AVALON HEALTHCARE SOLUTIONS

PREVIEW OF 2024 LAB TREND REPORT - KEY INSIGHTS & TAKEAWAYS

May 7, 2024

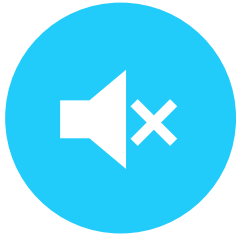
avalon

WELCOME & INTRODUCTIONS

Michele Norton - Senior Vice President, Product Marketing, Avalon

Before We Start

This meeting is being recorded.



We will be **MUTING** everyone except the presenter to make sure the audio is clean and clear.

Q&A will be done by using the **“Questions” feature**.

The recording and slides will be **available** on our website later during the week**.**

avalon

Agenda

Overview & Introductions

Michele Norton – SVP, Product Marketing, Avalon

2024 Policy and Regulatory Landscape

Julie Barnes, JD – CEO, Maverick Health Policy

2024 Lab Trend Report: Early Access to Key Lab Testing Trends

Mark Monane, MD, MBA - Chief Medical Officer and Principal, Monane Group

Q&A

Michele Norton, SVP, Product Marketing, Avalon

POLICY AND REGULATORY LANDSCAPE:

Julie Barnes, JD – CEO, Maverick Health Policy

Overview

- State of Medicare Advantage
- Increased Federal Gov’t Scrutiny (M&A, Cyber, Privacy)
- Future of Lab-Developed Tests

State of Medicare Advantage – Payment Scrutiny

MEDPAC

MA coding generates excess payments in 2024

Impact of coding intensity continues to grow

State of Medicare Advantage - UM

MA Utilization Management Rule (Effective January 1, 2024)	MA Proposed Rule - (Comments Closed January 5, 2024)	Request for Information on MA Data - (Comments Close May 29, 2024)
• Clarifies prior authorization parameters	• Requires health equity analysis of UM Policies and Procedures • Requires health equity expert on UM Committee	• CMS asked the industry what data it should collect on MA, including prior auth data

Electronic Prior Authorization Final Rule Finally Published

January 17, 2024

Applies to: Federally-contracted health plans

By January 1, 2026, health plans must:

- Comply with new prior auth reporting requirements
- Give a reason for prior auth denials
- Make prior auth decisions within 3-7 day timeframe

By January 1, 2027, health plans must:

- Send prior auth requests electronically via PARDD API
- Exchange data with providers and other payers via APIs

avalon

Medicare Advantage industry still very active, and reacting to CMS policy changes

- Jan: **SCAN Health Plan** and **Elevance** sue CMS over 2024 Star Rating calculations
- Jan. 31: **Cigna** announces it will sell its MA business to HCSC
- Apr. 24: **Humana** predicts cut to benefits in 2025 after MA rate announcement
- Apr. 30: **CVS** acquires MA broker, Hella Health
- May 1: **CVS** stocks drop after admitting Aetna's unexpectedly higher claims and changing MA reimbursement

Increased Federal Scrutiny - M&A Activity

- **White House "Strike Force"** on unfair and illegal pricing
- **FTC / DOJ Workshop** on Private Equity in Health Care
- **HHS / FTC / DOJ Request for Information** on the impact of health care transactions on consolidation and patient care quality

Trade Org Perspectives

AHIP

American Hospital Association™

AMA

M&A Activity

- **May 1, 2024**: Senate Finance Committee hearing on the cyberattack on **Change Healthcare** – is UHG too big to fail?
- **May 1, 2024: Quest Diagnostics** acquired **PathAI Diagnostics**, a digital pathology laboratory services business, to increase the adoption of AI in pathology diagnostics.
- **May 6, 2024: CVS** acquired tech-enabled MA broker company, **Hella Health**
- **May 7, 2024: Labcorp's** offer to buy **Invitae** will be approved in bankruptcy court
- **March 28, 204: Labcorp** bought the clinical diagnostics business of **BioReference Health**

Increased Federal Scrutiny – Cyber and Privacy

Recent Cyberattack Unprecedented for Health Care

CHANGE HEALTHCARE

United Healthcare

Office of the National Cyber Director

- Will update the national cybersecurity implementation plan before end of summer

National Privacy Law

- U.S. Senator Cassidy released white paper on data privacy
- Fourteen states have passed a law
- Congressional Commerce Committees released the “American Privacy Rights Act”

Increased Federal Scrutiny – Price Transparency

November 2, 2023
Hospitals must use a CMS template for machine-readable files

December 11, 2023
The U.S. House of Representatives passed the Lower Costs, More Transparency Act -- price transparency and site neutral payments

January 1, 2024
Health plans price comparison tools must include all items and services

There are new transparency requirements and tools; while others ask if the No Surprises Act is actually working

- **Jan. 26**: AHIP / BCBSA survey says that No Surprises Act **prevented at least 10M surprise medical bills** in first nine months of 2023
- **Feb. 15**: CMS report on 2023 data from the No Surprises Act IDR process shows that higher-than-expected volume of disputes, and that **78% of all disputes were initiated by 10 parties**
- **Mar. 27:** Brookings report says No Surprises Act IDR resolutions are favoring providers; results in higher payments than Medicare or traditional in-network rates
- **Apr. 2:** CMS announces new tools to help hospitals comply with new transparency requirements
- **Apr. 23**: CMS publishes a report on AEOB rulemaking progress

AHIP

BlueCross BlueShield Association

BROOKINGS

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

The FDA's Lab-Developed Test (LDT) Final Rule's Long Road Ahead

Final Rule Published on 5/6/24

- Classifies in vitro diagnostics (IVDs) as medical devices even when the manufacturer is a laboratory (LDTs)
- With LDTs now subject to FDA approval, there will be a phase-down of "enforcement discretion" over LDTs that would begin 60 days after publication of a final rule.
- FDA also issued two draft guidances about public health responses with and without a declared PHE
- Many key stakeholders released statements highlighting their concerns about the rule

2024 LAB TREND REPORT: EARLY ACCESS TO KEY LAB TESTING TRENDS

Mark Monane, MD, MBA - Chief Medical Officer and Principal, Monane Group

avalon

Discussion Topics

- Fundamental facts and questions
- Routine testing
- Genetic testing
- Looking into the future – assorted testing topics
- Summary and take-home points

FUNDAMENTAL FACTS AND QUESTIONS

Some Fundamental Facts – What Are Routine and Genetic Testing ? And Why Do They Matter?

- Routine tests - 14B tests per year - evaluate health metrics, can be repeated over time to monitor[1]
- Genetic tests – driven by Human Genome Project, measure traits or conditions passed down, biomarkers, and direct tumor testing[2]
- Lab testing accounts for only a tiny fraction (~3–5%) of healthcare spending, but 70% of all downstream treatment decisions[3,4]
- So why do you need Avalon?
  - Overutilizing and underutilization – right patient and right test at the right time
  - Quality and cost consideration – right test at the right cost
  - Partner in decision making through data management

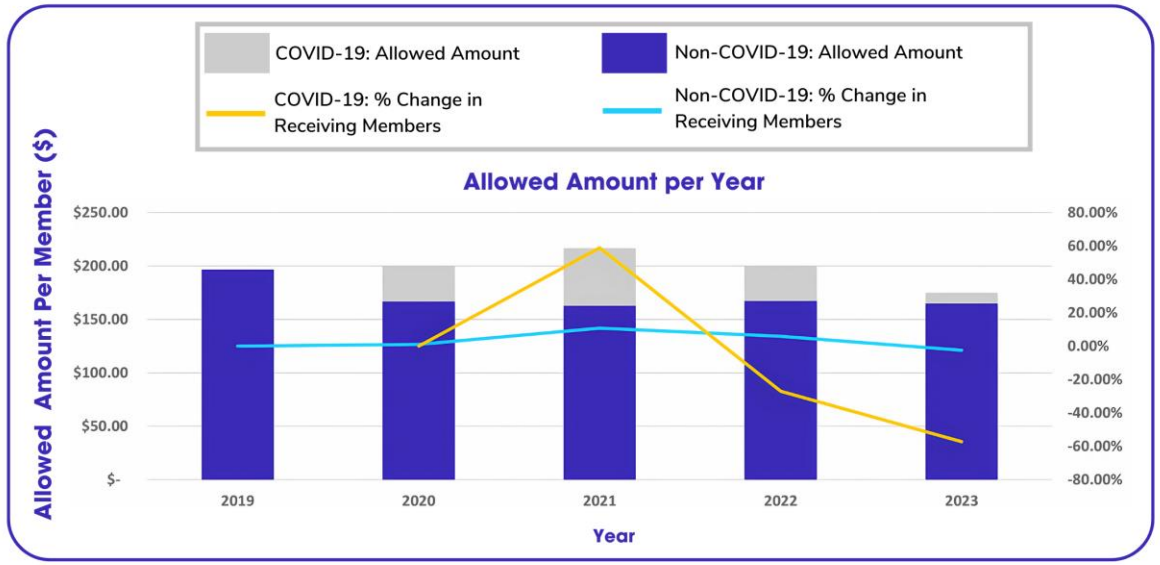
[1]Zhi M, Ding EL, Theisen-Toupal J, Whelan J, Arnaout R. The landscape of inappropriate laboratory testing: a 15-year meta-analysis. PLoS One. 2013;8(11):e78962.; Rohr UP, Binder C, Dieterle T, et al. The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. PLoS One. 2016;11(3):e0149856.
[2]https://3billion.io/blog/whole-genome-sequencing-cost-2023
[3] Song Z, Safran DG, Landon BE, et al. Health care spending and quality in year 1 of the alternative quality contract. N Engl J Med. 2011;365(10):909-918. doi:10.1056/NEJMsa1101416
[4] Forsman RW. Why is the laboratory an afterthought for managed care organizations?. Clin Chem. 1996;42(5):813-816.

avalon

ROUTINE TESTING

Routine Testing in 2023 – Stable General Testing, Decreased COVID Spend, Better Mix, Optimizing Care

- **Average spend $175 per member per year**
  - General testing was $165 in 2023 (stable versus 2022 versus industry trend of 2-5% CAGR)[1,2]
  - 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 suggests (6%) consistent with better mix and Avalon controlled spend/utilization trend



Reference: Avalon data on file

The Avalon routine test management solution effectively controls spending and reduces overutilization, **resulting in significant savings of 10-20% in outpatient lab expenses for our clients.**

avalon

[1] https://www.researchandmarkets.com/reports/5336116/u-s-clinical-laboratory-test-market-industry.

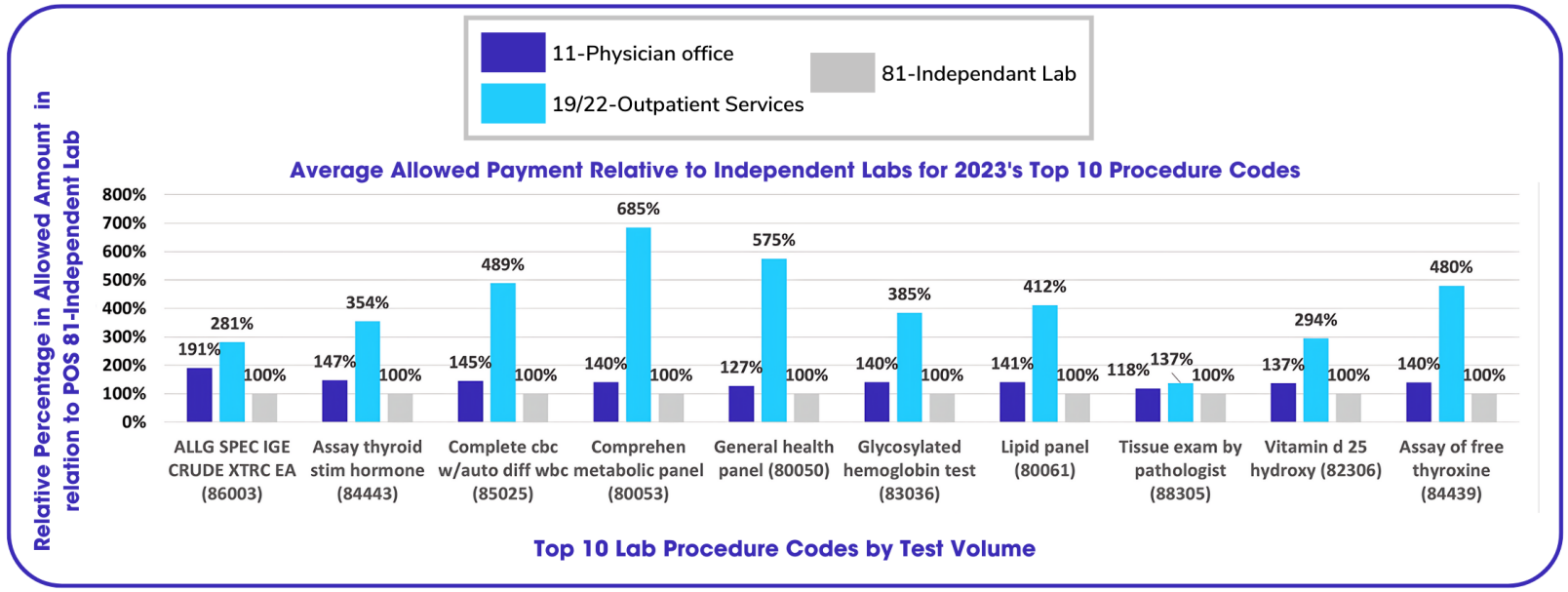
[2] https://www.ibisworld.com/united-states/market-research-reports/diagnostic-medical-laboratories-industry/

Poll Question: What is the percent difference in pricing for a general health panel test done in a hospital lab setting versus an independent lab setting?

a. 0% - a lab test is a lab test, regardless of location
b. 50% increase
c. 100% increase
d. 500% increase
e. 1000% increase

Price Arbitrage is Alive and Well with Profound Adverse Effects on Spend

- Location, Location, Location
- Price of general health panel rest (CPT 80050):
  - Independent lab - $27
  - Physician office - $35 (30% higher)
  - Outpatient services - $157 (575% higher)
- Hospital lab prices are growing faster than independent labs **(46% increase in price for hospital lab 2023 versus 2022)**
- Price disparities provide incentives for hospitals to purchase HCP practices



Reference: Avalon data on file

Routine Testing in 2023 – Drivers and Challenges

Factors driving utilization and spend:

- 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

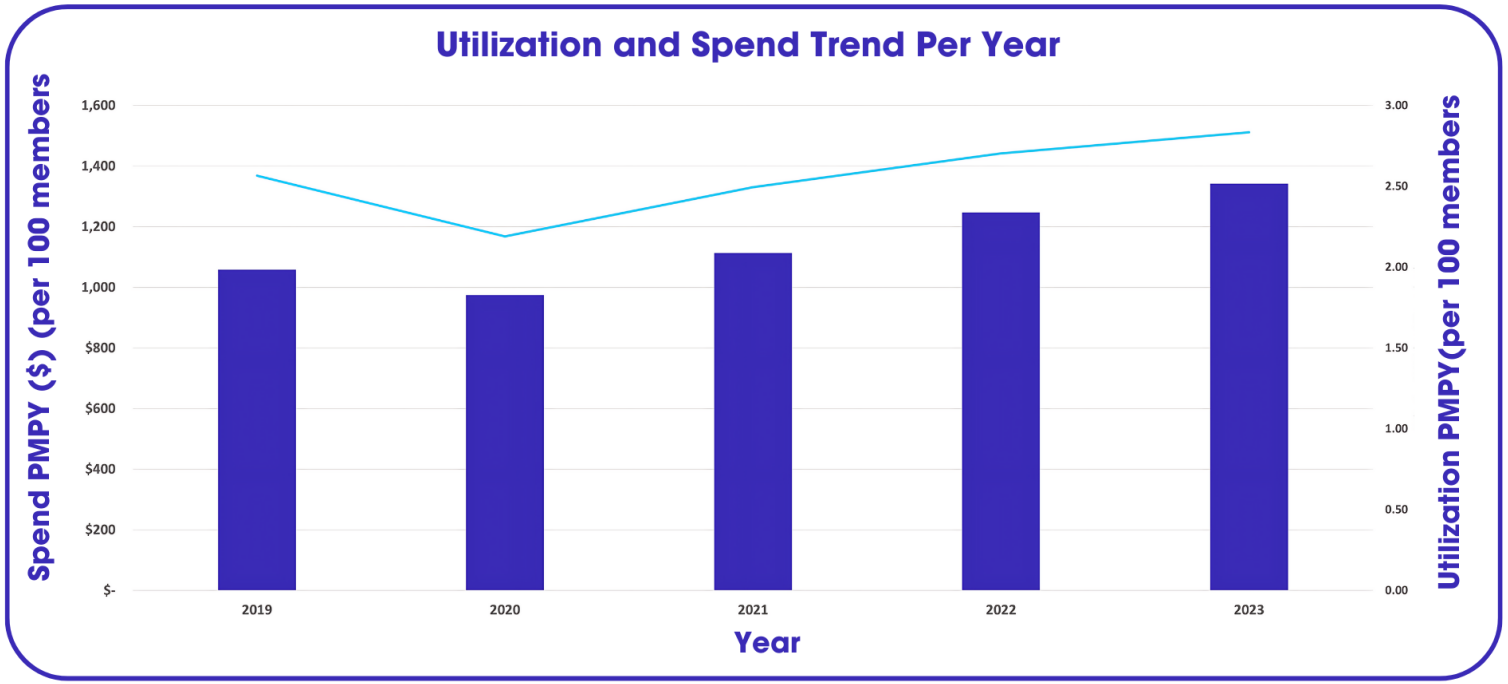
Challenges in monitoring and optimizing routine testing continue and include:

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

GENETIC TESTING

Genetic Testing in 2023 – Utilization and Spend Figures Had Continued Increases from 2022

- Average spend $13 per member per year
  - Utilization up 5% YoY
  - Spend up 8% YoY (versus expected 11% CAGR from industry trends related to Avalon program management)[1]
- % increase in spend > % increase in utilization suggests worsened mix
- Approximately 65 genetic test outpatient laboratory policies are in place with clients who have selected the GTM program
- Avalon can help address utilization and spend on genetic tests



Reference: Avalon data on file

[1] https://www.ascp.org/content/news-archive/news-detail/2023/07/25/special-report-financial-firms-project-rapid-growth-of-genetic-testing-market-through-2030#.

avalon

Poll Question: What health and disease areas are included in the top 5 genetic tests by spend ?

a. fetal and child health
b. oncological and hematological diseases
c. cerebrovascular health
d. a and b
e. all of the above

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 US with only ~500 CPT codes[1]
- Fetal and child health (NIPT) and oncological and hematological diseases (prognosis and treatment) continues to grow and dominate list
- Miscellaneous code **81479 as #1 on list for non-compliant codes** as determined by prior authorization
- Overutilization is a concern as is underutilization
  - Overutilization may be apparent – data are misinterpreted or wrong test ordered
  - Underutilization seen in oncology care, with only ~7% receiving additional genetic testing within 2 years of cancer diagnosis[2]

CPT Code	Utilization Rank
81420	Fetal chrmoml aneuploidy
81220	Cfr gene com variants
81519	Oncology breast mrna
81162	BRCA 1&2 gen full seq dup/del
81416	Exome sequence analysis

Reference: Avalon data on file

[1]https://www.darkintelligencegroup.com/the-dark-report/clinical-laboratory-trends/eight-macro-trends-for-clinical-labs-in-2023/

[2] Kurian AW, Abrahamse P, Furgal A, et al. Germline Genetic Testing After Cancer Diagnosis. JAMA. 2023;330(1):43-51. doi:10.1001/jama.2023.9526

avalon

Genetic Testing in 2023 – Drivers and Challenges

Factors driving utilization and spend:

- Increase in incidences and prevalence of genetic disorders and chronic disease
- Growth in awareness & acceptance of personalized medicine by physicians
- Growth in awareness & acceptance of personalized medicine by patients
- Advancements in genetic testing techniques
  - There are 10+ new genetic tests introduced in the US every day

Challenges in monitoring and optimizing genetic testing continue and include:

- Coding
  - ~40,000 tests coded under 81479
- Quality control
  - 453 labs running genetic tests
  - Dearth of trained lab professionals
- Pricing
- Clinical utility

LOOKING INTO THE FUTURE

Multi-cancer Early Detection (MCED)

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

avalon

Polygenic Risk Score (PRS)

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-hereditary 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

Biomarkers

- Cancer biomarkers – for diagnosis/ prognosis/ disease monitoring/ treatment monitoring
- Cardiac biomarkers – leptin gene for prognosis from coronary disease to heart failure
- Infectious disease biomarkers – sepsis diagnosis, bacterial v nonbacterial etiology
- Central nervous system disease biomarkers – Alzheimer’s disease, Parkinson’s disease
- AI in laboratory and patient care – biomarker discovery

New Blood Biomarker Tests – How Can Avalon Help Health Plans Prepare?

- Provide ongoing surveillance of advances
- Multiple programs to evaluate new technology
- Assist in evaluation of the literature for:
  - Clinical validity
  - Clinical utility
  - Cost utility
- Help in drafting appropriate coverage policies

SUMMARY AND TAKE HOME POINTS

Summary and Take Home Points

- Labs matter and will matter more going forward
- Routine testing - stable general testing spend despite industry trends, decreased COVID spend, better mix
- Genetic testing - increased single digits YoY, trend suggests higher spend and utilization in future
- For members with at least one test
  - Routine testing account for **90% of utilization**
  - There are 9 routine tests for every 1 genetic test used by a member, but spend per member was 3.6x higher on genetic testing ($273 versus $975)
  - Genetic testing accounts for **almost 30% of spend**
- Looking in the future – the vein and blood biomarkers as a bigger portal to health and disease
- Avalon is evolving as well

Lab Trend Report- Coming Soon!

Shifting Lab Trends in 2024 – Public Policy and Other Drivers:

- Prior authorization
- Site neutral payment reform
- Fraud, waste, and abuse
- Investment in science – ARPA-H
- Biomarker Coverage Rules
- LDT and FDA governance

avalon

Q&A

Michele Norton, Senior Vice President, Product Marketing

Thank you

Clients Contact:
Kerri Fritsch, Chief Client Officer
813-751-3832
kerri.fritsch@avalonhcs.com

Prospects Contact:
Barry Davis, Chief Growth Officer
201-218-3425
barry.davis@avalonhcs.com

SAVE THE DATE

Avalon Webinar – Save the Date:

To register for our upcoming webinars, please visit: www.avalonhcs.com