



# **WELCOME & INTRODUCTIONS**

Michele Norton, SVP, Product Marketing



### **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.



## **Agenda**

### **OVERVIEW & INTRODUCTIONS**

Michele Norton, SVP, Product Marketing

### WHAT'S THE LATEST FROM WASHINGTON, DC

Julie Barnes, Principal, Maverick Health Policy

### 2023 LAB TREND REPORT: EARLY ACCESS TO KEY LAB TESTING TRENDS

Mark Monane, MD, MBA, Chief Medical Officer and Principal, Monane Group Jason Bush, Ph.D., Executive Vice President, Product, Avalon

Q&A

Michele Norton, SVP, Product Marketing





# WHAT'S THE LATEST FROM WASHINGTON, DC

Julie Barnes - Principal, Maverick Health Policy





- Debt Ceiling Crisis
- Congress Focused On
  - PBMs
  - Prior Authorization
  - Provider Directories

### Other Payer Issues

- MLR rebates
- Preventive care
- Medicaid redeterminations



# **Debt Ceiling Crisis: What Is Happening?**



January 2023	U.S. hit debt ceiling (\$31T)
Jan-May 2023	Extraordinary measures to cover bills
June 2023	Actual default



#### **Consequences:**

- Stock market reacts badly
- U.S. credit rating at risk

#### The federal gov't stops paying...

- Medicare providers
- Social Security beneficiaries
- Tax refunds
- Military and civilian federal personnel
- Interest on the national debt (interest payments est. \$663B for 2023

#### **Negotiations this week:**

- White House -- spending freeze for FY2024 with tax increases on corporations and wealthy Americans to close the deficit (McCarthy won't even consider this idea)
- House R's -- lower spending with "Limit, Save, Grow" Act

#### Other options:

- •14th Amendment
- •Discharge petition to pass clean debt-limit increase (Ds have 213 signatures; need Rs to make 218)







### Congress is Busy – PBMs and Drug Costs

#### **U.S. Senate HELP Committee**

- Pharmacy Benefit Manager Reform Act
- Ensuring Timely Access to Generics Act of 2023
- Expanding Access to Low-Cost Generics Act of 2023

#### **U.S. House E&C Committee**

- Transparent PRICE Act
- Transparency and oversight of the 340B drug discount program













# **Congress is Busy – Automated Prior Authorization**

# PI PROPUBLICA **Health Care How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them** by Patrick Rucker, Maya Miller and David Armstrong March 25, 5 a.m. EDT

### **E&C Republicans Ask Cigna to Explain** after ProPublica Report Alleges It **Denied Claims Without Review**

CATHY McMORRIS RODGERS, WASHINGTON

FRANK PALLONE, JR., NEW JERSEY

ONE HUNDRED EIGHTEENTH CONGRESS

#### Congress of the United States

House of Representatives

#### COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115 Majority (202) 225-3641 Minority (202) 225-2927

May 16, 2023

Mr. David Cordani President and CEO The Cigna Group 900 Cottage Grove Road Bloomfield, CT 06002

Dear Mr. Cordani.

Pursuant to Rules X and XI of the U.S. House of Representatives, we are requesting documents and information related to Cigna's procedure-to-diagnosis (PXDX) review process.

A recent investigative report alleges that Cigna utilizes a system that indiscriminately denies payments for claims and may lead to improper denials of coverage for medically necessary tests and procedures. The article claims the PXDX review process automatically categorizes certain claims as unnecessary using an algorithm in place of a clinician's judgement, 2 Patients are then told that a clinician has decided such claims were not necessary and therefore not covered, despite the clinician having never reviewed individual claims.3

The reporting estimates that only 5 percent of policy-holders appeal denials of coverage.4 By contrast in Cigna's Medicare Advantage plans nearly one in five prior authorization denials were appealed.<sup>5</sup> Perhaps more concerningly, 80 percent of denials were overturned.<sup>6</sup> If these figures are at all illustrative of Cigna's commercial appeal and reversal rates, it would suggest that





Patrick Rucker, Maya Miller, and David Armstrong, How Ciena Saves Millions by Having its Doctors Reject Claims Without Reading Them. PROPUBLICA, (Mar. 25, 2023), https://www.propublica.org/article/cigna-pxdx-

<sup>&</sup>lt;sup>5</sup> Jeannie Fuglesten Biniek and Nathan Sroczynski, Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021, KAISER FAMILY FOUNDATION, (Feb. 2, 2023),

https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicareadvantage-plans-in-2021/#:~:text=Discussion,decisions%20when%20they%20were%20reconsidered

## **Congress is Busy – Provider Directories**

#### **U.S. Senate Committee on Finance**

- Hearing on mental health "ghost networks"
- Secret Shopper Study reviewed directories from 12 different plans















May 03, 2023

Senate Committee on Finance

#### Majority Study Findings: Medicare Advantage Plan Directories Haunted by Ghost Networks

#### **Executive Summary**

Ghost networks occur when a health plan's provider directory is filled with inaccurate provider listings or unavailable providers. Academic research has examined ghost networks across many provider specialty types within group and nongroup health plans and Medicare Advantage (MA). However, it is not known how pervasive ghost networks are for mental health care providers within the MA program. Senate Committee on Finance's Majority staff conducted a brief secret shopper study to examine the extent of mental health provider ghost networks in the MA program.

Staff reviewed directories from 12 different plans in a total of 6 states, calling 10 systematically selected providers from each plan, for a total of 120 calls. Of the total 120 proteil tistings contacted by phone, 33% were inaccurate, non-working numbers, or unreturned calls. Staff could only make appointments 18% of the time. Appointment rates varied by plan and state, ranging from 0% in Oregon to 50% in Colorado. More than 80% of the listed, in-network, mental health providers staff attempted to contact were therefore "ghosts," as they were either unreachable, not accepting new patients, or not in-network.

It is particularly troubling to consider how this report's findings may acutely affect an individual struggling with a mental health condition and attempting to navigate the process of identifying an in-network provider in a directory where 80% of the listed providers are inaccurate or unavailable. CMS should increase its oversight efforts to audit health plan directories to ensure they hold MA plans accountable for these directories and for accurately documenting their networks. Congress can also require additional steps to ensure provider directory accuracy including regular audits, transparency, and financial penalties for non-compliance.

#### Introduction

In the United States, approximately one in five adults suffer from a diagnosable mental health illness. In 2021, it was estimated that less than half of the 57.8 million adults living with a mental illness received mental health services in the past year. Delayed access to mental health care and inadequate treatment results in suffering, lost productivity, worsening of other health conditions, and even death. Therefore, access to timely and quality mental health care is imperative and life-saving. Tragically, many Americans experience the complete opposite.

To ensure that consumers are aware of and able to seek care from in-network providers, health plans publish "provider directories." These documents list the health plan's in-network

<sup>1</sup>National Institute of Mental Health. "Mental Illness." National Institute of Mental Health Office of Science Policy, Planning, and Communications, https://www.nimh.nih.gov/health/statistics/mental-illness. Accessed April 24, 2023.

# **Other Payer Issues**

# Medical Loss Ratio (MLR) Rebates

- MLR threshold 80% of premium income
- Plans must pay enrollees an estimated \$1.1B in rebates in 2023

#### **Preventative Care**

- U.S. District Judge in TX prevents gov't from enforcing ACA's preventative care requirements
- Appeals court issued an administrative stay on the ruling
- Most employers (72%) expect to continue 100% coverage

### Medicaid Redeterminations

- Worse than expected
- HHS: 15 million people will lose Medicaid coverage
- Florida: ~250,000 individuals were disenrolled from the state's Medicaid program
- Arkansas: ~70,000
- Indiana: ~53,000





## **Lab Trend Report**

# Shifting Lab Trends in 2022 – Public Policy Drivers:

- Post-PHE policies
- Prior authorization
- Site neutral payment reform
- Fraud, waste, and abuse
- Investment in science ARPA-H







# 2023 LAB TREND REPORT: EARLY ACCESS TO KEY LAB TESTING TRENDS



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

Jason Bush, Ph.D. – Executive Vice President, Product, Avalon



## **Discussion Topics**

- Fundamental facts
- Routine testing
- Genetic testing
- New screening tests



### **Some Fundamental Facts**

- ~70% of HCP encounters end in a lab test<sup>1</sup>
- Routine tests evaluate health metrics, can be repeated over time to monitor
  - 14 billion clinical lab tests were performed in the US per year, mostly routine tests<sup>2</sup>
  - COVID testing represents a new kind of routine testing
- Genetic tests measure traits or conditions passed down, biomarkers and direct tumor testing
  - The costs for genome sequencing has decreased from \$1MM in 2007 to \$1000 in 2014 to \$600 in 2023<sup>3</sup>
  - Between 2012 and 2022, a total of 51,803 new genetic tests were made available in the U.S.<sup>4</sup>

<sup>1</sup>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.

 $<sup>^4</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10142561/\#: ^: text = Of \%20 the \%2051\%2C803\%20 new \%20 genetic, in \%20 the \%20 US \%20 are \%20 diagnostic.$ 

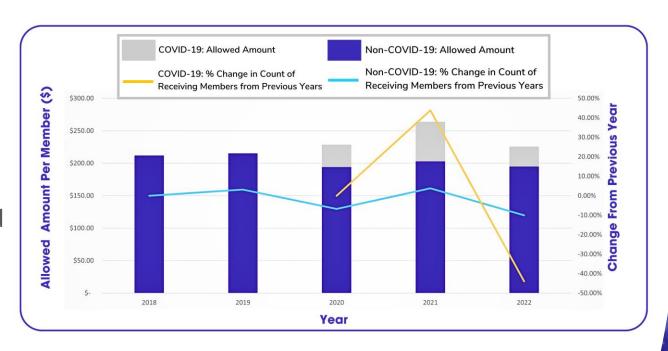


<sup>&</sup>lt;sup>2</sup>https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html

<sup>&</sup>lt;sup>3</sup>https://3billion.io/blog/whole-genome-sequencing-cost-2023

# Routine Testing in 2022 – Decreased Utilization and Spend as COVID Testing Decreased

- Routine tests make up 90% of all lab tests
- Average spend \$226 per member per year in 2022
  - Utilization down 10% YoY
  - Spend down 15% YoY
  - Decreased utilization and spend is mostly related to decreased spend on COVID-related testing
- Approximately 65 routine test outpatient laboratory policies are in place with clients
- Avalon can help address utilization and spend on routine tests





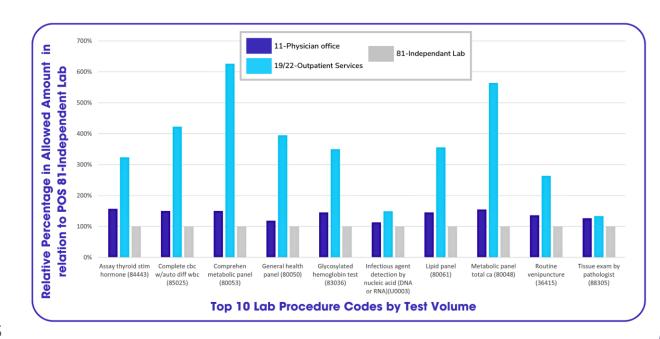
# Poll Question: What is the percent difference in pricing for a HbA1C test done in a hospital lab setting versus an independent lab setting?

- a. 0% a lab test is a lab test, regardless of location
- b. 25%
- c. 52%
- d. 125%
- e. 250%



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

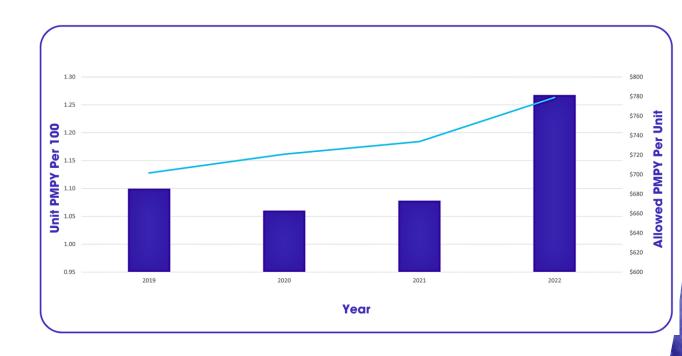
- Location, Location
- Price of HbA1c test (CPT 83036):
  - Independent lab \$9.29
  - Physician office \$13.50 (45% higher)
  - Outpatient services \$32.53 (250% higher)
- Hospital lab prices are growing faster than independent labs
- Price disparities provide incentives for hospitals to purchase HCP practices





# Genetic Testing in 2022 – Utilization and Spend Figures Had Double Digit Increases

- By November 2022, a total of 129,624 genetic tests in the U.S. were submitted to the genetic testing registry<sup>1</sup>
- Genetic tests make up 10% of all lab tests
- Average spend \$779 per member per year
  - Utilization up 15% YoY
  - Spend up 11% YoY
- Approximately 75 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



<sup>1</sup>https://www.mdpi.com/2075-4426/13/4/638



# Genetic Testing – Top 5 Tests Driven by Prenatal Care and an Old Coding Nemesis

- Non-invasive prenatal testing (NIPT) continues to grow and dominate genetic test utilization
- Miscellaneous code 81479 continues to accrue high utilization
- Challenges in monitoring and optimizing genetic testing continue and include:
  - Coding
  - Pricing
  - Quality control
  - Clinical utility

CPT Code	Utilization Rank
81420	Fetal chrmoml aneuploidy
81220	Cfr gene com variants
81329	SMN1 gene dos/deletion alys
81479	Unlisted molecular pathology
81241	F5 gene



# **Looking into the Future – New Screening Blood Tests**

- Examples:
  - Multi-cancer early detection (MCED)
  - Polygenic risk scores (PRS)
- Blood tests that allow for access and convenience
- Enhanced use of genetics and genomics due to the decreased costs of DNA technology and availability of large databases



# Poll Question: What Are The Characteristics of a High Value Screening Test?

- a. Use in asymptomatic phase
- b. Actionable result
- c. Early detection = better outcomes
- d. Reasonable clinical and cost utility
- e. All of the above



# **Characteristics of a Good Screening Test**

- Opportunity to use at onset of the disease process before signs and symptoms appear
- The critical point at which intervention is more effective than later intervention
- High sensitivity and specificity
- Widely available at a reasonable cost
- Safe to administer
- Associated with improved health outcomes



# Multi-cancer Early Detection (MCED)

#### **OPPORTUNITY**

- 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



# Polygenic Risks Scores (PRS)

#### **OPPORTUNITY**

- 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 nonheredity 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



# Looking into the Future – New Screening Tests – How Can Avalon Help Healthplans 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



# Coming in June—2023 Lab Trend Report

#### **EMERGING TRENDS AND ACTIONABLE INFORMATION**

- Market forces affecting the laboratory space and health plans
- Avalon's view of laboratory trends
- Future lab Tests and their impact
- How Avalon can help address market needs





Q&A
Michele Norton, SVP, Product Marketing



# Thank you



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### **SAVE THE DATE**

Avalon Webinar – July 18 | 2:00 - 3:00 PM EDT

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