# 2024 LAB TREND REPORT

Key Points and Highlights





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From the Desk of Bill Kerr, MD

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From the Desk of Pamela Stahl





2023 was no exception to this rule:

Improving clinical outcomes is dependent
on appropriate lab testing

## From the Desk of Bill Kerr, MD

CEO, Avalon

Avalon's 2024 Lab Trend Report is made possible through our work with health plans across the country. We are privileged to manage their lab benefits across 39+ million lives.

In this report, you will find:

- Statistics and analyses that will offer insight into lab testing trends.
- Typical routine testing activity and the increased reliance on genetic testing to predict disease conditions.
- Emerging trends biomarkers, FDA's regulatory oversight of lab-developed tests, multicancer early detection tests and polygenic risks scores.
- In future reports, we expect to explore next-generation sequencing (NGS).



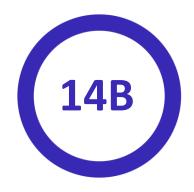
Click here to read more from Dr. Kerr



# **EXECUTIVE SUMMARY**



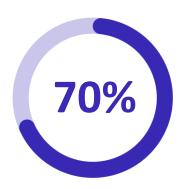
# **Executive Summary - Lab Testing Is Undercelebrated**



Roughly 14 billion clinical laboratory tests are performed every year in the U.S., making them the most utilized medical benefit.



Routine tests account for 90% of the annual 14 billion clinical lab tests performed in the U.S.



Laboratory testing affects ~70% of downstream treatment decisions.





### **Executive Summary - In the Lab Trend Report**

#### **Lab Testing Landscape:**

A complete introduction to routine and genetic testing, including the top 5 tests in spend and utilization.

#### **Snapshot of 2023 Lab Testing Data:**

A review of the data Avalon collected in 2023, concluding that the overall spend on routine lab tests was \$175 per member per year, and that the amount of spend on the top 5 genetic tests increased in 2023 as compared to 2022.

#### 2023 Lab Trends:

How to address the growth and costs of routine and genetic testing, including insights into why the site of lab testing and thoughtful prior authorization processes matter so much.

#### **Lab Value Management and Averted Costs:**

Two examples and a case study of how Avalon is combining lab values with the appropriate action steps in patient care to create opportunities for delaying disease progression and reducing costs.

#### **Emerging Trends:**

A peek into the future of clinical laboratory testing: multicancer early detection (MCED) tests and polygenic risks scores (PRS), blood biomarker testing, and the FDA's plan to regulate lab-developed tests (LDTs).







# LAB TESTING LANDSCAPE





# Lab Testing Is a Key Component of the Healthcare System

Lab testing accounts for 3-4% of healthcare spending, but 70% of all downstream treatment decisions with two main types:

#### **Routine Tests**

**90%** of lab tests are routine. These tests evaluate health metrics over time to monitor and compare an individual's changing health condition.

#### **Genetic Tests**

10 new genetic tests are introduced every day. These tests measure traits or conditions passed down in DNA, biomarkers, and direct tumor testing.

## **How Can Avalon Help?**



#### Overutilization and Underutilization

Right patient and right test at the right time



# Quality and Cost Consideration

Right test at the right cost



#### Partner in Decisionmaking

Decision-making through data management





### **Most Common Routine Lab Tests in 2023**

#### **Top 5 Tests by Spend**

01	CPT Code: 88305 Level IV – Surgical pathology, gross and microscopic examination	\$15.00 PMPY
02	CPT Code: 80053 Basic & Comprehensive Metabolic Panel	\$7.49 PMPY
03	CPT Code: 80061 Lipid Panel	\$4.87 PMPY
04	CPT Code: 85025 Complete Automated Blood Count	\$4.33 PMPY
05	CPT Code: 80050 Complete Health Panel	\$4.19 PMPY

#### **Top 5 Tests by Utilization**

01	CPT Code: 80053 Basic & Comprehensive Metabolic Panel	2658 Units/10K Members
02	CPT Code: 85025 Complete Automated Blood Count	2478 Units/10K Members
03	CPT Code: 80061 Lipid Panel	2405 Units/10K Members
04	CPT Code: 88305 Level IV - Surgical pathology, gross and microscopic examination	1592 Units/10K Members
05	CPT Code: 83036 Hemoglobin; Glycosylated (A1c)	1575 Units/10K Members





## **Genetic Testing Is Increasingly Being Used in Clinical Care**

Both lists feature genetic tests for fetal/child health: CPT codes 81420 and CPT 81220. Oncology tests appeared on the spend list, but not the utilization list, consistent with the high price associated with these tests that are intended to help with diagnosis and prognosis of cancer patients.

#### **Top 5 Tests by Spend**

01	CPT Code: 81420 Fetal Chromosomal Aneuploidy	\$2.62/100 Members
02	CPT Code: 81220 CFTR Gene Com Variants	\$0.94/100 Members
03	CPT Code: 81519 Oncology Breast mRNA	\$0.80/100 Members
04	CPT Code: 81162 BRCA1&2 Gen Full Seq Dup/Del	\$0.66/100 Members
05	CPT Code: 81416 Exome Sequence Analysis	\$0.50/100 Members

#### **Top 5 Tests by Utilization**

01	CPT Code: 81420 Fetal Chromosomal Aneuploidy	54.93 Units/10K Members
02	CPT Code: 81220 CFTR Gene Com Variants	26.21 Units/10K Members
03	CPT Code: 81329 SMN1 Gene Dos/Deletion Alys	15.44 Units/10K Members
04	CPT Code: 81374 HLA Typing 1 Antigen	10.62 Units/10K Members
05	CPT Code: 88271 Cytogenetics DNA Probe	9.41 Units/10K Members

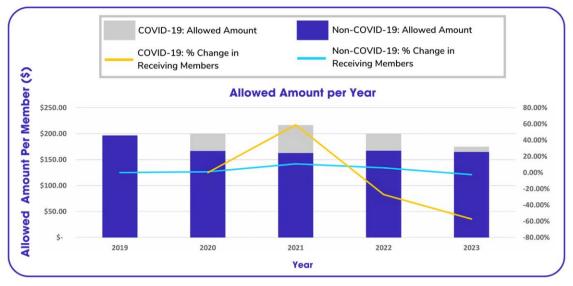




# SNAPSHOT OF 2023 LAB TESTING DATA & TRENDS

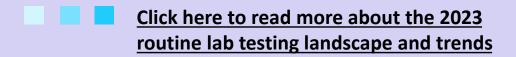


# Routine Testing in 2023 – Stable General Testing, Decreased COVID Spend, Better Mix & Management, Optimized Care



Trends in Spend and Trend for Routine Testing 2019 – 2023 Showed NON-COVID and COVID Related Testing

- Average spend \$175 per member per year
   General testing was \$165 in 2023 (Avalon client data was stable versus 2022 versus industry trend of 2-5% CAGR)
   COVID testing was \$10 (decreased from \$33)
- Overall, decreased utilization and spend is mostly related to decreased COVID-related testing and Avalon program management
   % decrease spend (13%) > % decrease utilization (6%) is consistent with better mix and Avalon controlled spend/utilization trend
- Avalon can help optimize care and address utilization and spend on routine tests
   Approximately 65 routine test outpatient laboratory policies are in place with clients
- The Avalon Routine Test Management program effectively controls spending and reduces overutilization, resulting in significant savings of 10-20% in outpatient lab expenses for our clients.





## **Routine Testing in 2023 – Drivers and Challenges**

# **Factors**

driving utilization and spend in routine testing

- Increasing age of population
- Rising prevalence of chronic diseases, with associated needs for diagnosis and monitoring
- Higher market penetration of technologically advanced and new diagnostic techniques, which are replacing and enhancing current testing strategies and care pathways
- Integration of hospitals and independent lab companies, which leads to decreased competition

# Challenges

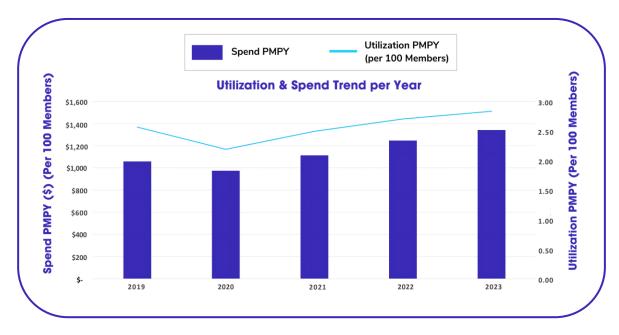
in monitoring and optimizing routine testing continue and include

- Overutilization
- Underutilization
- Need for disease specific care models
- Place of service discrepancies
- Fraud, waste, and abuse





# Genetic Testing in 2023 – Utilization and Spend Increased from 2022



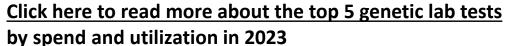
Trends in Genetic Testing 2019 - 2023 Show an Increase in Spend and Utilization Noted Over Time

- Average spend \$13 per member per year
   Utilization up 5% YoY
   Spend up 8% YoY (versus expected 11% CAGR increase from industry trends related to Avalon program management)
- % increase in spend > % increase in utilization suggests worsened mix
- Approximately 65 genetic outpatient laboratory policies covering 100% of genetic tests are in place with Avalon clients who have selected the GTM program
- The Avalon Genetic Test Management program provides health plans with a comprehensive solution to manage the growth and costs of genetic testing while providing access and quality of care in this emerging field at a reasonable cost.
- Click here to read more about the 2023 genetic lab testing landscape and trends

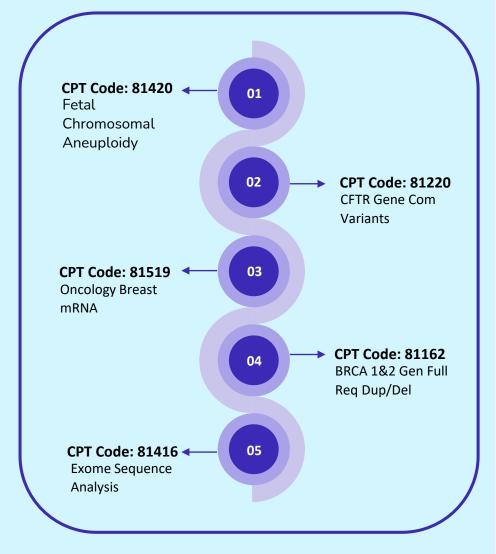


# Genetic Testing in 2023 – Top 5 Tests Driven by Fetal and Child Health and Oncology

- There are now over 175,000 genetic tests in the U.S. with only ~500 CPT codes.
- Fetal and child health (NIPT) and oncological and hematological diseases (prognosis and treatment) continues to grow and dominate list.
- Miscellaneous code 81479 is #1 on list for being non-compliant with health plan policies as determined by prior authorization.
- Overutilization is a concern, as is underutilization:
  - Overutilization may be apparent data are misinterpreted or the wrong test ordered.
  - Underutilization seen in oncology care, with only ~7% of members receiving necessary additional genetic testing within 2 years of cancer diagnosis.







Genetic Test Management - Top 5 Genetic
Tests by Spend

# Numerous Genetic Tests Are Noncompliant with Health Plan Policy and Prior Authorization Processes

Genetic testing is a rapidly evolving area that present billing and coding challenges.

- The CMS Clinical Laboratory Fee Schedule pricing methodology does not account for the unique characteristics of these tests.
- Due to these challenges, services are being incorrectly coded and improperly billed.

The top five tests determined to be noncompliant represent a combination of discriminate, non-well-defined codes (e.g., CPT 81479) often used with genetic test orders.

 Making genetic tests difficult to document and even more challenging to manage.

Percent of Total Units Determined Non-Compliant
11.81%
7.67%
7.48%
2.67%
2.47%

Top 5 Codes Determined to Be Noncompliant by Prior Authorization





# **Genetic Testing in 2023 – Drivers and Challenges**

# **Factors**

driving utilization and spend in genetic testing

#### Three major factors driving utilization and spend:

- Companion Diagnostics that allow doctors and patients to better understand if therapies will respond for specific patients
- Non-Invasive Prenatal Testing (NIPT) in the form of liquid biopsies and new biomarkers
- Direct-to-Consumer Testing to help people understand their predilection for genetic variations

Also: advances in genetic testing techniques and novel biomarkers linked to clinical conditions

 There are 10+ new genetic tests introduced in the U.S. every day

# Challenges

in monitoring and optimizing genetic testing continue and include

#### Coding

~40,000 tests coded under catch-all CPT 81479

#### **Quality control**

- Strong concentration of labs that run genetic tests
- Dearth of trained lab professionals

#### **Pricing**

Clinical utility





# **Lab Test Prices Vary Widely According to Site of Service**

**Example, Price of Complete Health Panel Test 80050** 

\$27

**Lab** Testing

\$35

**30% Higher** at Physician's Office

\$157

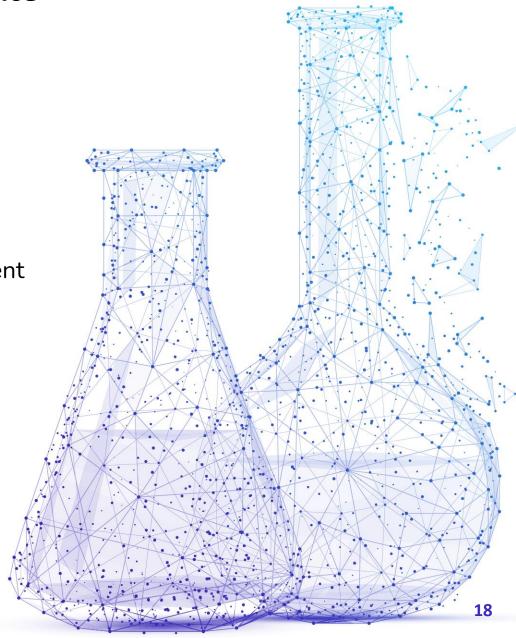
**475% Higher** at Hospital Outpatient Lab Services



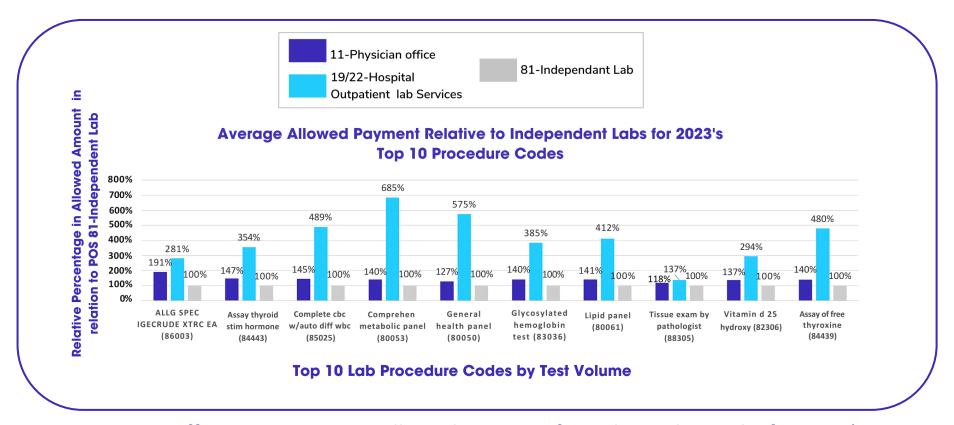
Location, Location







## **Lab Test Prices Vary Widely According to Site of Service**



Percent Difference in Average Allowed Payment for Independent Labs for 2023's Top 10 Procedure Codes



Hospital outpatient lab prices are growing faster than independent labs (46% increase in price for hospital outpatient labs in 2023 versus 2022)



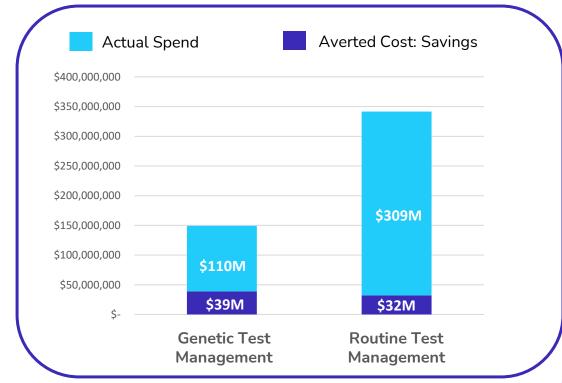
# AVERTED COSTS AND LAB VALUE MANAGEMENT



## **Thoughtful Management Strategies Can Avert Costs: A Case Study**

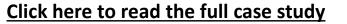
A case study of  $\sim$ 4.5 million members for routine testing and  $\sim$ 6.1 million members for genetic testing examining averted costs attributed to Avalon's automated policy enforcement and utilization management strategies for both Routine and Genetic Testing Management programs.

- **10%** averted cost savings for Routine Test Management (RTM)
- **35%** averted cost savings for Genetic Test Management (GTM)
- 5% 15% In addition to averted costs, Avalon's RTM and GTM programs drive 5% -15% lab behavior change, which further increases health plan savings



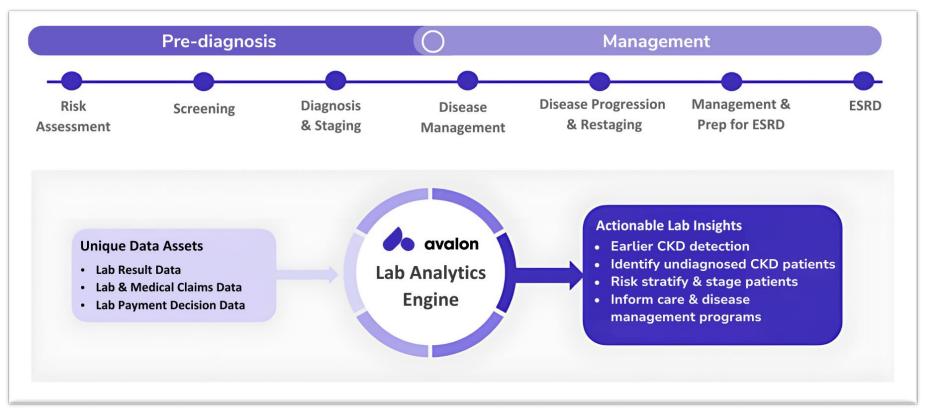
Comparison of Averted Costs for Routine Test Management (RTM) and Genetic Test Management (GTM) Selected Member Population





# Impacting Chronic Kidney Disease is Possible Through Early Detection: Lab Values Management

CKD is a multi-faceted problem requiring a multi-disciplinary and data-driven approach. Combining lab values with the appropriate action steps in patient care creates an opportunity for cost-effective solutions for delaying disease progression.



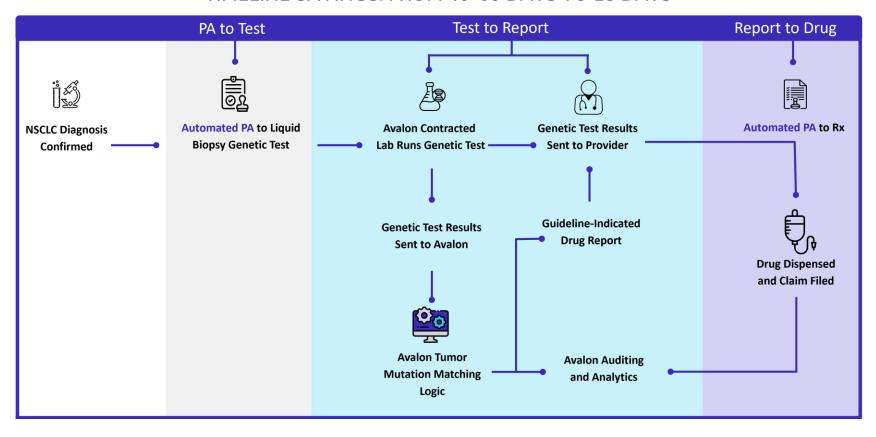
The interaction between Avalon Program in CKD and the CKD Patient Journey is Active throughout



# Improving Quality and Total Cost of Care in Cancer: Lab Values Management Oncology

A lab values management plan in oncology can speed time to genetic testing and appropriate medication prescribing and use.

#### TIMELINE SAVINGS: FROM 40-60 DAYS TO 15 DAYS





# **EMERGING THEMES**



# **Emerging Themes**

Update on Avalon's 2023 Lab Trend Report – progress on multicancer early detection (MCED) tests and polygenic risks scores (PRS).

#### Multi-cancer Early Detection (MCED)

## Polygenic Risks Scores (PRS)

#### **OPPORTUNITIES**

- Liquid biopsy that use a sample of blood to identify specific biologic signals released by cancer cells into the blood
- 70% of all cancer deaths come from cancers for which there are currently no proven screening tests
- Supplement current screening tests

#### CHALLENGES

- Early detection may not equal to a better outcome
- Clinical and cost utility
- Risk of anxiety / untoward effects

#### **UPDATES**

- Breakthrough Device Designation 3 tests
- Several large trials underway
- MCED Screening Coverage Act in review

#### **OPPORTUNITIES**

- Simple blood draw that generate a polygenic risk scores that represents a single value estimate of an individual's common genetic risk for a disease
- Applicable to many chronic diseases
- Adding genomic risk to standard non-heredity risks can aid in the risk stratification process.

#### **CHALLENGES**

- Relative risk versus absolute risk
   Most data derived from
- European ancestry databases
- Clinical and cost utility
- Risk of anxiety / untoward effects

#### **UPDATES**

- AHA Guideline released on cardiac PRS
- PRS clinical utility study published
- One test measures risk of 11 cancers





## **Future Lab Trends - Two New Emerging Themes**



#### **Blood Biomarkers**

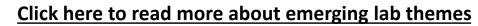
- Cardiac
- Infectious disease
- Central nervous system disease (Alzheimer's disease)



#### Regulation of Lab Developed Tests

On May 6, 2024, the FDA issued a final rule to regulate LDTs as medical devices for the first time. May restrict access to rare-disease tests and delay responses to future pandemics.





# **2024 Lab Trend Report Takeaways**

- Lab testing is an essential part of the patient journey and will matter more going forward
- Routine testing accounts for 90% of lab testing utilization but spend per member was 3.6x higher on genetic testing (\$273 versus \$975)
- The location of lab testing makes a big difference in price
- Looking into the future blood biomarkers are a bigger portal to health and disease
- Avalon is the right partner to address lab testing utilization and quality issues

Every day, we work to help our clients reduce waste in routine testing and assist with the challenging arena of genetic test decision-making.



Pamela Stahl
President, Avalon Healthcare
Solutions

# **Download the 2024 Full Lab Trend Report**



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