independent labs. Additionally, the drive toward value-based care and alternative payment models may reduce overall spend with hospital outreach services.

AVALON'S LBM SERVICES MANAGE VOLUME AND ACCESS

When health plan members receive care that is not evidence-based, it can lead to misdiagnosis, be potentially harmful, and increase overall medical costs. Laboratory tests often have outcomes that are not definitive, but instead yield results with sufficient uncertainty to justify additional downstream diagnostics, some of which may be harmful due to their invasive nature or because they expose patients to drugs, chemicals (e.g., contrast agents), or radiation. Thus, inappropriate diagnostic odysseys reduce the quality of care that health plan members receive, in addition to increasing costs. Avalon's review of numerous health plans' data—spanning many years and more than 50 million members—consistently shows that approximately 10% of laboratory testing may lead to unnecessary follow-up treatments.

Typical commercial insurance products save $1.50 to $2.00 PMPM due to 8-12 % of outpatient laboratory testing found to be clinically inappropriate.

To help health plans reduce the extent to which their members receive inappropriate lab tests, Avalon compiles the latest scientific research to develop evidence-based laboratory policies for determining the appropriateness of lab testing. Avalon presents potential policies to an independent Clinical Advisory Board (CAB) for commentary, review, and approval. All five members of the CAB have one or more doctorates and currently hold or have recently held academic appointments. These experts have well-renowned expertise in their fields of hematology, laboratory science, molecular genetics, and pathology, and

they bring practical insights, front-line laboratory experience, and real-world use cases for the latest technologies. The CAB annually reviews Avalon's catalog of roughly 140 evidence-based policies and makes additional updates whenever there is a material change in the scientific consensus.

Health Plan Adoption of Laboratory Policies

After Avalon produces a policy, it is presented to clients for review and adoption. Clients may adopt a policy in total, with variances, or not at all, depending upon their needs and preferences. Avalon's automated policy enforcement and prior authorization programs apply the health plan's policies.

Avalon's 140 Lab Policies are the most comprehensive in the industry and address nearly 75% of outpatient laboratory spend.

There are two primary means that Avalon utilizes to ensure compliance with published health plan policies. First, the automated policy enforcement program automates the administration of coverage criteria to remove inappropriate utilization on high-volume, low-cost tests. Second, the preservice review/prior authorization program alters the care pathways for members with orders for high-cost genetic tests before laboratories actually conduct those tests.

Compliance Through Automated Policy Enforcement

The automated policy enforcement program is a post-service, pre-payment solution that implements Avalon's proprietary clinical lab editing application known as the Automated Policy Enforcement Application (APEA). Using over 2M unique rules extracted from scientific-based coverage criteria, Avalon's software provides real-time support for each payer's policy decisions to approve claim lines, reduce them, or categorize them as non-complaint. When making a recommendation other than for approval, Avalon references the applicable policy used to make the determination. While policy enforcement does not alter members' testing trajectory directly, it enables the plan to detect inappropriate and/or non-compliant testing, and to make payment adjustments accordingly. Furthermore, the policy guidance and provider education provided by the program when making adverse determinations helps to change physicians' ordering behaviors and rendering laboratories' order menus or laboratory panels. Since this solution is based on the science, there is no physician abrasion, and less than 1% of claims become reconsiderations.

Avalon's APEA algorithms contain more than 2M unique rules.

Compliance Through Prior Authorization

In contrast to the automated policy enforcement program, the prior authorization program is a pre-service, pre-payment review that manages utilization by requiring ordering physicians or laboratory providers to receive approval before performing testing on members. This is primarily utilized to manage the high-cost, low-volume, genetic tests. When a provider orders a test covered by prior authorization, it undergoes an evaluation by a nurse or physician reviewer to determine if it is medically appropriate. If the reviewer requires additional information to decide if the test is appropriate, the reviewer may outreach to the ordering provider. When the program approves an order, the ordering and rendering providers are both notified. If the prior authorization program cannot approve an order, the member, along with the ordering and designated rendering provider, receive a detailed description of the reasoning behind the adverse determination. Appeal support has an educative component to it, and often includes peer-to-peer consultation. By informing ordering providers about the latest evidence-based practices, it is possible to improve the appropriateness of their ordering over time. Likewise, the mere presence of prior authorization improves the appropriateness of orders because of the sentinel effect.[28]

Avalon introduced seven new policies in 2020 covering oncology, infectious disease, and neuropsychiatry.

New Policies Introduced in 2020

Avalon continuously evolves the policies that guide the policy enforcement program and the prior authorization program to ensure that they account for the latest evidence and the development of new types of tests.

1. M2171 Esophageal Pathology Testing

Esophageal conditions—including eosinophilic esophagitis, Barrett's esophagus, and esophageal cancer—may have few nonspecific symptoms (such as pain or difficulty in swallowing). A general inflammatory response may also accompany these conditions. Labs have used both serological and genetic markers to identify, diagnose, or assess risk of these conditions in the esophagus. Avalon's policy addresses a variety of esophageal pathology-associated tests, from genetic testing for targeted therapy and liquid biopsy to wide-area transepithelial sampling (WATS) and Esophageal String Test (EST).

2. M2172 Onychomycosis Testing

Nucleic acid-based tests to diagnose onychomycosis—an infection of the finger or toenail typically caused by a fungus or yeast—have become widely available. Avalon's policy outlines clinically appropriate onychomycosis testing and discusses the use of PCR and NGS technology within this field.

3. G2173 Gamma-Glutamyl Transferase

Gamma-glutamyl transferase (GGT) is an enzyme present in the cell membrane of many tissues throughout the body. Clinicians traditionally have considered an elevated GGT level as a predictive marker for liver dysfunction; however, more recent research has suggested that there may be a linkage between GGT and additional conditions, including heart failure, atherosclerosis, diabetes, and cancer. Avalon's policy addresses serum GGT testing in adult individuals within outpatient settings.

4. G2174 Coronavirus Testing in the Outpatient Setting

The COVID-19 pandemic has led to an increase in the variety of tests offered in the screening and diagnosis of coronaviruses, including antigen, host antibody, neutralization antibody, and nucleic acid testing. In addition to SARS-CoV-2 (the causative agent of COVID-19), six additional human coronaviruses are known, including four endemic strains associated with common respiratory ailments, (such as the common cold). The Avalon policy addresses all coronavirus testing within the outpatient setting, including the strains other than SARS-CoV-2.

5. M2170 Red Blood Cell Molecular Testing

Several chronic conditions may warrant a blood transfusion, and the phenotypic and genotypic determination of red blood cell antigens assist in limiting immune responses in individuals with these conditions. Avalon's policy outlines when such testing is clinically useful and addresses many recent advances in proprietary testing within this field.

6. M2175 Minimal Residual Disease (MRD)

Minimal residual disease—also called measurable residual disease or MRD—refers to subclinical levels of residual disease occurring with many types of cancer, such as acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), and multiple myeloma (MM). MRD is a prognostic indicator utilized for risk stratification and, when used alongside other clinical and molecular data, to guide therapeutic options. The Avalon policy addresses all MRD methodologies, including PCR, NGS, and flow cytometry.

7. M2176 Testing for Autism Spectrum Disorder and Developmental Delay

Autism Spectrum Disorder (ASD) is a complex condition typically associated with deficits in social interaction and communication, as well as restrictive and repetitive behaviors and sensory issues. Both genetic and environmental factors

play a part in the etiology of ASD, and new proprietary tests are now available that assess ASD and developmental delay. This Avalon policy addresses all aspects of testing for ASD, including genetic testing, serum testing, and microbiome analysis.

Trend Management Experienced by Avalon's Clients

From 2018 to 2020, Avalon's clients had a multitude of factors influence their lab utilization trends. In spite of increases in unit costs, increases in inappropriate utilization, and shifts in the mix types of tests ordered, Avalon's solutions and laboratory policy updates reduced lab expenditures. Furthermore, strategic behavior by both labs and payers in response to PAMA and other policies influenced the place of service in which testing occurred. The following sections unpack aggregate trends and provide insights into how the types of labs used shifted over the period.

Aggregate Allowed and Unit Trends

Monthly allowed PMPM laboratory fees (Figure 6) did not grow over time. While there were both monthly decreases and increases in utilization relative to the level seen in January 2018, much of this is likely due to seasonality—except for the dip in utilization occurring from February through June of 2020 due to COVID-19. The average allowed PMPM in the fourth quarter of 2020 was 8% higher than the average allowed PMPM in January of 2018. As can be seen, the increase from 2018 is solely attributable to the impact of COVID-19. Allowed PMPM levels continued a slow decline over time.

Quarterly paid units PMPM (Figure 7) steadily declined from the first quarter of 2018 through the last quarter of 2020, save for the period between March and May 2020 when there was a substantial decrease in utilization due to COVID-19. The average number of paid units PMPM in Q4 of 2020 was 9% less than the average number of paid units PMPM had been in Q1 of 2018. Looking at the years on an annualized basis, annual-allowed PMPM for 2020 was 94.9% of what it had been in 2019. Combined with the findings from Figure 6, these findings suggest that an increase in per-unit costs (attributable primarily to COVID-19 unit costs) offset the decrease in utilization.

Lab tests remained frequently used by health plan members during the COVID-19 pandemic. The percentage of health plan members served by Avalon's clients that used lab services was 68.3% in 2020—nearly unchanged from 2019 during which 69.3% of members used lab services. That said, through a combination of lab benefit management,

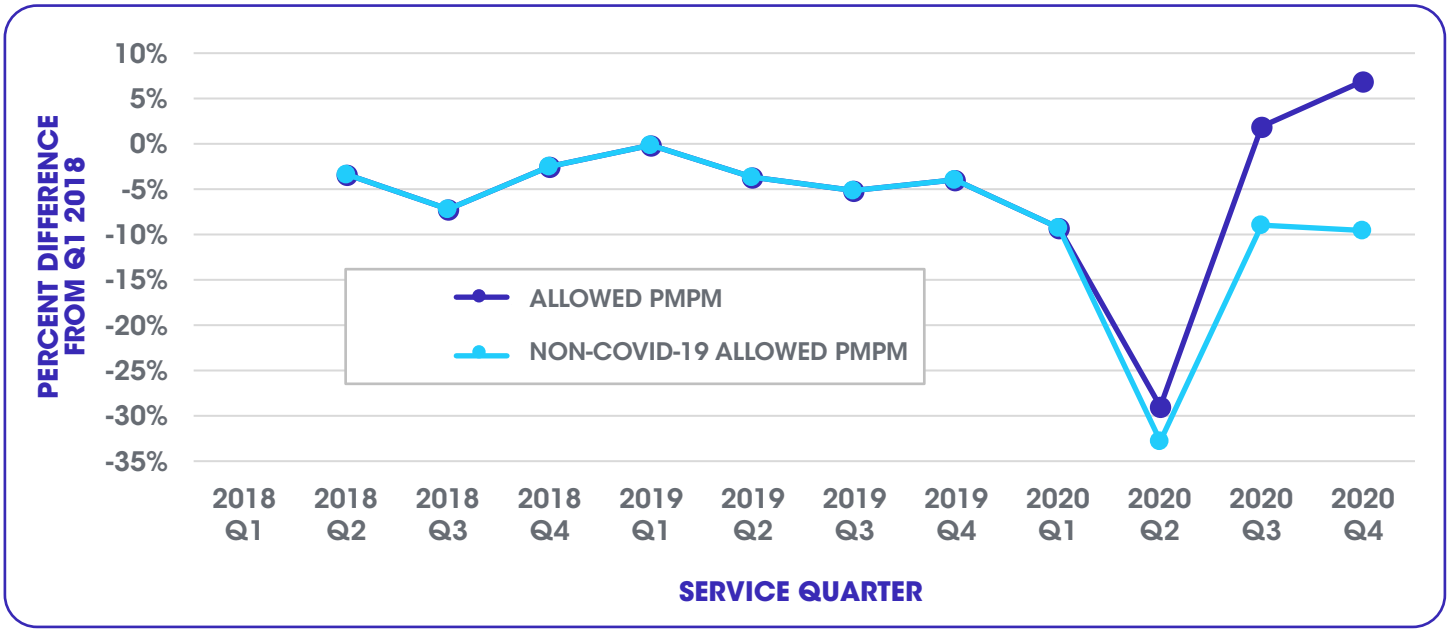

Figure 6: Percentage Change in Monthly Allowed Payments PMPM, Relative to January 2018

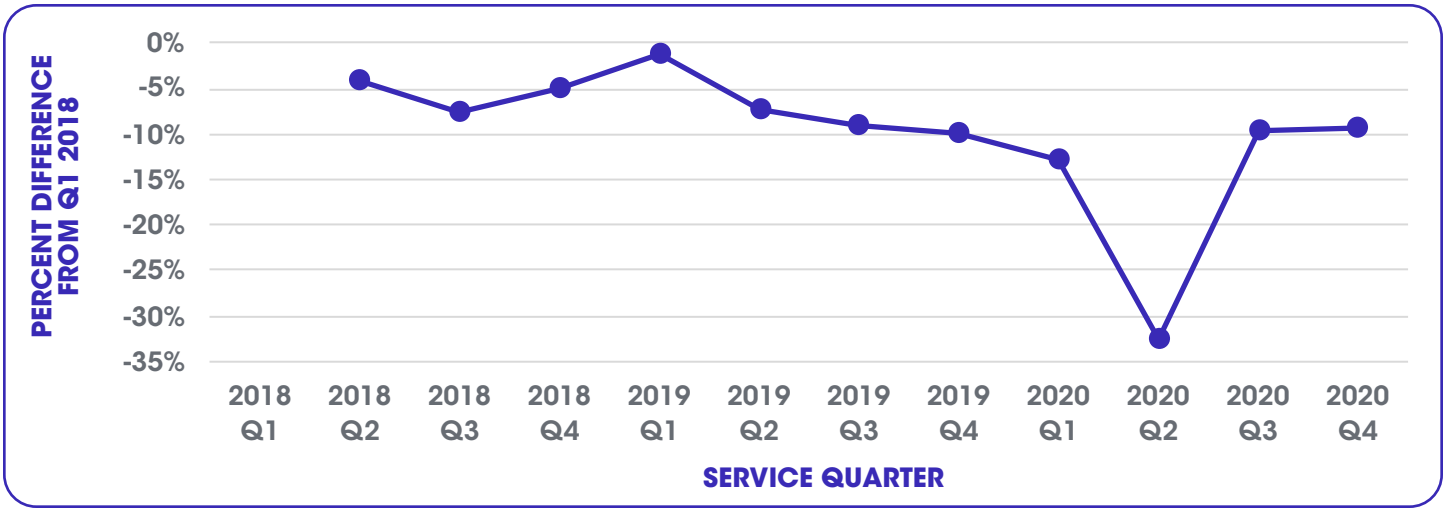

Figure 7: Percentage Change in Monthly Paid Units PMPM, Relative to January 2018

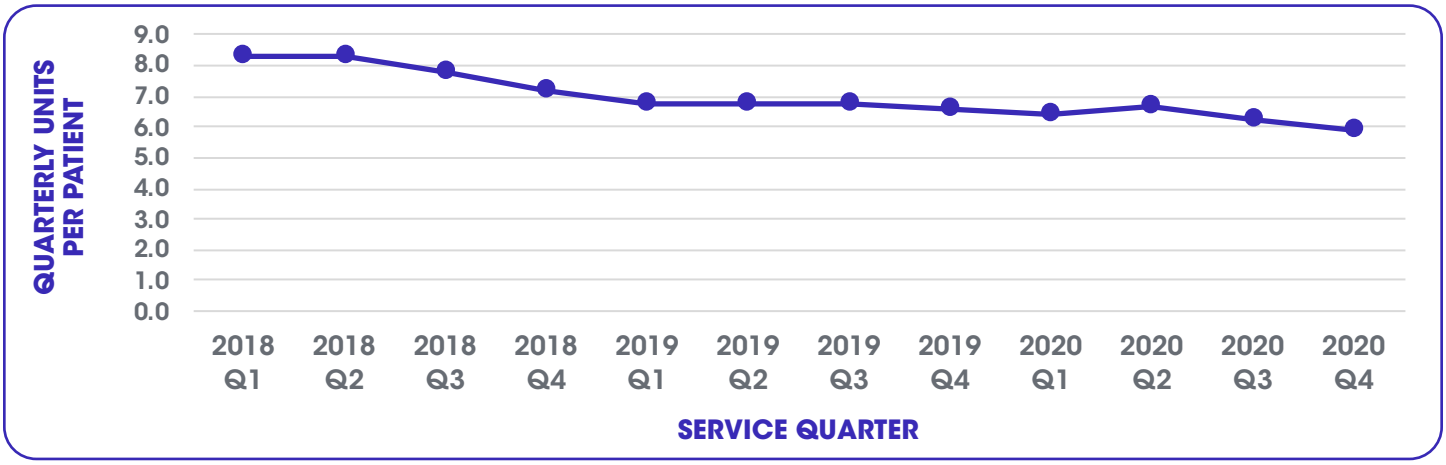

Figure 8: Units Per Patient by Month

decreases in access due to the pandemic (2020 only), and increased patient aversion to testing during the pandemic (2020 only), units of lab services utilization per patient steadily declined from 2018 to 2020, as shown in Figure 8.

Avalon's programs have reduced utilization per patient per month over time.

Consistent with the reduction in physician office visits during the early stages of the pandemic, from 2019 to 2020, the percentage of members receiving labs fell by 1.5%, paid units PMPM fell by 11.8%, and allowed PMPM decreased by 5.4% (Figure 9). As expected, non-COVID-19-allowed PMPM decreased proportionally with the reduction in paid unit PMPM. However, the increased COVID-19 testing materially reduced the reduction in overall allowed.

IMPACT OF AVALON'S PROGRAMS

Policy Enforcement and Prior Authorization – Avalon's Approach to Savings

Avalon's programs impact the utilization trends that its clients have experienced. As mentioned in the section Avalon as a provider of LBM services, Avalon reduces the laboratory expenditures of health plans broadly in two ways. First, its automated policy enforcement program, powered by Avalon's Automated Policy Enforcement

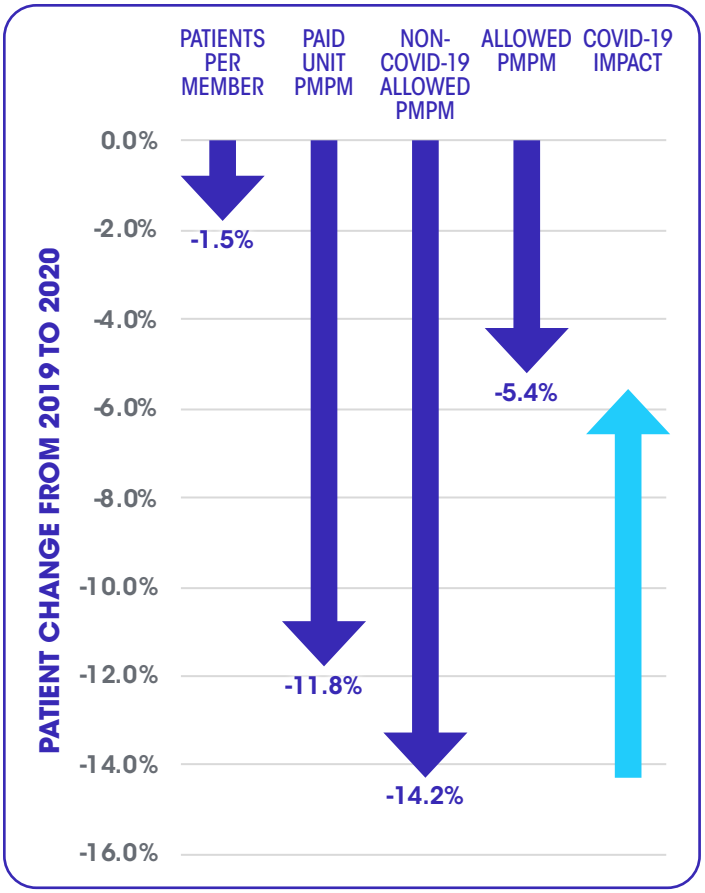

Figure 9: Percentage Change From 2019 to 2020, Units of Utilization Decreased, Allowed PMPM Decreased, COVID-19 Increased Allowed PMPM

Application (APEA) makes post-service, pre-payment determinations regarding whether health plans should approve the lab claims they receive, reduce them, or not provide reimbursement due to non-compliance with policy. Second, its prior authorization program provides a pre-service, pre-payment intervention that changes the course of care if necessary. As the prior authorization program takes an educative approach with ordering providers, Avalon offers them the scientific rationale behind adverse determinations. Thus, inappropriate orders decrease over time. Furthermore, as providers are aware that Avalon is closely monitoring their utilization, there is a reduction in fraud, waste, and abuse due to the sentinel effect. Although both the policy enforcement and prior authorization programs are quite powerful and work in combination, most of the savings that Avalon has delivered for clients has been from the APEA. The magnitude of the savings resulting from policy enforcement during the reimbursement process was on average more than double the value of the utilization averted through prior authorization. While the genetic tests averted through prior authorization are often quite costly, there are substantially more claims for routine testing managed by the policy enforcement program.

Avalon's utilization management programs reduce outpatient laboratory spend by 8-12% for commercial, fully insured, and ASO lines of business.

Managed CPT codes and services indicate a clinical policy exists to give providers and patients an understanding of coverage criteria, and the codes are subject to utilization management.

Unmanaged CPT codes are not currently aligned with a health plan policy.

Avalon manages the forms of lab testing with the biggest potential for savings, but does not manage forms of testing where the potential for savings is low, the frequency of utilization is low, or management is impractical. Consequently, there have been different trends seen for managed codes than for unmanaged codes.

As seen in Figure 10, managed codes decreased in overall spend by nearly 10% relative to January 2018, while unmanaged codes over the same period of time increased spend nearly 5%.

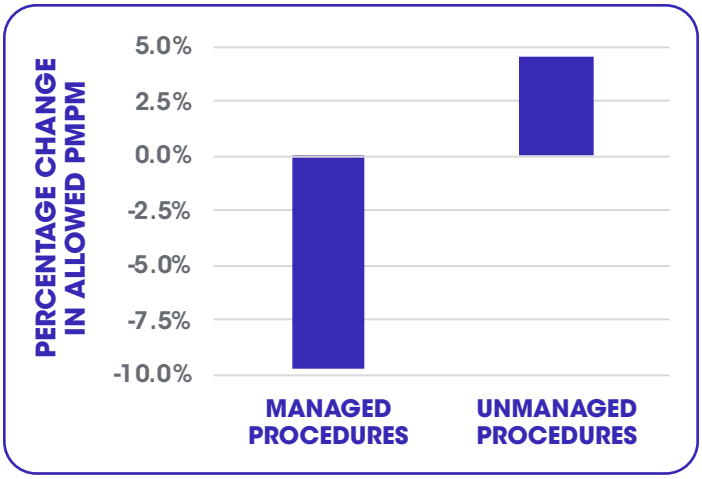

Figure 10: Percentage Change in Monthly Allowed Payments PMPM From January 2018, by Managed Code Status

Utilization Management From Policy Enforcement

The absolute number of monthly non-compliant units decreased dramatically, relative to January 2020 levels, for all places of service between March and May (Figure 11)—the period of COVID-19 lockdowns. The decrease in denied units likely reflects the overall reduced volume of laboratory testing during this period. Labs from outpatient services settings rebounded the least following the COVID-19 dip, and labs from independent lab settings rebounded the most (exceeding utilization levels that occurred in January for much of the second half of 2020). Unsurprisingly, monthly changes in averted costs by place of service (Figure 12) mirrored monthly changes

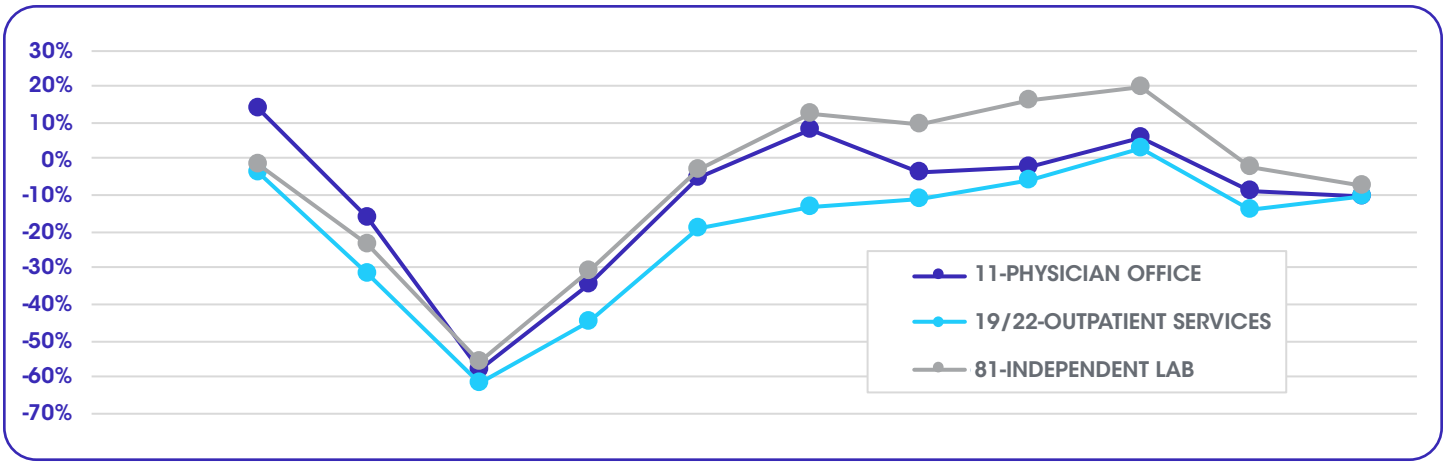

Figure 11: Percentage Change in Monthly Units Without Clinical Utility Relative to January 2020, by Place of Service

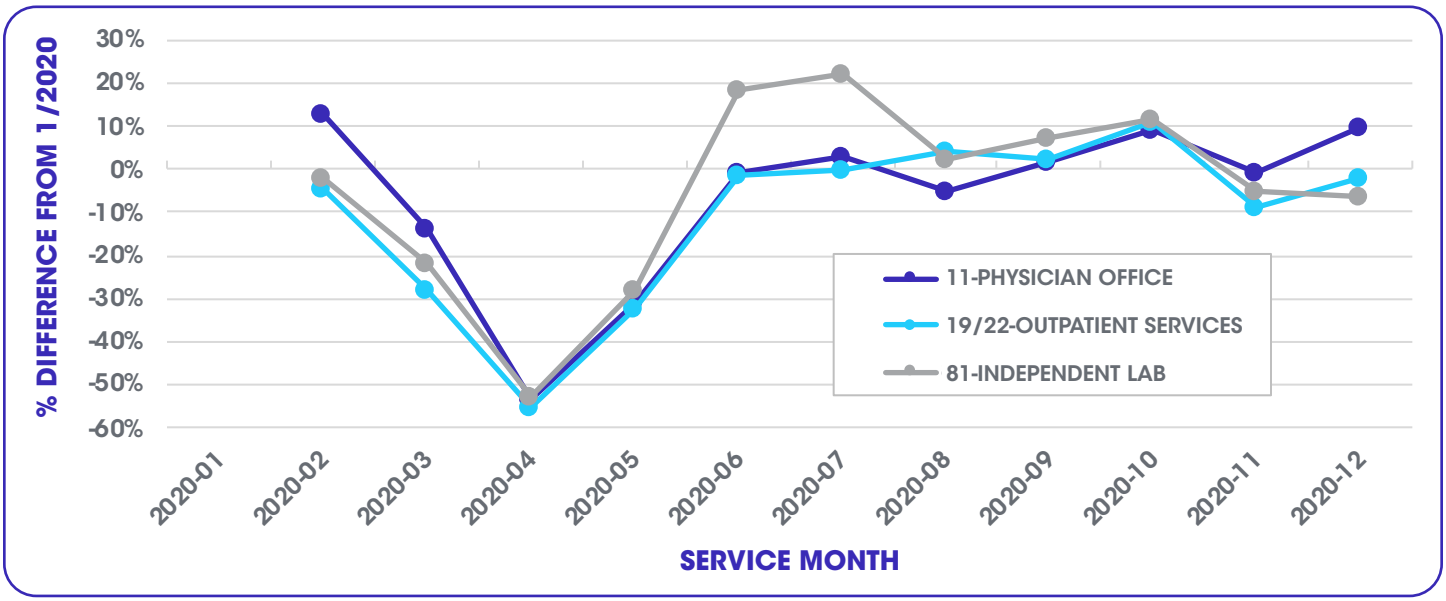

Figure 12: % Change in Monthly Averted Costs Relative to January 2020, by Place of Service

in non-compliant units. For much of the second half of 2020, the monthly averted costs related to independent labs were greater than they had been in January of 2020. When considering absolute rates of non-compliant units per capita (data not shown), hospitals had the lowest rates, and independent labs had the highest.

Utilization Management From Prior Authorization

While providers order some tests with highly specific codes that are only applicable to one test, they may also order tests with multipurpose codes which are not readily linkable to specific tests. The specificity with which providers order tests was highly correlated with whether the prior authorization program approved them or determined them to be non-compliant. All the top five codes determined to be non-compliant by prior authorization—representing 36.8% of the total number of units determined to be non-compliant—were for non-specific procedures as shown in Table 1. Keeping with this theme, the code most likely to be determined to be non-compliant by the prior authorization program was "Unlisted molecular pathology" (81479). Meanwhile, the top five codes approved, collectively accounting for 51.1% of approved units, were all specific.

Lack of coding specificity drives the need for prior authorization services. The top five procedure codes deemed non-compliant are non-specific codes for which automated claims adjudication is not possible.

% of Total Units Determined Non-Compliant	
Procedure Description	**%**
Unlisted molecular pathology (81479)	18.4
Molecular pathology procedure, Level 5 (81404)	5.2
Molecular pathology procedure, Level 4 (81403)	4.5
Molecular pathology procedure, Level 7 (81406)	4.5
Molecular pathology procedure, Level 2 (81401)	4.2
Total	**36.8**

Table 1: Top 5 Codes Determined to be Non-Compliant by Prior Authorization

% of Total Approved Units of All Approved Units	
Procedure Description	**%**
Fetal chromosomal aneuploidy (81420)	14.7
Hereditary breast cancer-related disorders (81432)	9.8
Hereditary breast cancer-related disorders (81433)	9.8
SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	8.5
Cytogenetics DNA probe (88271)	8.3
Total Approved Units	51.1

Table 2: Top 5 Codes Approved by Prior Authorization

A LABORATORIAN'S PERSPECTIVE – A MESSAGE FROM AVALON'S CLINICAL ADVISORY BOARD

The laboratory landscape is going to be challenging in the years to come. The trends that Avalon's clients experience in the future will be determined by the lasting impacts of COVID-19, regulatory change, and the actions of payers. While COVID-19 has had broad and pervasive impacts on nearly every part of life, the twelve-month period starting in March 2020 has heralded notable changes in the clinical laboratory industry. Until the advent of vaccines, laboratory testing was the only tool of substantial efficacy available to fight COVID-19. While laboratory test utilization has historically been of little public interest, in 2020, testing volumes for COVID-19 (as well as their positivity rates) became front-page news, as did

metrics to guide government decisions. Thus, clinical laboratories entered the spotlight, which is an unusual position for them to occupy, as they account for only a fraction of the overall global and national healthcare expenditures.

Although many laboratories have risen to the challenges posed by this unprecedented level of attention and demand, providing the "...right test, for the right patient, at the right time," 2020 also unearthed some of the industry's challenges: supply/demand mismatches; narrow networks not providing appropriate access; inequity in test availability; price and cost confusion; inaccuracy of certain types of tests; misinformation about the utility and interpretation of tests; and the sometimes competitive roles of government, commercial, and academic labs. As the clinical laboratory industry faces the next decade, it will need to address several issues.

Proprietary, esoteric tests are becoming increasingly common, but are more prone to error than non-proprietary tests, as their proprietary nature makes it impossible for external parties to verify their performance. As many proprietary tests use algorithms or analyses to produce risk estimates (rather than binary results), the actionability of their findings is often not as high as traditional laboratory tests with binary outcomes. Given the difficulty of evaluating the performance of proprietary tests and the vagueness of their findings, it will be necessary to evaluate these tests using different rubrics than the ones used to evaluate traditional tests. Greater regulation of proprietary tests will eventually occur, likely through legislation. The downstream effect of this could range from mild increases in bureaucracy and increased costs, to completely shuttering academic labs and halting innovation.

Over 13 billion clinical laboratory tests are performed each year, making it the #1 utilized medical benefit, and yet have the least amount of management. An estimated 70% of clinical decisions are based on laboratory testing and the results. These factors make it critical for payers to focus on this benefit to ensure that the right testing is done, that removal of waste and abuse occurs, and makes sure that clinicians implement the right treatment based on the laboratory results. For multiple reasons, fraud, waste, and abuse continue to plague corners of the laboratory industry. While the alleged fraud that occurred at Theranos has drawn a great deal of attention, there are other laboratories engaging in fraudulent, wasteful, or abusive practices involving providing tests with no clinical utility that have not received the same degree of scrutiny. For instance, in March of 2021, a federal grand jury charged the co-founders of uBiome, a laboratory focused on gut microbiomes, with a series of fraud charges related to both the lack of clinical utility of the tests and the lab's reimbursement practices.[29] Due to the potentially lucrative nature of laboratory tests, the market has responded with numerous new offerings with varying degrees of utility. Overutilization and non-indicated utilization of tests, even when not covered by payers, can lead patients to go on diagnostic journeys which may ultimately result in the generation of potentially unnecessary diagnostic and procedure claims.

However, underutilization of diagnostics is as great a challenge as overutilization. The financial incentives of the American healthcare system discourage spending extra money today to address underutilization, with the goal of saving money in the long-term due to decreased morbidity or mortality. As the mechanisms that health plans have enacted to discourage overutilization may in some instances be a factor in underutilization, there is thus a challenge in managing the two. Furthermore, the healthcare system does not deliver care in an equitable or inclusive manner, and accessing laboratory testing is challenging for some populations. There is a great deal of geographic and racial variation in the utilization of health services, including diagnostics. Going forward, payers will have to continue to balance promoting reducing

The DOJ recovered greater than $2B in fraudulent Medicare expenses in 2019.* Avalon supports payer's FWA programs through detection and identification of suspicious billing patterns, unexplained increases in volume, and more.

* https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020

overutilization with ensuring access to care. As expensive new tests are rapidly entering the market, the stakes have never been higher.

AVALON'S VALUE-BASED CARE FOCUSED EVOLUTION

Avalon seeks to make a greater impact on member health as they travel through the continuum of care in the years ahead. To do so, Avalon has developed the capability to collect, digitize, and analyze the results of the labs that client members receive.

Avalon has developed the capability to collect, digitize, and analyze the results of the labs that client members receive.

Laboratories and health plans do not speak the same language. Lab services are represented by LOINC codes for laboratories and CPT codes for health plans.

Numerous LOINC codes can be linked to one or more CPT codes, and digitizing and analyzing LOINC codes requires deep domain expertise to ensure proper matching.

Aggregating clinical results enables Avalon to build a more complete profile of the lab history of each patient than would otherwise be available to a health plan or any single provider. In doing so, Avalon provides health plans with clinical management guidelines based on the laboratory results. Thus, health plans can identify diseases earlier and boost the value of the care their members receive.

Lab testing plays a key role in influencing the trajectory of patient care across medical specialties. Although lab testing represents less than 10% of the healthcare dollar, it is the most common medical benefit with over 14 billion tests ordered annually. While at the unit level, lab test prices are often relatively low compared to other health services, these unit prices represent only the direct costs associated with lab testing. Overall, lab tests drive 70% of medical treatment decisions, and have a disproportionate impact on spending in other parts of the care continuum.[30]

In addition, proper analysis of lab results segment patients receiving evidence-based care from patients receiving suboptimal care. Several lab test results are used as outcome measures in HEDIS (Healthcare Effectiveness Data and Information Set) and Stars ratings; however, most lab test values are not used to evaluate performance of a population of members. Providers use lab tests to diagnose concussions via the Banyan Brain Trauma Indicator, heart attacks via cardiac troponin tests, breast cancer via TRU-QUANT... just to name a few impactful healthcare opportunities. Furthermore, there are large volumes of lab tests conducted each year.[30]

Since the creation of the Medicare Shared Savings Program via the Affordable Care Act, there has been an increasing push for healthcare providers to deliver value, and to think holistically about patients' costs rather than transactionally. In contrast to fee-for-service contracts, value-based contracts incentivize healthcare providers to maximize quality outcomes rather than transaction volume. The need to maximize quality while controlling costs has caused organizations to seek greater insights into the care patients receive and greater control over the quality delivered. Over the past ten years, many payers and physician and hospital providers have entered into value-based contracting (VBC) arrangements. However, the majority of these VBC arrangements leaned on financial metrics. Leveraging lab results data in VBC arrangements will increase the focus on quality outcomes.

Healthcare providers have historically not been able to review longitudinal laboratory results, especially on complex patients. While physicians have often been able to access laboratory results from within their practice, network of physicians, or affiliated hospitals' electronic health record, the information that is available has often been incomplete. Testing

Avalon's integration of lab test result values enables:

1) Early identification of members with emerging health risks: providing the potential opportunity for disease modification strategies and improved outcomes

2) Codification of providers' behavior and adherence to clinical pathways: identification of providers using evidence-based medicine

3) Production of decision support recommendations which payers can forward onto providers: aligning lab results with treatment recommendation

conducted by specialists, unaffiliated providers, and smaller clinics may be missing. If that breadth of information were available and digitized into actionable insights, it would be possible to increase the quality of care by making earlier diagnoses for new conditions, as well as to better manage changing treatment in line with patients' evolving trajectories—and, of course, reduce the overall volume of redundant testing across providers.

Health plans have traditionally received claims for lab tests, without the associated findings. Avalon can enable health plans to glean insights into what lab tests have found. Without access to lab results, health plans have had to infer lab findings by examining sequences of events, such as whether a member had claims mentioning a particular new diagnosis after receiving a laboratory test. When health plans must infer members' conditions through patterns in claims—rather than by directly observing them through lab tests—health plans can only gain an imperfect understanding of their members' conditions. Furthermore, healthcare providers may have misinterpreted or failed to fully incorporate lab findings when coding for downstream care.

By analyzing the clinical findings of lab tests, Avalon can deliver value to payers in three ways:

1. Early identification of members with emerging health risks
2. Codification of providers' behavior and adherence to clinical pathways
3. Production of decision support recommendations

Early Identification

Many patients experience deteriorations in health for several years before their condition reaches the point at which their physician perceives a need to address it. This can be the case for diabetes, heart disease, chronic kidney disease (CKD), and numerous other conditions. Currently, 90% of patients diagnosed with CKD are at Stage 3 or higher at the time of diagnosis (Figure 13). Late diagnosis hinders the ability of healthcare providers to limit disease progression and maximize the patient's quality of life. CKD, like many illnesses, is a progressive condition that is detectable through laboratory values. Unfortunately, healthcare providers may fail to recognize trends suggesting deteriorating kidney function. Providers may not have access to all the lab results that have been captured for the patient, as providers do not traditionally share these results with each other. By centrally capturing clinical results, Avalon will be able to identify trends—such as deteriorations in kidney function—even if a patient had their lab tests ordered by multiple providers and shared these trends with payers to potentially result in disease modification strategies and improved clinical outcomes for their members.†

† Assuming 5% of every million health plan members have undiagnosed CKD, and that ESRD costs $80,000 per year to treat, if one in eight members can delay developing ESRD by one year through earlier diagnosis, the savings is: 1,000,000 members* (5 members with undetected CKD/100 members)* (1 member with ESRD delayed by a year / 8 members with CKD)* $80,000 per member-year of ESRD = $500,000,000 per million health plan members

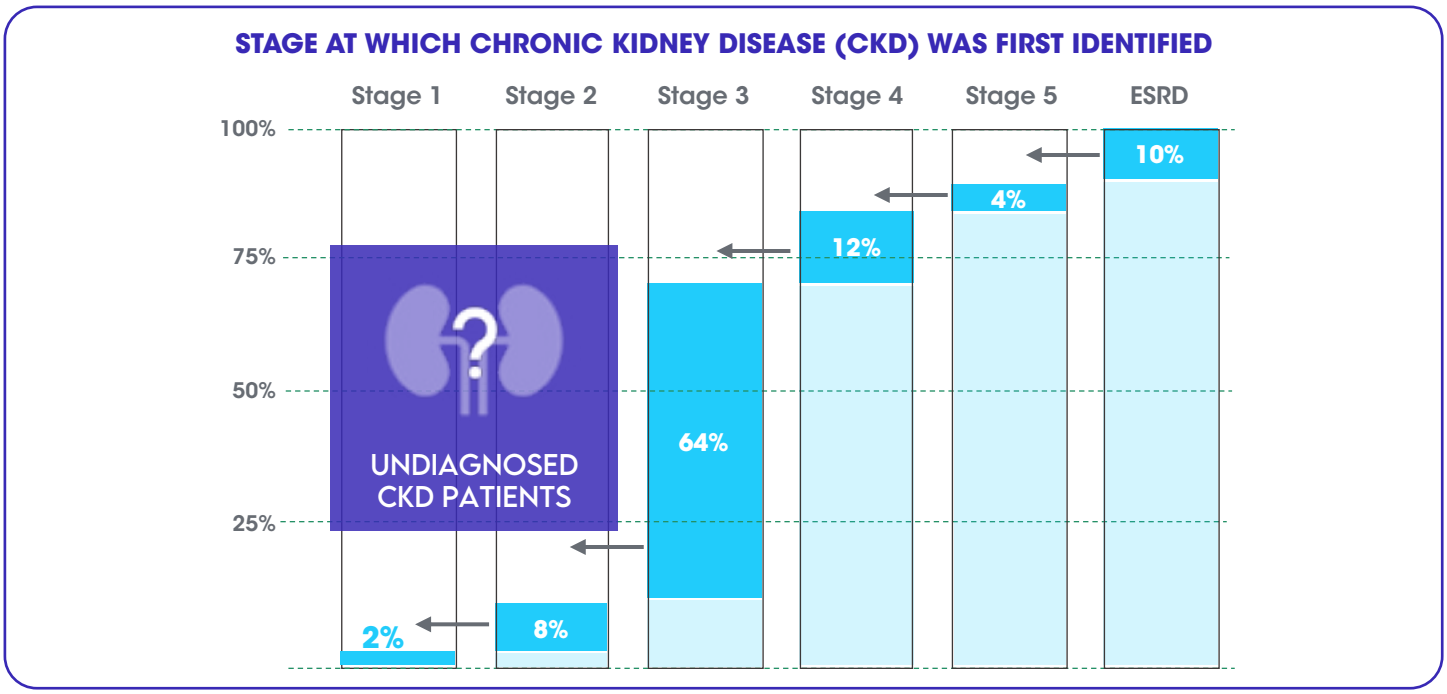

Figure 13: Distribution of Patients by Stage of Chronic Kidney Disease at Time of Diagnosis

Early identification, along with aggressive treatment, can slow the progression of CKD resulting in sizable savings. For example, treatment for members with end-stage renal disease costs roughly $80,000 per year. Avalon estimates that there are roughly 50,000 people with undiagnosed CKD per million health plan members. If just an eighth of those members could have their CKD detected at an earlier stage and have their progression to ESRD delayed by just one year, health plans would save a half-billion dollars in dialysis costs per million health plan members.

As Avalon can determine if lab results are indicative of a disease as soon as it receives them, it can notify the health plan of the need to engage in treatment planning at an earlier stage than would be possible by examining claims alone (Figure 14). For instance, if a member had a breast lump identified, and then had a biopsy and a genetic test performed to assess it, Avalon would learn about the member's diagnosis when a provider ordered the member a genetic test subject to prior authorization, when the biopsy claim was adjudicated, and then again when the provider received the genetic test results. Traditionally, health plans have had no insights into the results of biopsies or genetic tests, and thus would only learn if a member had breast cancer between forty-five to seventy days after the diagnosis, when processing a claim for a specialist visit in response to the findings from the biopsy and genetic test. By analyzing the results from the biopsy and genetic test, Avalon can identify members with newly diagnosed cancers earlier on their care journey, enabling health plans to be involved in the treatment planning process from an earlier juncture.

Evaluation of Treating Physician Behavior

Access to clinical findings empowers Avalon to identify providers best suited to the needs of specific members, measure provider adherence to clinical pathways, and profile provider based on patient performance. By having clinical data, it is possible to evaluate providers by the outcomes they achieve, rather than by the processes they follow. While structural quality and process quality are the easiest to measure, it is ultimately outcome quality that impacts the daily life of the member and the costs faced by a health plan.

A focus on process quality can mask the degree to which outcome quality varies within a population of providers that achieve good process quality. For instance, imagine a health plan evaluating the quality of care received by a population with diabetes using three process measures:

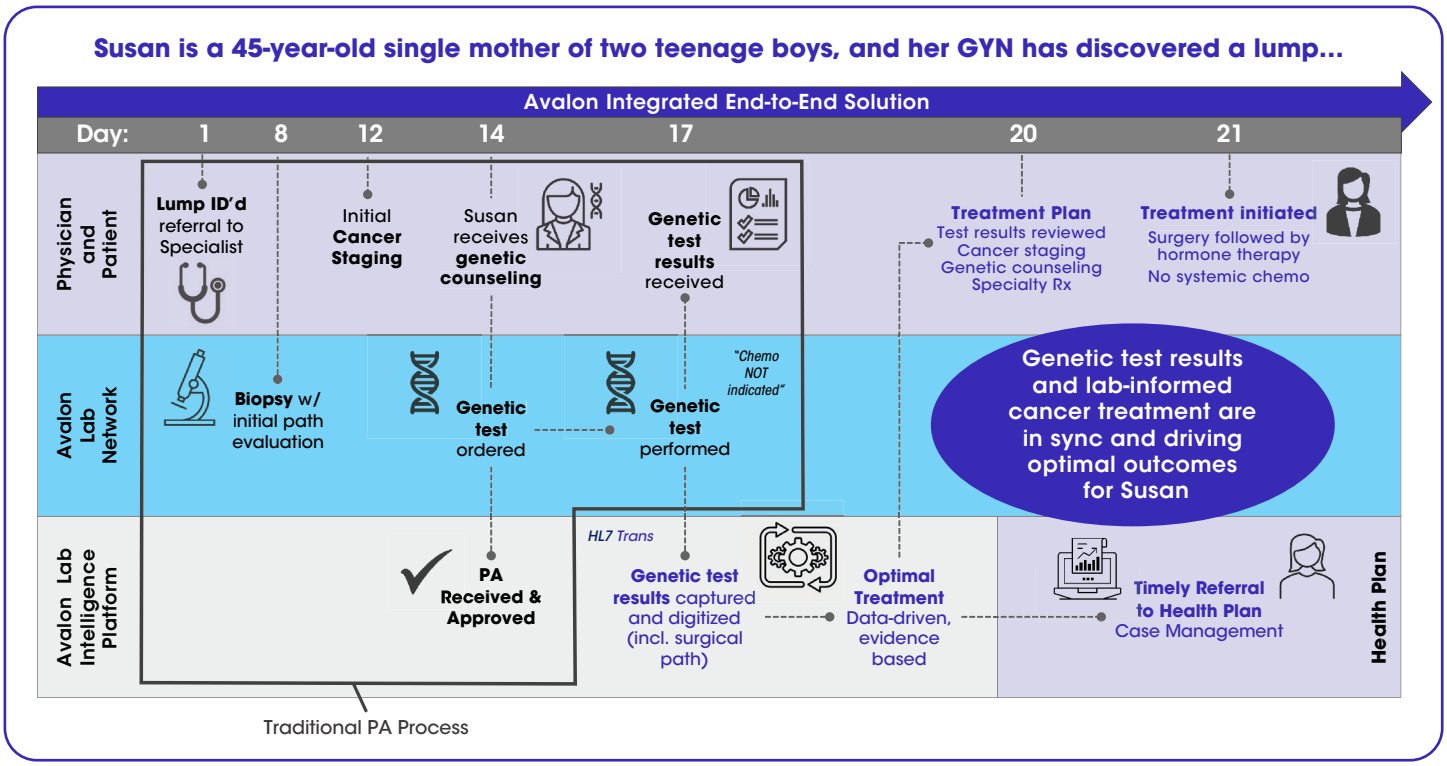

Figure 14: The Role of Avalon, the Lab, and the Physician in Diagnosing Breast Cancer

- ✓ If an annual HbA1c test was conducted
- ✓ If an annual lipid profile was conducted
- ✓ If there were two primary care visits within the year

While the above three process measures were associated with differences in cost of care, there was substantial variation in the costs that members experienced within each cohort. Furthermore, providers that performed similarly on process measures did not necessarily achieve similar outcomes.

Figure 15 compares the performance of three providers (circled in red), with process measures used in the left chart and outcome measures used in the right chart. The x-axis of both charts is the provider's panel size (the number of patients the primary care physician was responsible for managing). In the process measures chart on the left, the y-axis indicates the ratio of the number of patients meeting all three process measures to the number of patients meeting zero or one process measure. Meanwhile, the y-axis of the outcome measures chart on the right indicates the ratio of patients with well-controlled diabetes (HbA1c <7.5) to patients with more poorly controlled diabetes (HbA1c>8.2). As shown in Figure 15, while the three providers perform similarly when compared using process measures, there are dramatic differences in their performance when compared using outcome measures.

Further investigation into the performance of these three providers determined that the provider with the best outcome quality was more likely to change patients' prescriptions if their HbA1c exceeded 8.2 and was also more likely to retest patients with high A1c levels within four months. Avalon could only generate these insights because it had access to the underlying lab values. Thus, access to lab values enables Avalon not only to identify which providers have the best outcome quality, but also to explore the factors driving it. Avalon can then provide this information to the health plan for consideration when implementing a provider recommendation program or contracting a network. As the findings in Figure 15 suggest, the provider recommendation decisions made by a health plan using outcome-based measures of quality are likely to differ substantially from those made by a health plan using process-based measures of quality.

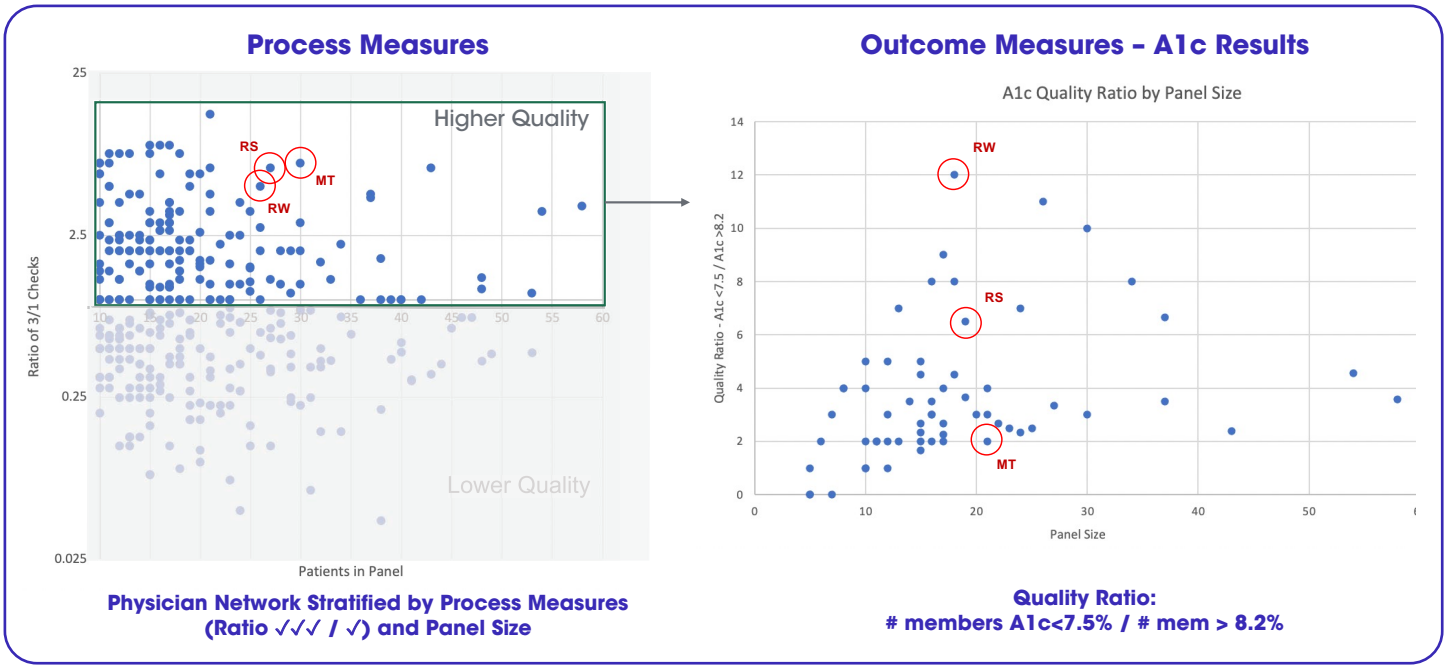

Figure 15: Evaluating Provider Performance Using Process Versus Outcome Measures

Production of Decision Support Recommendations

Using the clinical and claims information that it receives, it is possible for Avalon to provide clinical decision support to the physician and health plan's care management team. Avalon can provide more powerful lab-driven clinical decision support than would be available within a single lab or healthcare provider, as it is able to aggregate all information collected by participating labs. Thus, Avalon has a more holistic view of the patient's testing history and lab results.

Many specialty pharmaceuticals are only efficacious if a patient has specific tumor mutations. Furthermore, patients lacking the tumor mutations may experience harm if they take unnecessary specialty pharmaceuticals, as they often have harsh side-effect profiles and high associated costs. Using its access to lab results, Avalon can alert health plans as to which pharmaceuticals are appropriate for patients with specific tumor mutations. Using this information, health plans can then make tailored, clinically driven decisions regarding patients' eligibility for specialty pharmaceuticals, and can alert healthcare providers if patients are currently receiving medications which prior testing has suggested will not be beneficial.

Linking genetic laboratory results to specialty pharmaceutical administration ensures the proper alignment of therapeutic treatment with the patient.

Having a better understanding of a patient's healthcare trajectory transforms Avalon services from solely utilization management toward improvement and optimization of patient care. Working in its mission to help patients get the right testing at the right time, Avalon can additionally offer recommendations about tests that patients likely need but have not yet received. For instance, it is recommended that patients with well-controlled diabetes receive an HbA1c test twice a year, and that patients with poorly controlled diabetes receive an HbA1c test four times a year.[31] A health plan that simply sees that a member has had three claims for HbA1c testing in a given year cannot tell if the member is underutilizing the test (as would be the case with a member with poorly controlled diabetes) or overutilizing the test (as would be the case with a member with well-controlled diabetes). Using its access to clinical results, Avalon can provide health plans' guidance on testing that members may need to

Taking lab benefit management to a whole new level.

pursue in a targeted fashion. Thus, Avalon can advise a health plan to outreach to a member with poorly controlled diabetes to get a fourth HbA1c test, while refraining from advising the health plan to outreach to a member with well-controlled diabetes to get a fourth HbA1c test.

By aggregating and interpreting laboratory values, and then sharing insights with health plans in a manner of their choosing, Avalon is empowering health plans to use lab results to guide members more intelligently along their care trajectory. Although Avalon offers health plans savings by improving the appropriateness of lab test utilization, this is but one small component of the savings that Avalon can help health plans to realize. By identifying members early in the trajectory of chronic disease, capturing outcome-based measures of provider quality, and facilitating clinical decision making, Avalon can have a wide-reaching impact on health plans' abilities to deliver value and help achieve the triple aim[32] of improving the patient's experience of care (including quality and satisfaction), improving the health of populations, and reducing cost of healthcare.

From the desk of
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Avalon's publication of the industry's first Lab Trend Report continues our trend of defining and leading the Lab Benefit Management industry. Our mission is to leverage laboratory science, innovation, and technology to bring novel insights on the latest lab trends and to provide next-level solutions to payers. Our first set of solutions focused on removing waste and abuse from routine testing, bringing greater peer-to-peer education to make sure patients got the right genetic tests and helped plans reduce their independent lab network unit cost. Continuing our path of innovation, Avalon is launching new services to assist payers with value-based care. By digitizing laboratory results and integrating them into our advanced analytics, Avalon can now provide earlier disease detection and drive treatment protocols to help reach the triple aim of improving the patient experience of care, improving the health of populations, and reducing the per-member cost of healthcare.

Avalon knows that managing your lab benefit means much more than managing unit cost. If you would like to discuss your Lab Benefit Management strategy or see how Avalon's solutions can help your organization, please reach out to me.

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APPENDIX

Description of the Population

The data in this report pertains to patients with commercial and Medicare Advantage health plans, with the majority being commercially insured and under sixty-five years of age. We constructed the dataset used in the analysis by pooling data across multiple carriers. Including information from all client carriers was not possible for all the analyses. Prior researchers have established that there is substantial regional variation in laboratory testing practice patterns across the United States.[33] As the sample does not include patients residing in the western United States, it is not nationally representative, and it is likely that trends and values reported in subsequent analyses may shift if the composition of the patient base changes.

Glossary

Advanced Diagnostic Laboratory Test (ADLT): A test offered by only one lab, and not sold for use by other labs

Antibody Test: A test determining whether a person has experienced a prior infection

Antigen Test: A test detecting protein fragments located on the outside of a virus

Clinical Diagnostic Laboratory Test (CDLT): A lab test offered by multiple labs

Clinical Lab Fee Schedule (CLFS): The fee schedule that Medicare uses to set reimbursement for tests offered by multiple labs

The Coronavirus Aid, Relief, and Economic Security (CARES) Act: A law enacted in 2020 requiring health plans to reimburse COVID-19 diagnostic providers at their negotiated rates, if no negotiated rate exists, at the price listed on the provider's website

Families First Coronavirus Response Act (FFCRA): A law enacted in 2020 requiring health plans, both public and private, to provide coverage for COVID-19 testing without cost sharing

Healthcare Effectiveness Data and Information Set (HEDIS): A collection of measurements enabling consumers to compare performances of health plans

Logic Observation Identifiers Names and Codes (LOINC): A common standard for uniquely identifying medical laboratory observations and measurements.

Molecular Test: A test determining whether a specimen contains specific genetic material

Normalized: A quantity reported relative to another quantity, rather than in absolute terms

Per Member Per Month (PMPM): Utilization or expenditures in a given month, divided by the size of the applicable number of health plan members in a given month

Place of Service (POS): The location where a test was conducted

Protecting Access to Medicare Act (PAMA): A law enacted in 2014 which impacts how Medicare reimburses labs

Utilization Per Thousand (UPK): Utilization per thousand members during a period of time

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