LAB TREND REPORT 2022

from Avalon Healthcare Solutions

avalon

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From the Desk of

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The past few years have been both challenging and hopeful. This 2022 Lab Trend Report reflects that dichotomy by delving into the ongoing impact of COVID-19, the demand for lab testing, new government regulations advancing transparency, and the digitization of laboratory results.

Our nation continues to wrestle with COVID-19, as new variants have transitioned the virus from a pandemic toward an endemic disease. As the pathogen has remained in the spotlight, the healthcare industry and the general public have increased their awareness of laboratory testing, including its impact on informing care and variations in quality and price between test providers.

The importance of lab results in confirming a diagnosis, monitoring patients' response to treatments, and tracking diseases significant to public health cannot be overstated. As society returns to pre-pandemic behavior, the demand for lab testing is expected to grow. Genetic testing advancements are one reason for the increase in lab testing. While the price point for genetic tests is significantly lower than that for specialty drugs, the sheer volume of new genetic tests, the complexity in determining their acceptable clinical usage, the insufficiency in coding for claims processing, and the uncertainty around pricing create challenges and opportunities for health plans and medical directors. As genetic science advances, we will see parallel advances in technology and in clinical processes for determining the right test at the right time and at the right location to inform diagnoses and care plans.

> Avalon is leading the way toward real-time availability of lab test results in large volumes to promote a clearer understanding of patients' disease trajectories and to appropriately inform the right care at the right time.

These advances are changing the relationship between patients, providers, and health plans. We started Avalon Healthcare Solutions back in 2013 because lab testing is the gateway for appropriate diagnosis and treatment care planning, and it impacts the goal of achieving value-based care in this country. Healthcare affordability remains a big concern for Americans, and federal regulations like the No Surprises Act and the Transparency in Coverage Rule were enacted to improve access to pricing data and increase transparency around unexpected costs. These mandates on health systems and payers are resulting in increased cooperation within the healthcare industry to shape public policy and increase transparency.

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With pricing information becoming available to anyone willing to search for it and the expansion of over-the-counter testing, consumers are beginning to exercise greater control over their healthcare. The public will become more empowered as clinical data, especially lab results, are put into digitized formats. It's the next step in a long journey toward value-driven care.

The ability to analyze data at scale and combine it with other data sets will provide more accuracy in making diagnoses. Currently, diagnosis code determination is fraught with issues related to the inadequacy of the ICD-10 codes, which hampers health plans, care management programs, and evaluation of performance in value-based contracts.

Avalon is leading the way toward real-time availability of lab test results in large volumes to promote a clearer understanding of patients' disease trajectories and to appropriately inform the right care at the right time. Our goal is to move the country closer to improved population health by reducing waste in time and treatment that is not helping patients, while achieving cost alignment and driving the best clinical outcomes.

LAB TESTING: CORNERSTONE OF NATIONAL RESPONSE TO ONGOING COVID-19 PUBLIC HEALTH EMERGENCY

The public's awareness of the importance of laboratory testing increased significantly due to the pandemic. The federal government established new standards with the rapid expansion of available Food and Drug Administration (FDA)–approved COVID-19 tests. This included allowing pharmacists to order and administer clinical diagnostics, and the government also made testing free to the public through over-the-counter (OTC) and mail-order tests. The lab industry responded with OTC testing for COVID-19, further entrenching at-home tests as a regular part of healthcare. The consequences of COVID-19, federal policies, and consumer testing will play out for years to come.

SARS-CoV-2 continued to produce upheaval around the world in 2021, despite the many measures in place aimed at containing its spread. The U.S. recorded more than 900,000 virus-related deaths, even while the U.S. vaccination rate exceeded 60% by the conclusion of the year.[1] The rise of viral variants took an enormous toll, and what initially seemed like an acute public health emergency quickly became endemic.

The rapid detection of COVID-19 cases in the United States required wide availability of testing. As lab testing was essential to the national response toward the continuing public health crisis, several different types of COVID-19 tests became available:

- **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 results.
- **Antigen tests** (Ag) 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. OTC and rapid tests fall into this category.
- **Antibody tests** (Ab) 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 or treatment decisions, as they are unable to provide insight into whether a person has an active infection at the time of the test.
- **Respiratory panel tests** measure levels or presence of multiple viruses at a time, such as influenza, the common cold, and COVID-19.

COVID-19 Testing: New Federal Policies Enhanced Access

Combined with robust vaccination efforts, laboratory testing was labeled a "cornerstone of the national response."[2] Several levels of public policies were developed to meet the need for increased access to testing.

FDA: The FDA focused on enhancing access to COVID-19 tests, including rapid diagnostic tests such as point-of-care and direct-to-consumer testing. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may authorize the use of unapproved medical products, or unapproved uses of approved medical products, in certain emergency circumstances. The Emergency Use Authorization allowed the FDA to strengthen the nation's public health protections against biological threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. By November 15, 2021, the FDA had authorized more than 420 tests for COVID-19, including more than 300 diagnostic and 90 serology tests.[3]

NIH: The National Institutes of Health (NIH) invested $70 million from the American Rescue Plan to expand access to diagnostics and created an accelerated pathway to support large-scale COVID-19 test manufacturing with its Independent Test Assessment Program.[4] The program is an extension of the NIH Rapid Acceleration of

Diagnostics (RADx) initiative,[5] which encouraged manufacturers to bring their tests to the U.S. market, increasing options for people and overall supply while potentially lowering costs.

NIH worked in collaboration with other federal agency experts to conduct studies on over-the-counter tests, then partnered with companies to compile data and develop benchmarks for performance. NIH also provided the FDA with data to provide to test manufacturers; this allowed test manufacturers to scale up quickly. If the tests met the FDA's performance and quality standards, the FDA used the information to grant emergency use authorizations. The priority of the program was to develop new over-the-counter test applications that had the potential for manufacturing at significant scale.

Legislation Required COVID-19 Lab Tests to Be Covered: Federal policy required all insurers to cover COVID-19 testing with no cost-sharing for enrollees in private health insurance, Medicare, or Medicaid. In 2021, federal guidance clarified that insurers must cover testing with no cost-sharing for asymptomatic individuals without requiring medical screening, but not if testing was part of an employee return-to-work program. When testing was not covered by federal policy, individuals were responsible for the costs of testing.

The efforts of the federal government to increase awareness and access had the effect of increasing testing through insurers, who bore the brunt of COVID-19 testing costs because of limited ability to control lab test prices. The Medicare program was the only program that established set prices for COVID-19 tests during the public health emergency. Accordingly, charges for commercial and Medicaid-covered COVID-19 lab testing varied widely, and several labs and providers were accused of price gouging.[6]

Administration Issued Free Testing Policy: In December of 2021, the Biden administration released guidance in the form of a nine-point action plan. Group health plans and insurers were required to reimburse rapid testing without patient cost-sharing or out-of-pocket payment.[7]

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For those not covered by private insurance, at-home tests were distributed through key community sites, such as health centers and rural clinics, in addition to more than 20,000 federally supported free testing sites across the U.S.

More details were released in January 2022. A federal requirement for health plans to cover the cost of over-the-counter, at-home COVID-19 tests was authorized until the end of the Public Health Emergency. This mandate provides reimbursement by health insurers for up to eight lab tests per member per month beginning January 15, 2022. Additionally, under the guidance, there is no limit to the amount of tests health insurers must cover if, and when, a test is ordered by a provider.[7]

Outpatient PCR Testing Was the Most Utilized COVID-19 Diagnostic

PCR remains the dominant test for COVID-19. Conversely, antibody tests have fallen out of favor.

PCR tests provide the gold-standard measurement of active viral infection. As seen in Figure 1, Avalon data show the overall dominance of PCR testing in relation to other types of COVID-19 diagnostics utilized in outpatient testing throughout the pandemic. Rapid antigen testing billed through health plans increased at the end of 2020 but has since remained at a relatively consistent rate, flexing slightly with the reported surge events. Antibody testing fell out of favor among clinicians, as these tests were not designed to address active infection.[8] The volume of combination panels (eg, COVID-19 and flu) remained low despite the

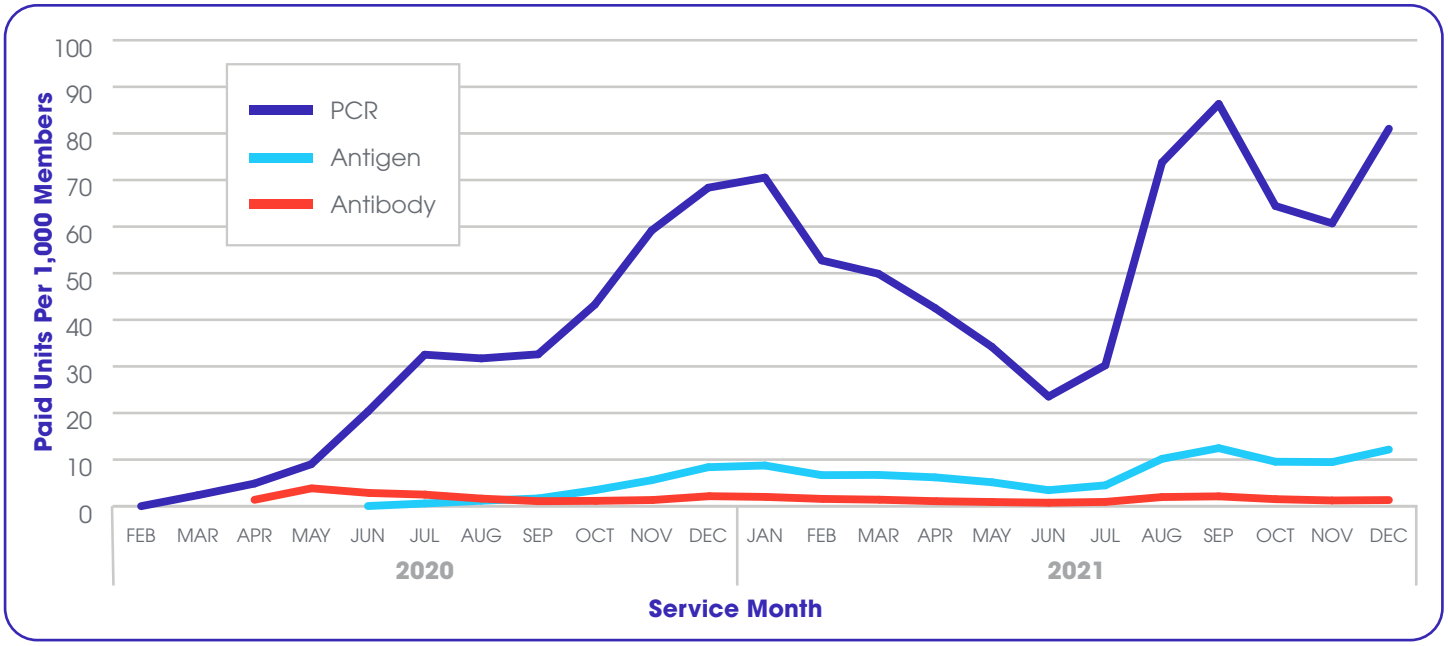

Figure 1: COVID-19 Testing Monthly Paid Units Per 1,000 Members by Type of Test

annual return of the flu. PCR was the main driver, and independent labs performed the majority of COVID-19 testing. Physician offices were limited in the types of lab tests they could perform. Note that the data does not show the high number of rapid antigen tests administered by government testing centers or purchased over the counter.

By the end of 2021, direct-to-consumer antigen tests were widely available to the public at grocery stores, pharmacies, and by mail. However, supply chain roadblocks and expired testing kits intermittently contributed to sparse or inconsistent availability of rapid diagnostics, particularly during the Omicron variant surge.[9] Combined with price gouging for over-the-counter tests, people proactively sought out prescribed PCR or Ag tests when experiencing symptoms or having been in close contact with other exposed individuals. As a result, many people turned to tests that could be billed through health plans.

Most People Had 1-3 COVID-19 Lab Tests, but a Few Members Drove Excessive Testing

According to Avalon data (Figure 2), 95% of members who had a health plan–billed COVID-19 test encounter in 2021 had 1-3 tests performed.

The statistical outliers, however, present a serious challenge to payers, as 42 members within Avalon's data were responsible for an astronomical 2,712 total tests. The Coronavirus Aid, Relief, and Economic Security (CARES) Act prohibited health plans from imposing limits and from most management over members' use of COVID-19 tests during the emergency response. Overutilization by a minority had major cost impacts on the system, which in turn triggered fraud, waste, and abuse inquiries and lawsuits because of the outsized impact this utilization represented. Avalon's scientific-based policy combined with Avalon's Routine Test Management program provides effective monitoring of excessive use of COVID-19 tests and, once the public health emergency rules expire, can be leveraged by health plans to actively limit unnecessary and inappropriate testing before claims are paid. This can thereby reduce the amount of "pay and chase" a health plan may need to exert to prevent such unnecessary and inappropriate testing.

Are checks and balances important?

An astronomical 2,712 COVID-19 tests were performed for only 42 members at approximately $270,000.

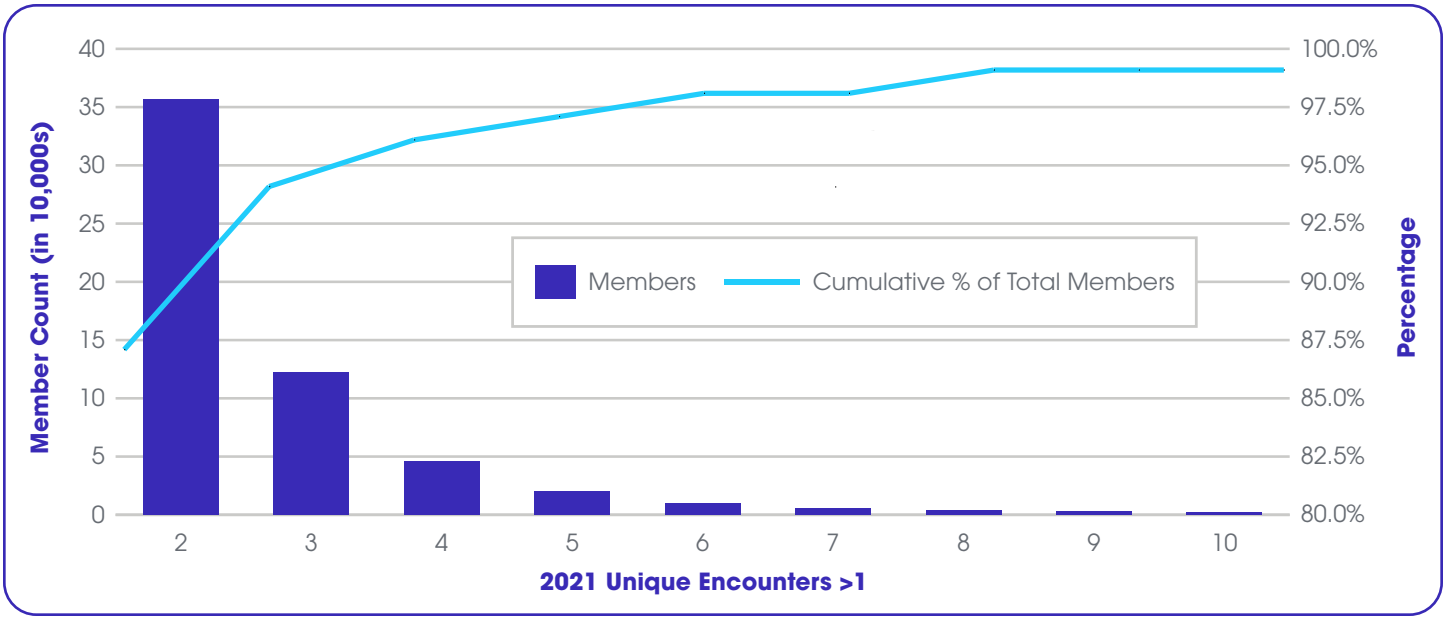

Figure 2: 2021 Histogram of Additional COVID-19 Testing Encounters in Population of Patients Who Received at Least One Test

Lack of Competitive Pricing for COVID-19 Testing

While the Centers for Medicare and Medicaid Services (CMS) tied pricing for COVID-19 testing to CPT codes, commercial health plans' obligations for pricing are tied to provider contracts, out-of-network fee schedules, and established charge rates. The resulting variability in pricing by type of test is shown in Figures 3 to 6.

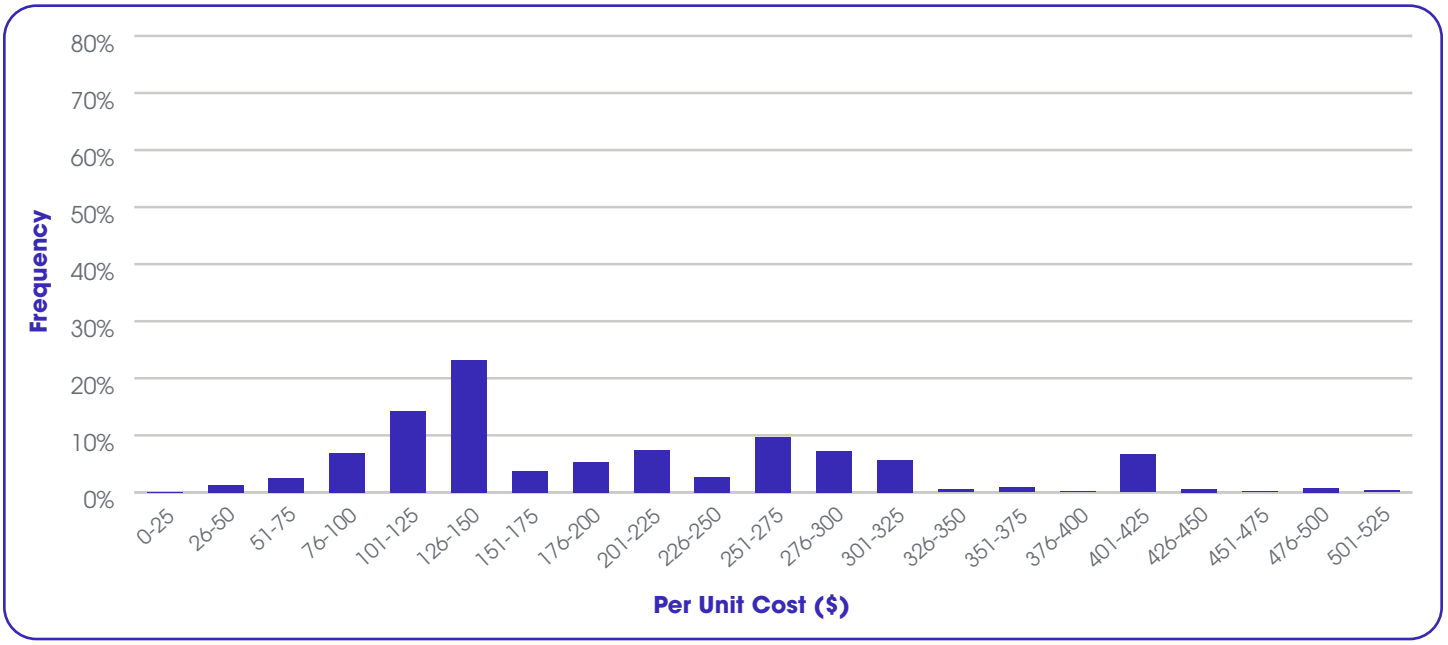

Figure 3: Histogram of Panel Test Cost for 2021

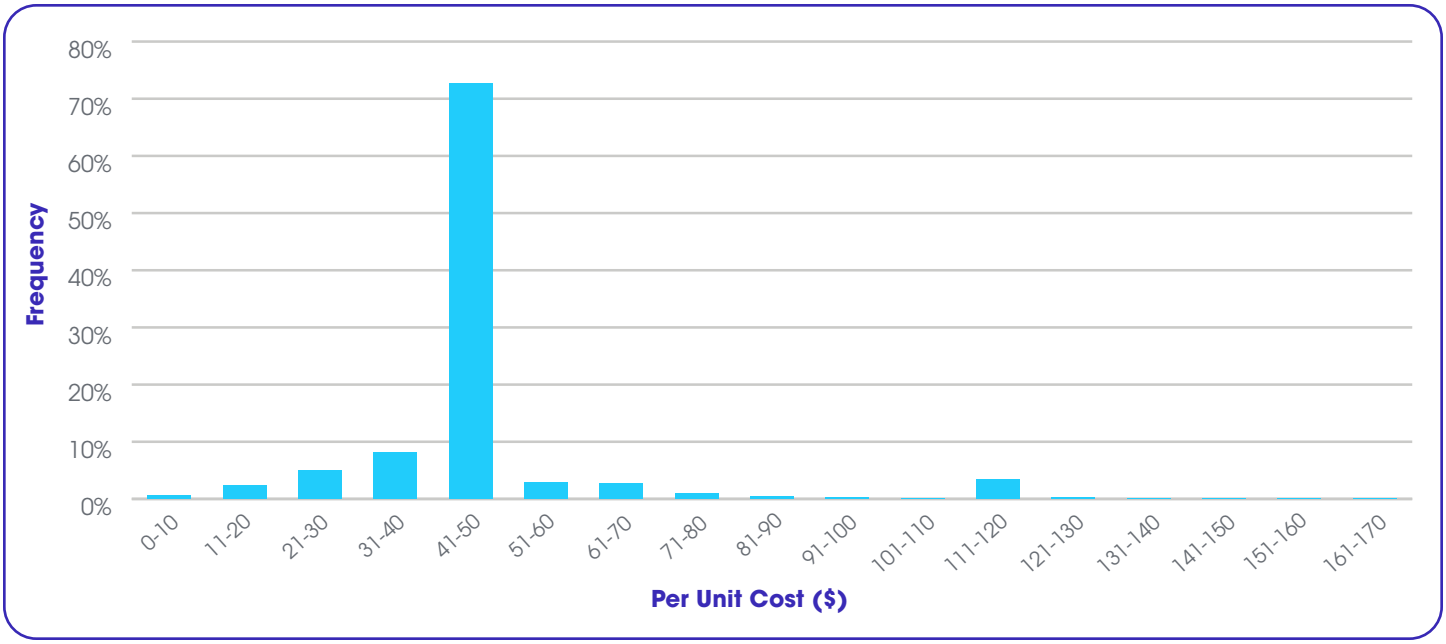

Figure 4: Histogram of Antibody Test Cost for 2021

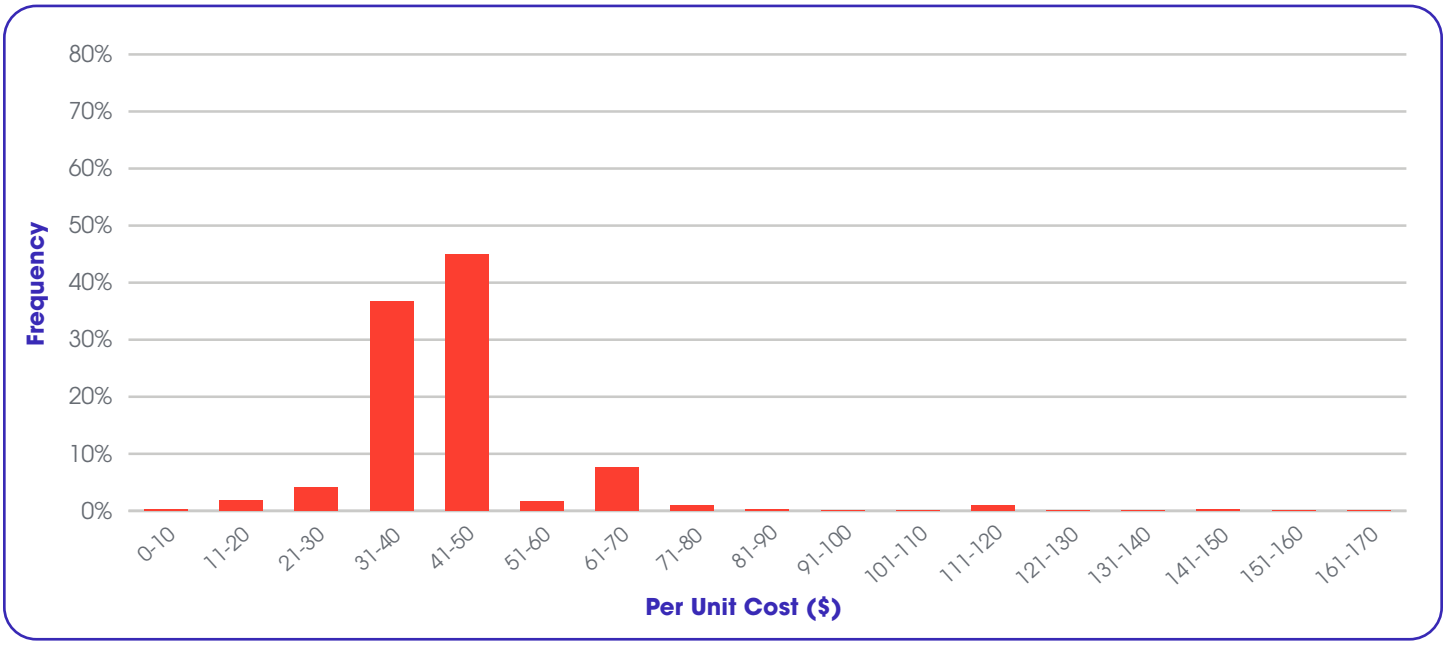

Figure 5: Histogram of Antigen Test Cost for 2021

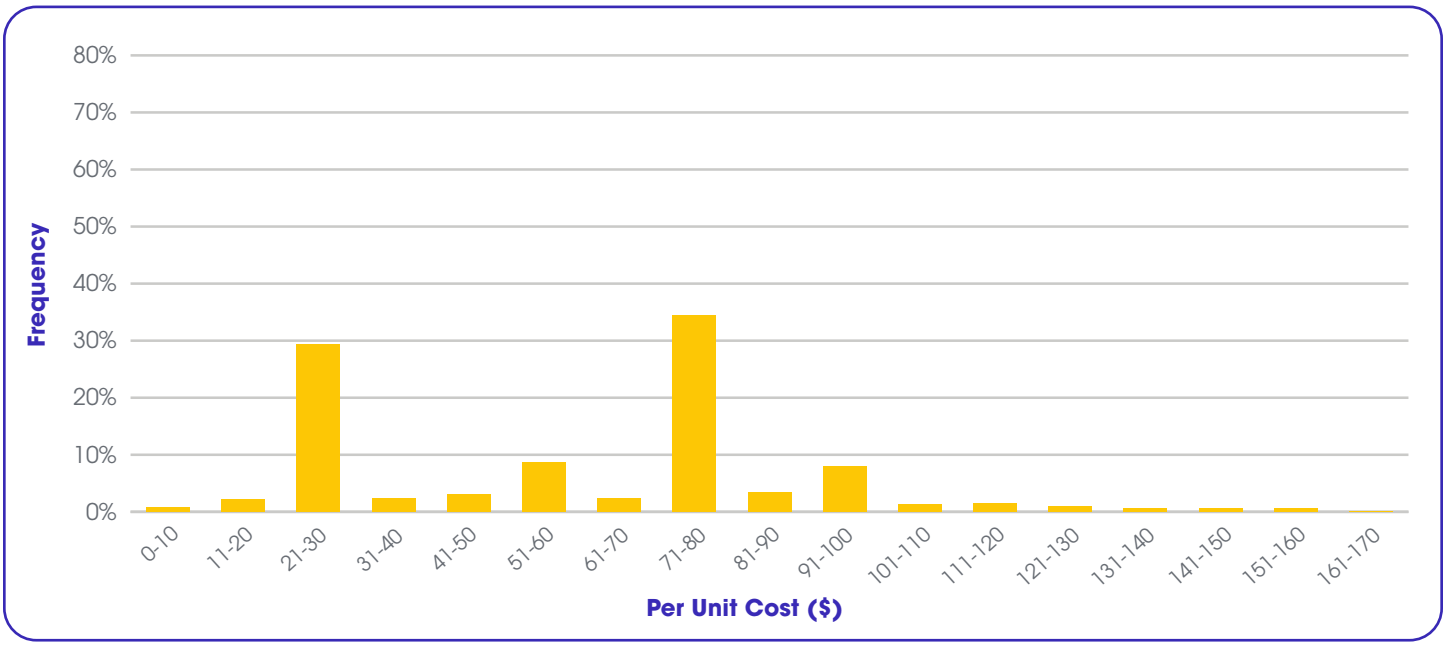

Figure 6: Histogram of PCR Test Cost for 2021

Key Takeaways (Figures 3, 4, 5, 6):

- PCR tests fluctuate widely in the cost billed, as evidenced in Figure 6, with most PCR tests bucketing into one of two bins: either the $21-$30 range or the $71-$80 per unit range.
- Antigen tests vary in cost from as low as $11 per test to as high as $120 per test. Most antigen tests cost between $31 and $50 (Figure 5).
- Antibody tests generally fall between $41 and $50 per unit, with markedly less variability by comparison (Figure 4).
- While most panel tests fall in the $126-$150 cost range (Figure 3), panels have high variability in pricing. Of the four COVID-19 tests, panel testing shows the widest range of differential pricing, between $26-$500 per unit cost (a 20-fold range), with an average of $206 per test.

Finally, the legal/regulatory environment contributed to the spread of allowed costs for tests. Antigen tests can be purchased over the counter for $12, but at least one test was billed to a health plan at an outlier cost of $812 (not shown in graph). The lack of constraints and controls in this area is evidenced by the range between the max allowed per unit and the minimum allowed per unit, particularly with

Panel testing shows the widest range of differential pricing, between $26-$500 per unit cost (a 20-fold range).

the range of panel testing costs. The importance of regulating cost for tests widely used as COVID-19 diagnostics cannot be overstated, but government regulations currently limit the competitive pricing of tests until further guidance. Health plans have learned significant lessons in 2021, especially the necessity of being more actively involved in public policy and the education of lawmakers. A new multistakeholder alliance, called the Laboratory Access & Benefits (LAB) Coalition, is educating and advocating about pivotal policy issues related to lab testing.

LAB
LABORATORY ACCESS & BENEFITS COALITION

By bringing together payer, manufacturer, patient, consumer, provider, laboratory professionals, and healthcare thought leaders, the LAB Coalition is committed to advocating for legislative and regulatory solutions that can be brought to the attention of Congress and the Administration. Policy priorities include lab test coverage and prices, FDA oversight of lab-developed tests, and automation of prior authorization. Join here: https://www.labcoalition.org/contact.

COVID-19 Changed the Laboratory Market Landscape

Direct-to-Consumer Testing Increased. One of the biggest market changes due to the COVID-19 pandemic was the massive acceleration in direct-to-consumer (DTC) testing. An entire menu of tests is available for direct access by consumers, split into two high-level categories: (1) at-home collection tests and (2) self-performed tests. At-home collection involves collecting a sample, then sending the sample to the lab for processing. Self-performed tests involve the patient collecting his or her own sample, conducting the test, and reading the result independently—but these vary in accuracy and reliability.[10]

"COVID-19 brought home-based testing into focus for a greater population," said Mike Snyder, EVP of Avalon Networks. Convenience, confidentiality, and cost are three reasons this type of test has gained popularity with consumers. The North American direct access testing market is projected to grow at an approximately 22.6% compound annual growth rate over 10 years. One firm predicts it will reach a valuation of $8.8 billion by 2031 (from $929 million in 2020), establishing it as a sector to watch.[11]

Varied and inconsistent quality from direct-to-consumer tests may result in false concerns and consequential member expenses for health plans.

The bottom line: an increase in over-the-counter disease testing is a lingering impact of COVID-19, with undetermined impacts to health plans moving forward. The federal government has established a precedent that health plans, in the case of COVID-19, will reimburse for DTC tests. Current pandemic-related legal obligations require commercial health plans to reimburse as well, conditioning the public to expect similar (or expanded) DTC test coverage and reimbursement in the future. In many cases, a significant percentage of costs for DTC tests will be borne by the consumer, however, health plans will need to maintain scientific oversight and coverage decisions regarding DTC testing. Health plans will need to consider quality when constructing policies that address DTC tests; otherwise, lower-quality tests may result in false concerns and consequential member expenses for health plans.

Monitoring Lab Test Results Is Challenging. A patchwork system of government and individual COVID-19 testing in 2021 led to an inability to accurately account for all COVID-19 cases, especially the Omicron caseload, as there was no cohesive strategy for counting or capturing results from rapid home tests. A lack of coordination between local and federal officials, health professionals, and health plans in the face of a rapidly transforming crisis meant there were gaps and areas for industry-wide improvement. As the DTC market grows, the challenge of integrating test results from home-based tests will become more important.

The expectation that COVID-19 will become endemic is now a reality; seasonal variation that mimics the pattern of flu virus is evident in testing trends.

Avalon's Response to COVID-19

Evidence-Based Clinical Policy. Avalon helped clients address challenges related to COVID-19 through lab testing services and guidance, while Avalon's Clinical Advisory Board and executive team kept a finger on the pulse of scientific advancements. To assist clients with rapid changes brought about

by COVID-19, Avalon took immediate action by developing an evidence-based COVID-19 testing policy. Avalon then updated the policy concurrently with advances in testing and clinical understanding, including research-based coverage criteria. Though coverage was unable to be implemented during the public health emergency, upon expiration, Avalon's clients will have ready guidance and the necessary operational systems to ensure that COVID-19 testing adheres to policy.

Educational Insights on Changing Landscape. Throughout 2021, Avalon offered webinars designed to inform the public and insurers about public policy issues, trends, and laboratory performance. Avalon hosted several COVID-19–related events as part of its Avalon Lab Insights Forum series, as well as issued timely newsletters and bulletins as part of Avalon's Washington, D.C., Policy Newsletter series. To keep clients informed about the latest information on health policy and related legal changes, coding, and coverage requirements, as well as science and lab science quality, these reports included information and insights gleaned from Avalon's proprietary data, providing unique information complementing other available resources.

Avalon's Commitment: Science Is the True North. Throughout the uncertainty and ambiguity of COVID-19 testing, Avalon has maintained science as the guiding principle. Avalon has shared insights derived from reasoned analysis of scientific data, including recommendations for the appropriate use of different test methodologies (and frequencies). As prices have fluctuated for tests offering equivalent test outcomes (eg, positive or negative for COVID-19), Avalon has worked with clients to identify outliers and egregious pricing practices.

Avalon developed and updated its science-based policy—"Coronavirus Testing in the Outpatient Setting"—for health plans to consider for adoption along with Avalon's webinar resources.

MARKET AND PUBLIC POLICY DRIVERS: IMPACT ON GENETIC TESTING

COVID-19 drove up medical spend for health plans through uninhibited utilization and, occasionally, excessive provider prices. While overall utilization has been decreasing since 2019 (Figure 7),

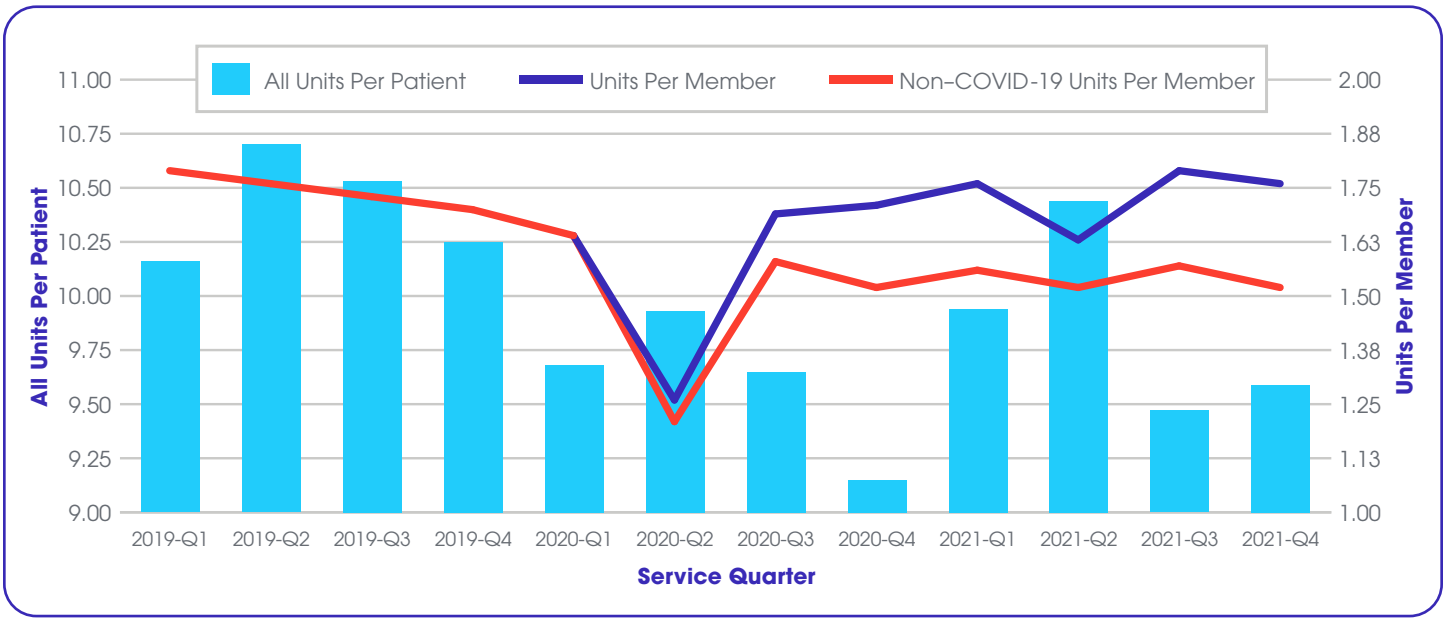

Figure 7: Quarterly Paid Units Per Member and Per Patient, Relative to Q1, 2019

numerous market and public policy changes threaten to increase overall medical spend and impact operational costs to manage laboratory benefits. Different drivers affect genetic testing compared to routine testing, and both require the attention of health plans.

Molecular Diagnostics (MDx) and Genetic Testing

Molecular and genetic testing can determine infections and disease at early stages, helping physicians identify more precise treatment and prevent challenging and costly healthcare conditions. A wide menu of new molecular diagnostics (MDx) and genetic tests surfaces each year. Health plans face a daunting task moving forward. They need to navigate a tsunami of novel tests and methodologies, sift through the clinical support for distinct tests, and create new policies with streamlined coverage criteria.

The Office of the Inspector General (OIG) flagged that Medicare spending on MDx and genetic tests is rising exponentially. In the past few years, "total Medicare payments to laboratories for genetic tests quadrupled." Specifically, in 2015, total spend reached $289 million for genetic tests, versus $1.36 billion in 2019—a greater than four-fold increase in costs. In addition, the OIG also reported that the number of genetic testing procedure codes covered by Medicare increased by 161%.[12]

Over 55 cancer drugs commercially available have a companion diagnostic, and Avalon is pioneering novel laboratory value-based solutions to optimize the impact of oncology care.

Molecular oncology testing is a quickly growing subset of the genetics marketplace. While many molecular oncology tests face high claims denials from health plans (approximately 50% of molecular oncology test claims are denied),[13] the molecular and genetic testing markets continue to gain market share through heavy sales tactics directed toward prescribers and by marketing to patients directly. During the period of 2016 to 2019, Medicare payments to laboratories for genetic tests increased by 302%, rising from $351 million to $1.41 billion.[12] Since Medicare's population has higher incidences of cancer and many oncology therapies marketed in 2021 required a genetic assessment of the tumor prior to authorization of the pharmaceutical, an increase in growth can be anticipated. Moreover, the development and evolution of precision medicine and targeted therapies underscore the need for companion diagnostics.

During the period of 2016 to 2019, Medicare payments to laboratories for genetic tests increased by 302%, rising from $351 million to $1.41 billion.[12]

Genetic testing in commercial health plans has been increasing significantly due to the increase in marketed genetic tests, the reduction in pricing over time, and increased consumer demand. The four-year trend in commercially paid genetic tests in Figure 8 reflects a 17% compounded annual growth rate, contrasted against Medicare's elevated rate

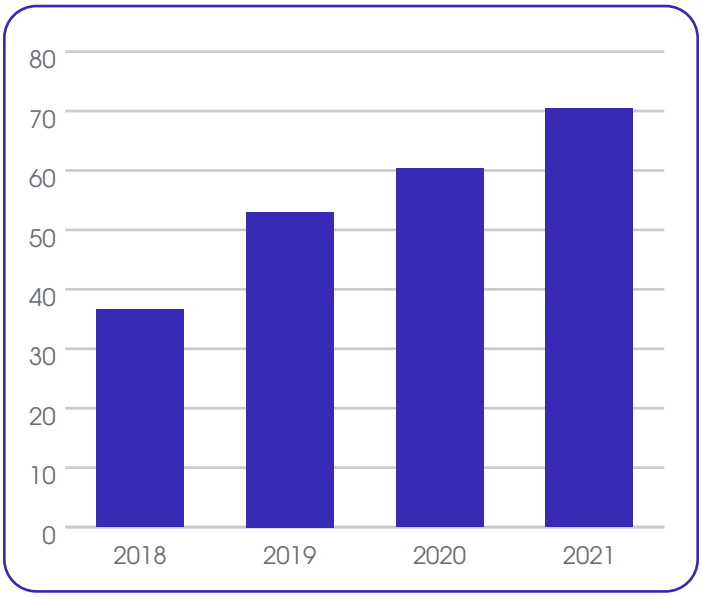

Figure 8: Ordered Genetic Testing Units Per 10,000 Members by Year

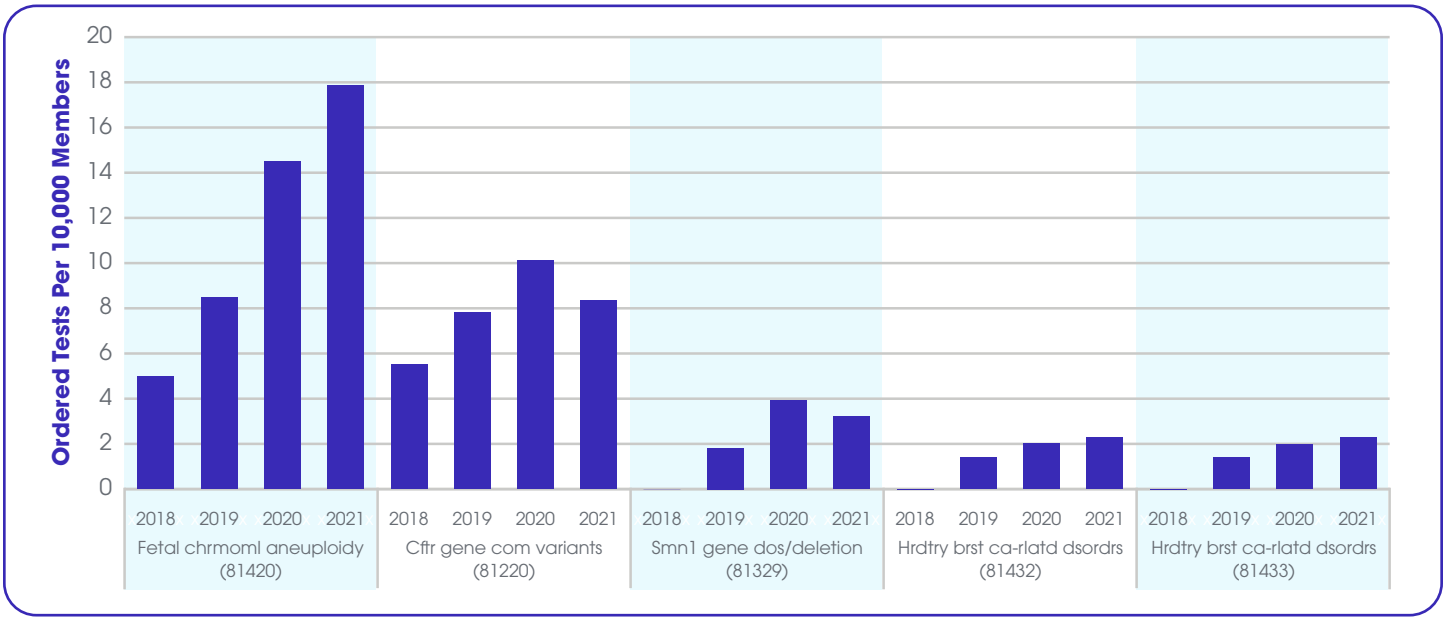

Figure 9: Top 5 Genetic Tests, Number of Units Per 10,000 Members by Year

of growth of nearly 50%. As shown in Figure 9, the dominant testing in the commercial population revolves around preconception and prenatal testing.

Health plans will need to incorporate significant changes to policies and operational practices as genetic correlations between complex traits and diseases are identified. This will include integrating precision medicine (ie, genetic variations associated with enhanced therapeutic response) into care practices. The goal is to ensure members receive the most appropriate care.

ADLTs: Advanced Diagnostic Lab Tests

ADLTs are highly complex tests that generally combine measurements of DNA, RNA, and/or other proteins into an algorithm to produce a patient-specific result relevant to the diagnosis or subsequent treatment of a clinical condition. In almost all cases, the combination of measurements is not intuitively obvious, or the algorithm may be opaque or not available to the ordering provider, resulting in challenges to explain the test result and to its integration into clinical decision making. Often, clinical trials are required to demonstrate the efficacy of the ADLT and its appropriate use in medicine.

Establishing the clinical value of an ADLT in an ever-growing marketplace is a challenge for health plans, who need to determine which tests provide the best patient outcome and thus policy coverage when there is a proliferation of thousands of tests. Payers must also create policies and guidance as well as genetic test reimbursement processes that add value. Many of the tests will use an unlisted procedure code for billing purposes, increasing operational challenges in assessing the necessity of the test and the pricing. Generally, these tests require individual patient analysis to determine medical necessity and appropriateness, and therefore they are subject to prior authorization or other utilization management to mitigate wasteful and abusive ordering.

Additionally, CMS establishes its price as the median market rate negotiated by the laboratory for the ADLT after three quarters on the market. This pricing structure incentivizes the laboratories to negotiate high prices for their tests, leaving health plans with uncertainty about the appropriateness of the pricing. As the laboratories negotiate higher prices, the CMS price will increase, which provides further reasoning for increasing prices.

Without uniqueness to the ADLT codes for billing purposes, operational inefficiencies will occur in

the determination of medical necessity and claims adjudication. High prices due to how ADLT pricing is established then further compound the problem of increased processing costs, resulting in costly ADLT adjudication for health plans.

Electronic Prior Authorization (ePA)

For years, federal policymakers have signaled their interest in automating the prior-authorization process. At the agency level, work is ongoing to generate electronic prior-authorization (ePA) rules that would require payers to streamline their process by embedding it within providers' electronic health record systems. Congress is also prioritizing this issue, with bipartisan and bicameral support for the legislative proposal called the Seniors' Timely Access to Care Act. Both approaches focus on increased automation and reduction of the burden of prior authorization. In 2022, we may see one or both realized, which is likely to have an impact on lab testing as well as on coverage of treatment that depends on lab results.

Avalon's Genetic Test Management Solution

The Genetic Test Management (GTM) program provides health plans with solutions to overcome the challenges presented by genetic tests, molecular diagnostic tests, and ADLTs. First, Avalon focuses on science, leveraging internal and external laboratory experts, the evaluation of new genetic tests, and ADLTs, to create robust, scientific, and clinically sound policies and coverage criteria. As new tests launch into the market, policies are updated in response. A provider-friendly prior-authorization portal minimizes abrasion while the authorization process can inform physicians of genetic testing requirements. Finally, the specificity of codes for genetic tests and ADLTs streamlines prior authorization, claims adjudication, and pricing activities.

GTM Prior Authorization. Prior-authorization services generally focus on high-priced, lower-volume genetic testing and involve evaluation and authorization prior to the service being rendered. The evaluation assesses the clinical situation and history of the patient against coverage criteria derived from the health plan policies. Authorizations are granted when the patient's situation matches the coverage criteria. Alternatively, when the criteria on the policy fail to match the patient's case, the authorization is denied, and the patient and physician are notified.

Avalon serves clients with evidence-based policies, prior-authorization services, and automated policy enforcement during claims adjudication—a full suite of options for lab benefit management.

In Table 1, the top five procedures by percentage of total prior-authorization denials are listed. As shown in Table 2, the top five requested prior-authorization procedure codes represent 36.9% of all approved services.

% of Total Units Determined Noncompliant	
Procedure Description	**%**
Unlisted molecular pathology (81479)	8.8
Mopath procedure level 7 (81406)	4.4
Hrdtry brst ca-rlatd dsordrs (81433)	3.9
Hrdtry brst ca-rlatd dsordrs (81432)	3.9
Mopath procedure level 6 (81405)	3.5
Total	**24.5**

Table 1: Top 5 Codes Determined to Be Noncompliant by Prior Authorization

% of Total Approved Prior-Authorization Request Units of All Approved Units	
Procedure Description	**%**
Smn1 gene dos/deletion alys (81329)	10.0
Hrdtry brst ca-rlatd dsordrs (81432)	9.9
Hrdtry brst ca-rlatd dsordrs (81433)	9.9
Unlisted molecular pathology (81479)	3.8
Cftr gene com variants (81220)	3.4
Total Approved Units	**36.9**

Table 2: Top 5 Codes Approved by Prior Authorization

While some providers order tests with highly specific codes that are only applicable to a single gene or analyte, other tests use a nonspecific code. Many of these nonspecific codes flow through prior authorization for approval. These multipurpose codes are not readily linkable to specific tests. (For example, unlisted molecular pathology 81479 seen in Table 2 can be one of any number of technologies or procedures designated as molecular pathology.) Through the application of more specific code sets for genetic tests and ADLTs, Avalon continues to improve and refine the prior-authorization process. The rollout of these specific codes for molecular diagnostics and ADLTs throughout 2023 will help laboratories and payers by providing increased transparency to laboratory billing of tests. The use of specific codes for tests will also streamline the prior-authorization approval process.

GTM Automation. When specificity of the billing code and discrete, population-based criteria for evaluation of laboratory services coincide, Avalon can eliminate the need for prior-authorization processes completely. In those instances, post-service adjudication can be accomplished through Avalon's proprietary technology. The result: providers requesting and billing for these procedures realize the benefits from easier claims adjudication for their services (due to no prior authorization) and patients receive their treatment in a seamless and timely manner.

MARKET AND POLICY DRIVERS: IMPACT ON ROUTINE TESTING

The Protecting Access to Medicare Act (PAMA)

While Congress delayed further reductions in laboratory fee schedules through 2022, the Medicare Payment Advisory Commission (MedPAC) expects cuts across the lab industry will be 24% on average by 2025, primarily impacting nongenetic, routine laboratory tests.[14] As Medicare rates decline, health plans should recognize that clinical laboratories will respond with less appetite for reductions in their commercial fee schedule contract. Further, negotiated reductions in routine test prices will negatively compound future prices because of PAMA, and although the annual price reductions are capped each year, the cumulative result is material to laboratories' revenues.[15]

A policy change to PAMA was introduced in Congress called the Saving Access for Laboratory Services Act (SALSA). The purpose of SALSA is to soften the anticipated lower lab reimbursement rates when PAMA is fully implemented. It would do this by changing the PAMA formula—requiring a more balanced statistical sample of representative, private payer data from independent laboratories, hospital laboratories, and physician office labs. As of this writing, it is unclear whether SALSA will be considered by Congress, but Avalon will be monitoring this activity.

Outpatient Hospital Lab Headwinds

Hospital laboratory settings account for a large fraction (between 18% and 55%) of lab testing volume, depending on the market. The trend toward consolidation in the lab industry has been directly led by reconfiguration of reimbursement schedules and other lab industry pressures. Structural changes due to fragmentation in the laboratory industry have occurred as mergers and acquisitions favor the top players in the market. For the past few years, outpatient hospital labs have struggled to provide favorable reimbursement rates that grow their outreach business, and many of these labs have been sold to other private laboratories. In addition, the vertical integration of physician offices into hospitals, that is, the direct ownership and buy-out by hospitals of physicians' offices, has consistently increased outpatient hospital lab costs and Medicare reimbursements.[16]

Wasteful Spending Due to Price Discrepancies Between Places of Service

Where the member receives laboratory services materially impacts the unit price. Hospitals significantly outpace physician office labs and independent laboratories in prices for the same lab tests with the same quality. In three major test categories, Chemistry (eg, enzymes, proteins, vitamins), Organ or Disease-Oriented Panels (eg, metabolic panels, lipid panel, renal function panel), and Therapeutic Drug/Drug Assays (eg, presumptive, definitive, and specific drugs), hospital prices overshadow those of independent laboratories (Figure 10). Further, the rate of increase in hospital rates from 2018 to 2021 is concerning.

The same diagnostic lab test costs 2-4x more in a hospital outpatient setting.

Test type categorizations shown in Figure 10 blend all tests within the category. Outpatient hospital lab service costs for individual lab procedures showed an astonishing difference when compared with services rendered in independent labs. In many cases the average cost at a hospital lab was more than 200% more than the average cost at an independent lab (see the CPT codes for metabolic panel testing at more than 400% higher in Figure 11).

These striking differences in costs across laboratories provide a significant economic incentive for members to select lower-priced places of service. Until recently, consumers lacked knowledge of laboratory service pricing, hindering their ability to make informed choices. Recent price transparency legislation promises to empower consumers.

Price Transparency & No Surprises Act

In 2020, CMS issued two rules for health plans and hospitals, respectively, that require healthcare service prices to be posted publicly.[17] Shortly thereafter in the same year, Congress passed the No Surprises Act,[18] which, aside from its primary purpose to prohibit surprise medical bills, contained several price transparency provisions that overlapped with the other two rules. Rules and regulations for compliance with the Price Transparency Rule and No Surprises Act were phased in throughout 2021 and will continue through 2022 and 2023.

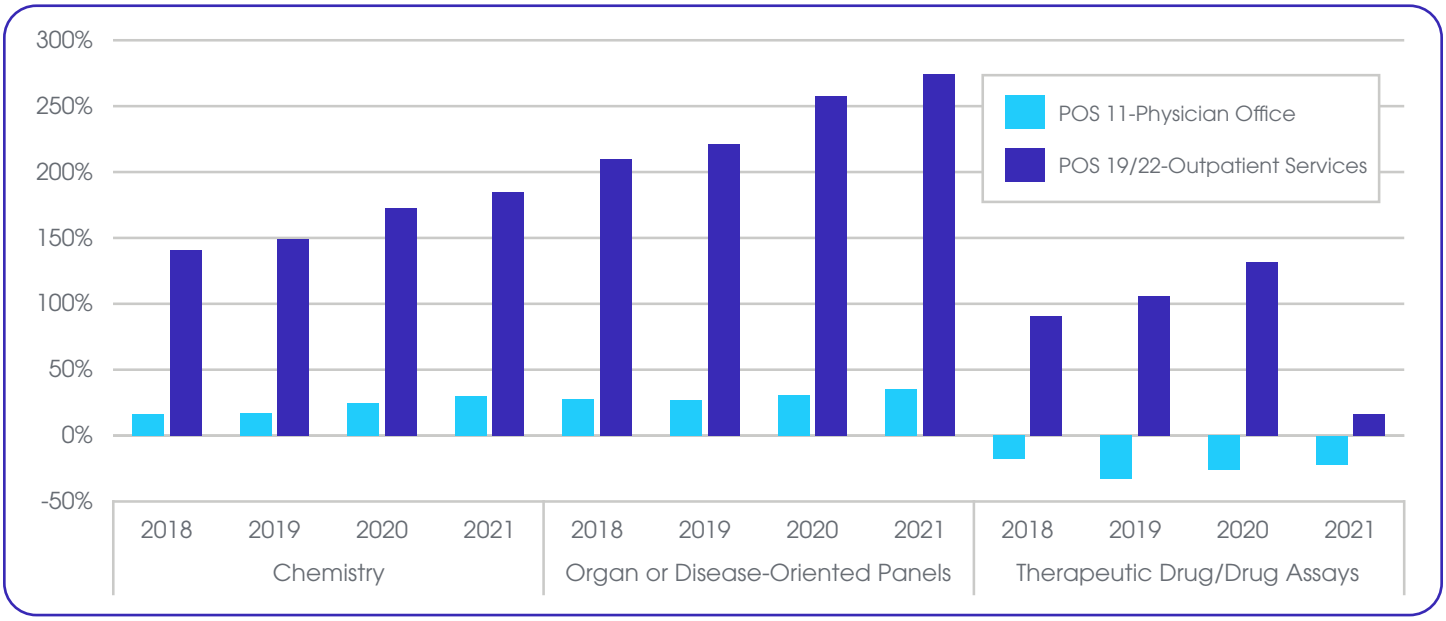

Figure 10: Percent Change in Average Cost Per Unit by Test Type, Year, and Place of Service (POS), Relative to Tests Rendered by Independent Labs

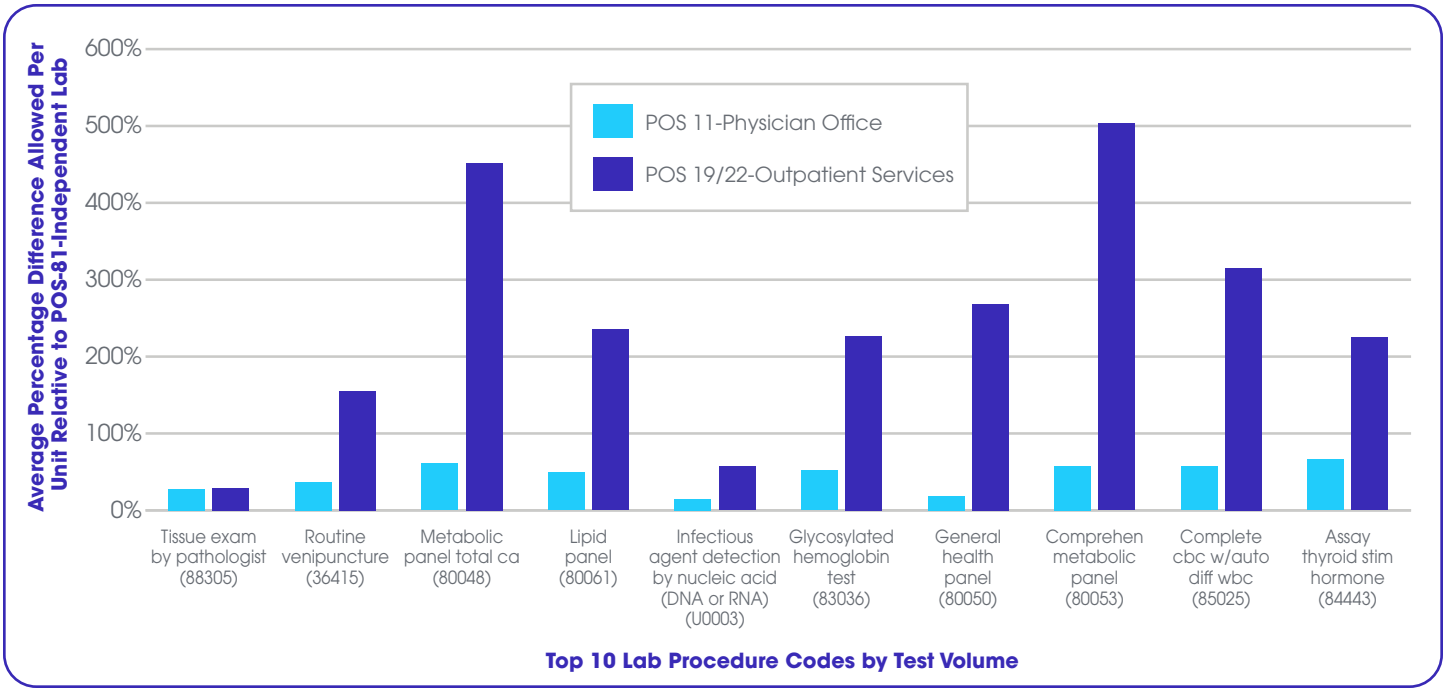

Figure 11: Percent Difference in Average Allowed Payments for Independent Labs for 2021's Top 10 Procedure Codes

The purported effect of these laws is to empower consumers of healthcare services. The pricing differences between hospitals and other providers can be significant (see Wasteful Spending Due to Price Discrepancies Between Places of Service above). Under the new laws, providers are required to provide estimates for services, and payers are obligated to publish negotiated rates. Other provisions, such as advanced explanation of benefits and laboratory service estimates in pass-through billing scenarios, are forthcoming.

Compliance With Health Plan Policies Varies

Though independent labs tend to be more competitive when it comes to test pricing—as opposed to hospital outreach labs—independent labs still have high rates of nonadherence before implementation of Avalon's comprehensive Routine Test Management (RTM) solution. In this context, nonadherence refers to the ordering of diagnostics that fail to comply with the health plan's published policies, which document the best-practice guidelines and evidence-based medicine.

Independent labs process more nonadherent test units, as evidenced by Avalon data in Figure 12. Through lab benefit management, lab and physician providers receive input on which types of tests are

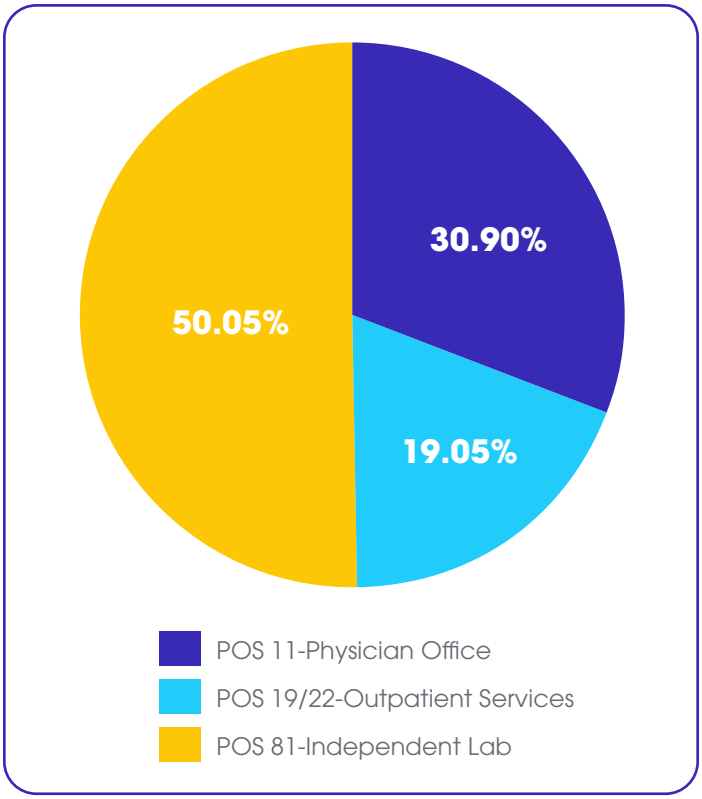

Figure 12: Percent of Total Nonadherent Units by Place of Service (POS)

inappropriate or outside of evidence-based policies, which leads to provider behavior modification that drives member-centric, outcome-based care. Ordering pattern adjustments by providers can result in lower medical spend by the plan and lower out-of-pocket expenses for members.

Avalon's Routine Test Management Solution

Routine tests are low-priced, high-volume services ubiquitous in healthcare and the most often-used medical benefit. Currently, they typically represent 90% of the outpatient lab spend. Avalon's comprehensive Routine Test Management (RTM) solution ensures payers and members are receiving appropriate tests, while reducing unnecessary, extraneous testing. Using the same robust process for policy development as GTM, the RTM policies lead to rules applicable to rapid evaluation through an interface with the health plan's claims adjudication system. Fast response times and secure encrypted transactions ensure seamless operation within the health plan's environment. Collectively, the policies and integration provide a high-quality process for the evaluation of lab services against the health plan's policies.

ANNUAL TRENDS IN OUTPATIENT LABORATORY UTILIZATION AND SPEND

Beyond COVID-19's impact on volume and medical spend, total non–COVID-19 units per member declined from 2018 to 2021. Correspondingly, the total laboratory expense decreased before including the impact of COVID-19. The long-term consequences due to reduced testing are undetermined. Current reductions may forecast higher future medical expenses due to deferrals of both screening and disease detection.

Figure 13 shows annual utilization including a reduction in laboratory testing from pre-pandemic levels. The chart supports the long-term decrease in non–COVID-19 paid units. Whether the reduction in non–COVID-19 volume is permanent or is an artifact of the pandemic and will return to prior levels remains to be seen.

Tracking downward with the lower utilization are allowed amounts per member. Allowed amounts per member increased only when including COVID-19 testing (Figure 14). Allowed amounts measured $225 per member pre-pandemic. In 2021, the allowed amount per member increased

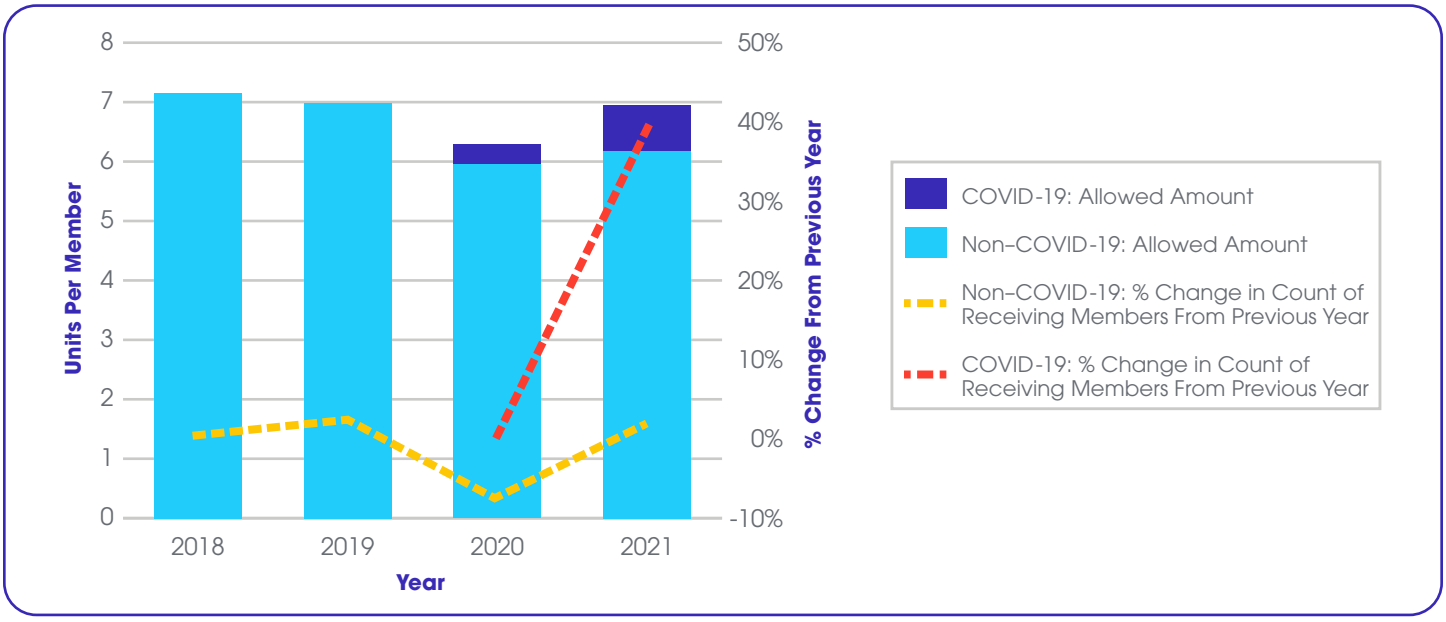

Figure 13: Units Per Member Per Year

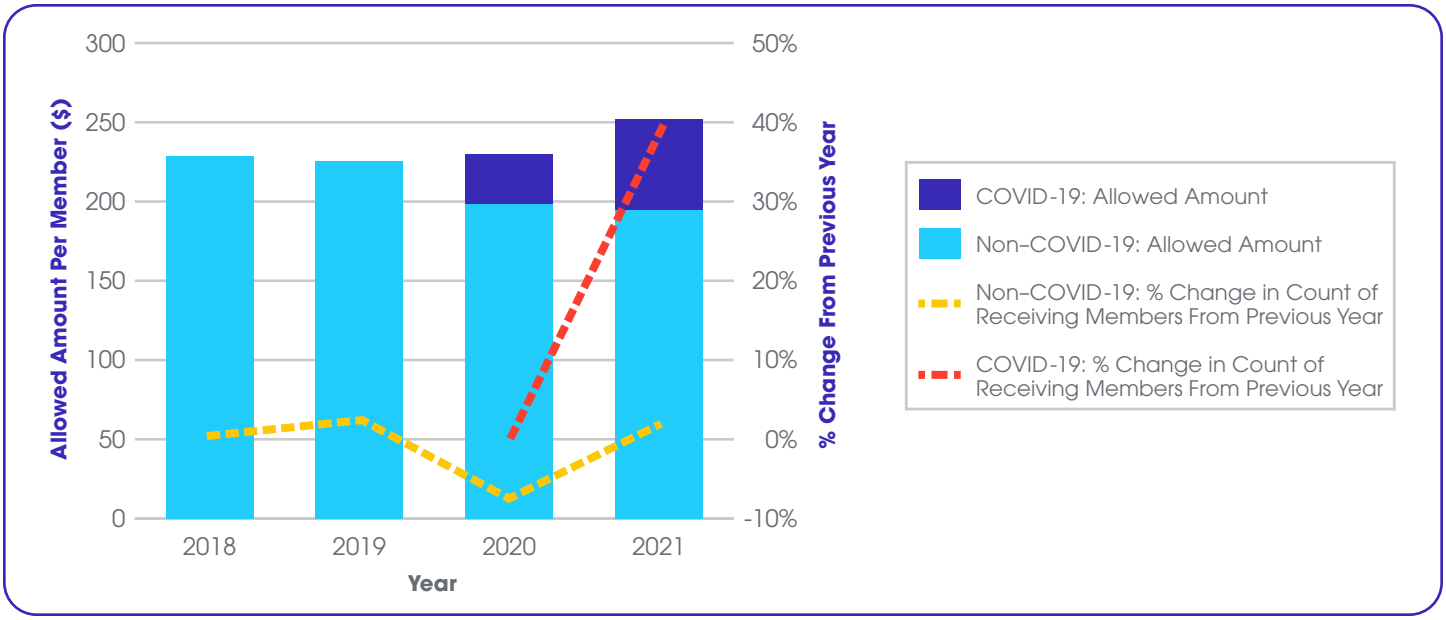

Figure 14: Allowed Amounts Per Member Per Year

to nearly $250, of which $58 was attributable to COVID-19 tests. Almost 25% of the average testing costs per member were due to COVID-19 testing.

More troubling for payers in the future is the reduction of diagnostic testing, which leads to the identification of diseases and influences care management, suggesting that many diseases may not be caught. This paints a concerning picture for future medical spend as these diseases may be detected later through emergency department visits requiring inpatient stays, resulting in more aggressive interventions and treatments. At least one study on pandemic-related declines in medical care concluded that almost 1 in 3 nonelderly adults experienced "foregone or delayed medical care between August and December 2020 in the United States" (a time when Avalon was seeing ~10% reduction in per-member per-month units). Finally, 2021 data indicate a persistence in the reduction of non–COVID-19 testing.

Nearly 25% of the 2021 average testing cost per member was attributable to COVID-19 testing.

Avalon is the only company with a Routine Test Management solution to ensure that lab testing follows science-based guidelines, resulting in proven cost savings that range from $1-$3 per member per month (PMPM).

Allowed PMPM savings by line of business (LOB) are as follows:

- Medicaid: $0.38–$0.70
- Commercial: $1.35–$1.80
- Medicare Advantage: $1.30–$1.80

AVALON'S IMPACT ON OUR CLIENTS

Increasing value and improving outcomes are key components of Avalon's collaboration with our clients. Health plans such as Blue Cross and Blue Shield of North Carolina (Blue Cross NC) collaborate with Avalon toward this objective.

Blue Cross NC has found success delivering more than $100 million in cost savings from the

implementation of Avalon's lab benefit management services (including GTM, RTM, and Network Management).[19] This ability to reduce costs goes hand-in-hand with improved health outcomes through the reduction of inappropriate lab testing and better adherence to clinical guidelines.

> "Our collaboration with Avalon has given us more insight into improving the quality and reducing the cost of lab services for our members."
>
> — BLUE CROSS BLUE SHIELD NORTH CAROLINA CHIEF MEDICAL OFFICER

Working with health plans across the country, Avalon covers more than 30 million lives and delivers 10%-20% outpatient lab benefit savings. Better management of lab services provides profound benefits to the healthcare system; adjudication of lab testing to provide the right care bolsters an ongoing effort to make healthcare simpler and more affordable for everyone. Strategies that keep best-practice medicine in the forefront while mitigating cost are vital to the triple aim of (1) improving the patient experience of care, (2) improving the health of populations, and (3) reducing per-member costs of healthcare.

LEVERAGING LAB VALUES NEAR REAL-TIME AT SCALE TO IMPROVE HEALTH OUTCOMES

For more than 20 years, health plans have deployed various Population Health Management (PHM) solutions with the goal of improving health outcomes, leading to lower costs (primarily through decreased hospitalizations in the healthier populations). There are numerous scientific papers that demonstrate PHM success in select populations, such as those with diabetes, heart failure, and asthma. Generally, PHM models focus on patients with advanced stages of illness or high-risk populations that have already been hospitalized. Identifying and engaging the "emerging risk" population has remained elusive.

In addition, over the past 10 years, value-based care (VBC) contracts between health plans and physician or hospital health systems are increasing in scope and volume. Scorecards to manage the VBC contracts are often focused on costs and a few retrospective health metrics. But the future of VBC lies with innovative solutions and new ways to measure success that incorporate rich data sources.

Critical to Leverage the Right Data

Both PHM and VBC models rely primarily on historical medical and pharmacy claims data. Although claims data are both well-structured and rich with information including ICD-10, CPT, NPI, and member demographics, claims data are retrospective views of past events. Once a member becomes hospitalized from a chronic disease and is deemed high risk, that patient rarely reverts to normal/low-risk population. Even with various health plan interventions, it is difficult to bend the future cost curve. More emphasis has recently been placed on identifying "emerging risk" members prior to hospitalization, and lagging indicators of hospitalizations are not helpful.

Laboratory data is a leading indicator of an individual's health. This is emphasized by the fact that 70% of medical treatment decisions are based on lab test results. Many PHM and VBC vendors claim that they import laboratory values on their data diagram; however, closer inspection reveals that the lab values imported by these organizations are limited in scope (eg, A1c, LDL cholesterol) and are often imported months after the lab test was performed.

AVALON LAB VALUES MANAGEMENT THROUGH DATA

Avalon has begun capturing, digitizing, and normalizing 100% of outpatient laboratory data in near real-time. Avalon's Lab Data Analytics Engine brings together a large-scale collection of lab values

and proprietary methods to identify at-risk patients and deliver actionable information to health plans, provider groups, and other healthcare stakeholders. Collectively, we are finding new Lab Insights that drive improved health outcomes while lowering the cost to health plans and members. Currently, Avalon has modules in chronic kidney disease (CKD), diabetes, and high-risk pregnancy, and is actively developing modules for liver disease and cancer care.

As opposed to using process measures (eg, whether the physician ordered an A1c last year) and historical events (hospitalizations, emergency department visits) from medical claims, Avalon leverages lab values as a leading indicator to identify emerging risk.

Consider one example of data-based decision making in diabetes care.

Case Study in Diabetes Care

Diabetes requires laboratory testing for diagnosis and successful patient management. When it comes to type 2 diabetes (T2D), there are key process measures that improve outcomes, such as an annual A1c test, annual lipid profile, and biannual checkups. Each process measure serves as a quality-of-care indicator. These measures are surrogates used when laboratory test results are unavailable. A physician's ability to improve health solely using process measures—eg, by monitoring patient response to treatment—is hindered by a lack of information. Lab values provide information that can help achieve the key objective: improving patients' health.

Figure 15 shows a typical distribution of member total cost of care based on categorization of process measures assessing quality of patient care. High-quality categorization includes each of three process measures: (1) at least annual testing for A1c, (2) at least annual lipid panel testing, and (3) at least two physician visits per year. Members classified as low have a single process measure, and those classified as medium have two process measures. There is a remarkable difference in cost per member, slightly more than twice as much, when only one quality process measure is followed, compared to the high-quality category of members who received better care.

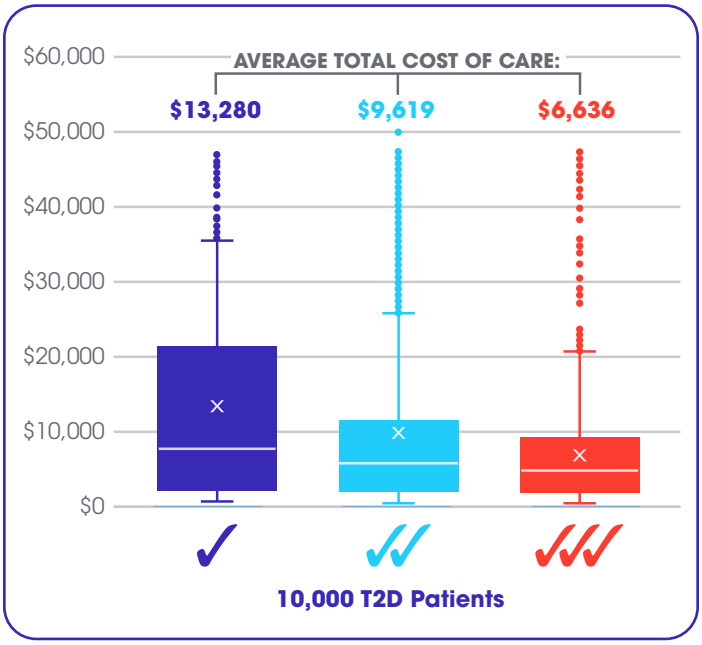

Figure 15: Distribution of Total Cost of Care by Categories of Quality

Process measures can confound the assessment of patient health, as shown in Figure 16. Three noted physicians (RS, MT, and RW) are similarly scored as high-quality providers based solely on process measures as noted above. Incorporating lab values shows that each physician has a quite different ratio of controlled to uncontrolled diabetes (RW > RS > MT). Understanding the health outcomes of patients and using laboratory values enable a better basis for alignment of goals in value-based contracts.

> "Lab values have always been a component of various workflows, but no one has ever been able to do lab values at scale in near real-time—meaning every single lab value that we capture and digitize serves to create a member-centric database."
>
> — RAHUL SINGAL, MD, CHIEF MEDICAL OFFICER

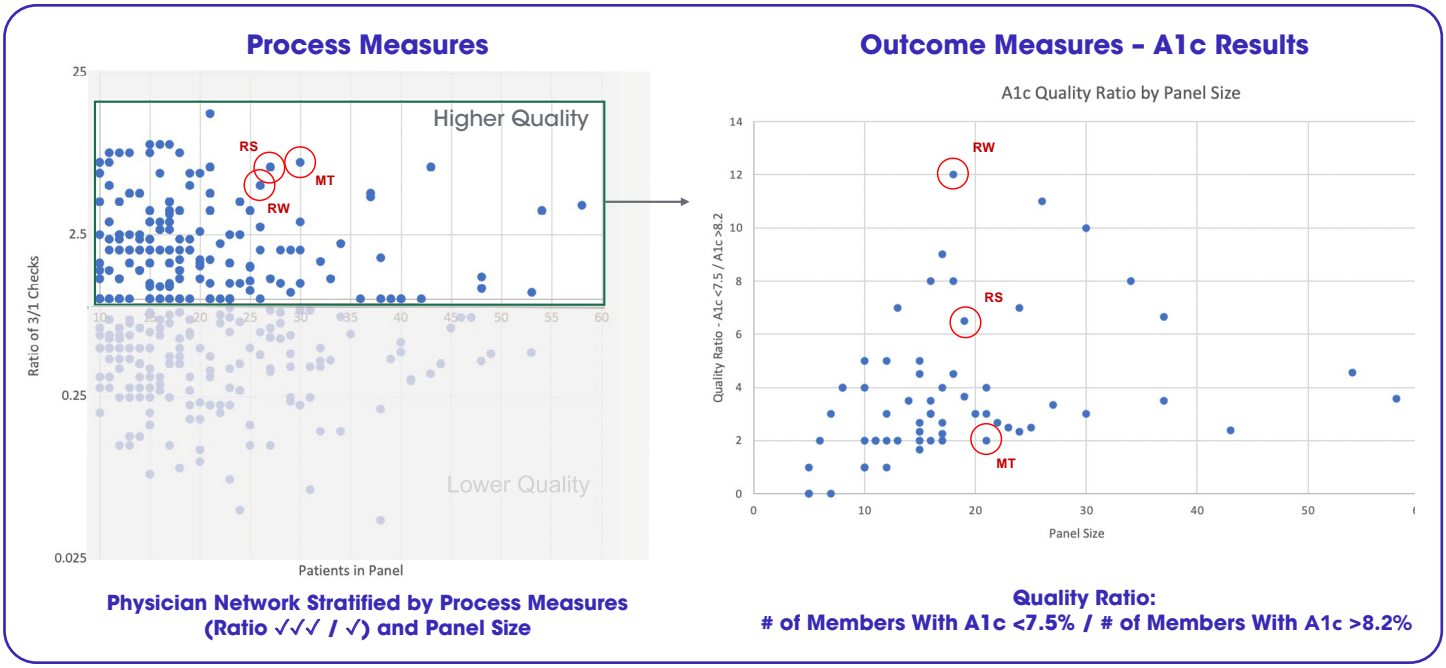

Figure 16: Process vs Outcome Measures in Diabetes

Process Measures shows the ratio of high-quality to low-quality patients in the physician's practice (y-axis) and the number of patients in the practice (x-axis). Outcome Measures is a subset of the high-quality process measures stratified by the quality ratio of patients with controlled diabetes to patients with uncontrolled diabetes. Higher ratios show a healthier patient population.

Avalon's Lab Insights Program

Lab testing is the gateway for appropriate diagnosis and treatment care planning. With at least 70% of treatment planning beginning with a lab test, it is important to start with the right test to generate the right data. Transforming healthcare requires significant increases in the large-scale aggregation and digitization of lab values and the delivery of actionable information to health plans. Lab values, when digitized at scale, provide unique insights into appropriate diagnosis and treatment planning for individuals and populations of members.

Avalon leverages its laboratory science expertise, combined with volumes of lab values, to create unparalleled visibility into the health of individual members, providing not just data, but actionable lab-driven insights in real time to proactively ensure appropriate care and enhance clinical outcomes. Whether the identification of at-risk members, the evaluation of member health for value-based contracting, or the detection of undertested populations of patients, Avalon's one-of-a-kind Lab Values Management provides actionable lab-driven insights for all stakeholders in the healthcare ecosystem. As a result, savings are realized, not just in dollars but also in time, waste, and uncertainty.

It is time to start thinking differently about lab testing's role in advancing value-based care and population health. Digitizing lab results across all care settings and unlocking the potential of lab values are helping health plans reach the triple aim of improving the patient experience, improving the health of populations, and reducing the per-member cost of healthcare. Previously, generalized processes were applied to entire populations and outcomes were assumed as a result, but now, with lab values helping to define outcomes clearly for all healthcare stakeholders, physicians, and health plans, ensuring the proper process is a goal for each individual patient. The ability to drive preventive and proactive patient care is moving from promise to practice.

ACKNOWLEDGMENTS

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