Transforming the management of genetic testing

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E-book introduction

New technologies don’t wait to emerge until the policies for handling them are in place. That’s certainly the case with genetic testing. It’s been coming over the horizon for years, but healthcare has been caught unprepared by the dramatic growth in the adoption of testing and the variety of tests. Providers and health plans are scrambling to determine the validity and utility of tests, while dealing with an inadequate system for coding and management.

If genetic testing is to fulfill its potential to improve healthcare, it must be conducted through a scientific, evidence-based system that recommends test use in diagnosing, treating, managing, and monitoring disease while ensuring the right test for the right member at the right time determines the right care to deliver. This system also gives providers, labs, and health plans greater transparency into ordering and reporting while controlling costs and preventing waste, fraud, and abuse.

This e-book explores the shortcomings of the current genetic test management system and how a tailored approach can unlock its full potential. The first two chapters highlight why genetic testing is a major medical advancement, its rapid growth, and the challenges in managing test programs. We'll outline the ideal management program that controls costs while ensuring the right test is ordered for the right patient at the right time, as demonstrated by Avalon and Optum's Precision Genetic Test Management.

Chapter three focuses on the benefits of Precision Genetic Test Management for patients, providers, health plans, and labs. By the end, you'll understand how effective management can revolutionize healthcare and fulfill the promise of personalized medicine.

Chapter 1
The promise and problems of genetic testing

Introduction

Genetic testing is one of the most promising developments in the history of medicine. The ability to identify the genetic causes of conditions and diseases, diagnose those conditions, and design treatments for them is transforming healthcare. Used correctly and managed adequately, genetic testing will lead to a healthier population served by a better-informed and more efficient healthcare industry.

And the enthusiasm for genetic testing is not limited to researchers and clinicians. Patients have embraced testing through their physicians and with at-home kits like 23andMe. Incorporating all the tests and resulting data into a comprehensive and effective healthcare program is a challenge for patients, providers, and insurance plans, but one that must be successfully met if we are to realize the full benefits of genetic testing.

Growth of testing

Since the human genome was mapped 20 years ago, genetic testing volume has dramatically accelerated and shows no signs of slowing.

More than 175,000[1] genetic tests are on the clinical market today, and 10[2] new tests are introduced daily. This is partly driven by the declining cost of gene sequencing, which fell from $1 million in 2007 to $600 in 2023.[3]

However, while the cost of individual genetic tests has decreased, overall spend on genetic testing has exploded. After analyzing the utilization and spend of genetic tests among Avalon clients across all books of business, we found that genetic tests comprised 10% of all lab tests in 2022, with an average spend of $779 per healthcare plan member per year. That was a 15% increase in utilization and an 11% increase in spending YOY.

More than 175,000[1] genetic tests are on the clinical market today, and 10[2] new tests are introduced daily.

The genetic testing market costs $5.2 billion to $14.8 billion in the United States, depending on the source.[4],[5],[6] Data from the Centers for Medicare and Medicaid Services (CMS) show a significant increase in its compounded annual growth rate for genetic testing from 2015 to 2021, with it accounting for 20.4% of CMS' total lab spending in 2021.[7],[8]

Medicare fee-for-service data

Year	Total Lab Spending	Genetic Test Spending	% Genetic Test Spend	CAGR Genetic
2015	$6.69 B	$ 289 MM	**4.2%**	
2016	$6.77 B	$ 393 MM	**5.8%**	36.0%
2017	$7.13 B	$ 473 MM	**6.6%**	27.9%
2018	$7.59 B	$ 969 MM	**12.8%**	49.7%
2019	$7.68 B	$1.58 B	**17.7%**	47.3%
2020	$8.00 B	$1.20 B	**15.0%**	-24.0%
2021	$9.30 B	$1.90 B	**20.4%**	58.3%

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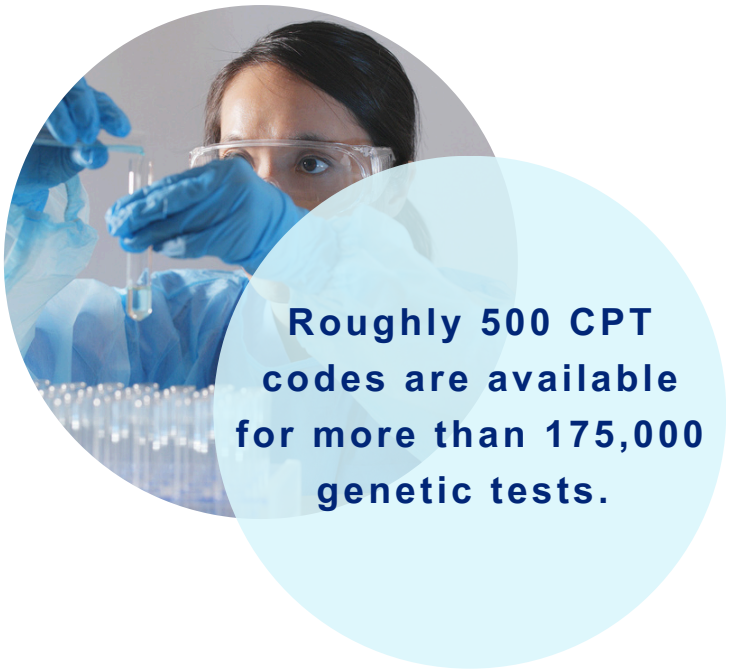
Insufficient CPT coding

Genetic tests are being created faster than new codes can be assigned to identify them. As a result, a wide range of genetic testing is lumped under a few nondescript Current Procedural Terminology (CPT) codes. While some genetic tests can be ordered using particular codes that apply only to a single gene or analyte, many other tests use a non-specific code that moves through prior authorization for approval. For example, there are more than 40,000 different tests with CPT 81479. In all, only about 500 CPT codes are available for more than 175,000 tests.



This creates problems and confusion for health plans, which must ensure regulatory compliance while keeping costs under control through prior approval and policies. The wide variation in cost for multiple tests under a single CPT code is also challenging.

A new coding system is required, which goes into greater specificity than CPT codes and allows for the identification and tracking of individual tests to make it easy for all parties involved to know what is ordered and why.

Order and provider confusion

The existing system for managing lab tests has been overwhelmed by the explosion in genetic testing. It's an unmanageable situation for providers and labs trying to put the enormous good of gene testing to work on behalf of patients. Most clinicians do not have the training or expertise to judge the validity and efficacy of genetic tests – and the challenge is only getting more complex. Consider these factors:

- The constantly growing body of knowledge of genetic medicine and the resulting test proliferation add to the complexity
- More complex panel combinations can increase waste
- Genetic lab orders are prone to being misunderstood or misordered
- There is a lot of variation and uncertainty about who provides test counseling to a patient or physician

Waste and errors caused by order and provider confusion can result in improper and missed diagnoses, unnecessary spending, and possible delays in treatment.

The health plan dilemma

The explosion in genetic testing has put health plans in the unenviable position of trying to determine the clinical validity and efficacy of hundreds of thousands of tests. The stakes are high. Needed tests that are performed correctly and whose results are used to inform treatment can save

lives. Unnecessary or poorly performed tests are a waste of money and resources and can potentially harm the patient.

Like clinicians, insurers do not have the resources or expertise to evaluate and validate the flood of tests, though controlling spend and serving members require them to make these difficult decisions. Health plans need a science-oriented partner that can evaluate the evidence and quality of new tests to establish their analytical and clinical validity and utility.

Drawing parallels from pharmaceuticals

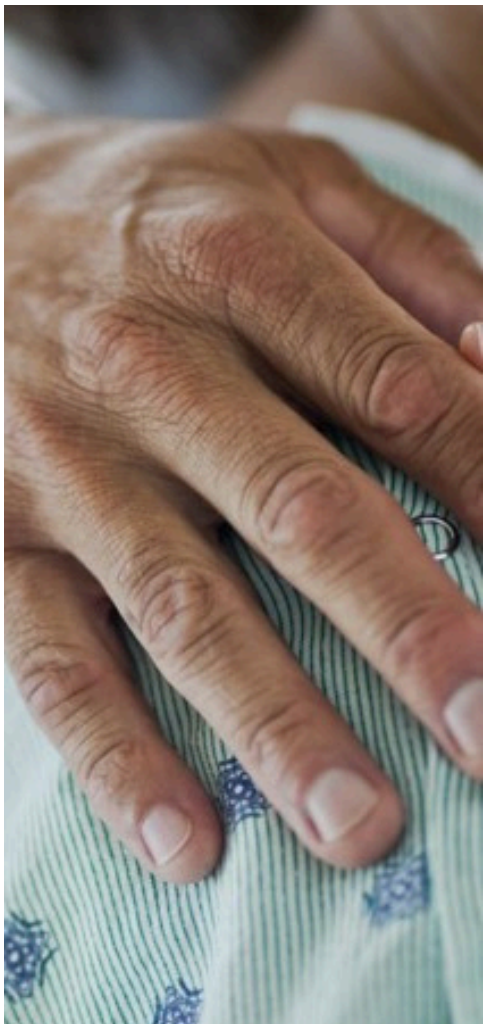
Pharmacy Benefit Management		Lab Benefit Management
Drugs are reviewed for efficacy and safety by the FDA before market approval.	REGULATION	Precision Medicine Tests do not require any review of quality data before being released to the market.
Each molecular entity has a unique identifier (NDC) that classifies the drugs, formulation, and manufacturer.	CODING	CPT codes are used to group tests based on broad indications. There is no national standard.
Clinical and cost benefit data submitted by the manufacturer is evaluated by multiple committees to determine the drug's place on a formulary and relevant utilization management criteria.	COVERAGE	Previews of quality data for Precision Medicine Tests are performed inconsistently or only across a small subset of tests.
Drugs are reviewed for efficacy and safety by the FDA before market approval.	REIMBURSEMENT	Fee schedules exist at a CPT level, not test level, leading to the missed opportunity to negotiate rates using a test formulary.

Vulnerability to fraud, waste, and abuse

Like many fast-growing fields with insufficient controls and oversight, genetic testing has been accompanied by high fraud, waste, and abuse rates. Measures to regulate and oversee the field have been patchwork and need help to keep up with the growth.

While Theranos is an extreme example of outright fraud, misuse also includes overordering. Up to 30% of laboratory testing might be unnecessary.[9,10] Providers might overorder tests for fear of missing something, or by practicing "defensive medicine," they can order an unnecessarily large battery of tests to reduce the threat of malpractice liability. This raises the risk of false-positive and false-negative results and subsequent harm to the patient. Failure to order the proper test affects about 50% of lab orders, which can lead to an incorrect or missed diagnosis.[11]

Independent validation of genetic tests and better management and control systems can reduce these problems.



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Chapter 2
How to manage genetic testing

The number of new genetic tests being developed each year is increasing rapidly. This increase raises concerns about the accuracy and usefulness of many of these tests. Health plans, doctors, and patients all need to have confidence in the accuracy of genetic test results to ensure good patient care. However, ensuring accuracy is becoming more challenging for health plans because of the many available tests and the clinical indications they cover. Health plans must ensure that their coverage policies keep up with the latest clinical medicine, that only quality laboratories provide results, and that laboratories are appropriately reimbursed. The following options may help health plans stay at the forefront of genetic testing management while also making it easier to authorize tests and improve the quality of testing available to members:

1. Develop and manage policy processes that ensure genetic and laboratory-experienced physicians review the latest science to establish coverage criteria. This review should occur minimally once a year and more frequently as the science changes rapidly.
2. Establish a continuous process for reviewing and optimizing the use of UM/PA or claims adjudication to evaluate a test's compliance with the plan's policies.
3. Increase provider, physician, and health plan operations efficiency and accuracy by implementing a unique test identifier that enables faster PA evaluations, streamlined claims adjudication determinations, and specific test-level pricing.
4. Establish a system for discouraging Fraud, Waste, and Abuse focused on genetic testing.

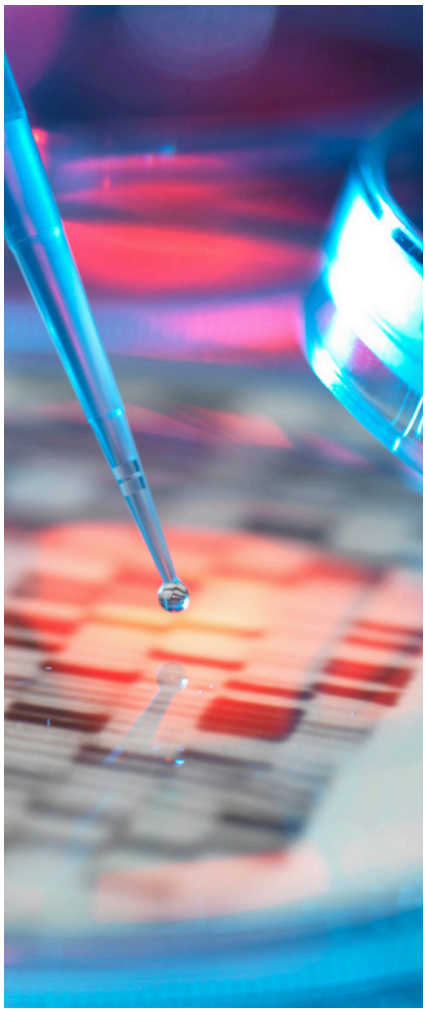
The proliferation of genetic testing is overwhelming the controls in place to manage it

The proliferation of genetic testing is overwhelming the controls in place to manage it, much like the out-of-control, bucket-carrying brooms in Disney's The Sorcerer's Apprentice. There are now so many tests available that there are not enough Current Procedural Terminology (CPT®) codes to cover them, and there is insufficient oversight by insurers. Additionally, the science-based evidence that is currently being used to determine when, how, and which test should be used is inadequate.

To address this issue, Avalon Healthcare Solutions and Optum have collaborated to create Precision Genetic Test Management (PGTM) - a solution designed to help health plans manage genetic testing spending while providing greater transparency into the testing process. PGTM rests on five pillars:

1. Policy development: Robust evidence-based outpatient laboratory policies and an exclusive partnership with Palmetto GBA® on DEX® Diagnostics Exchange, the same platform that powers the CMS MoIDX program.
2. Test identification and quality: A scalable framework to classify and evaluate a test based on the manufacturer's claims using industry-standard DEX® Z-Codes®.
3. Utilization management: NCQA-accredited utilization management and prior authorization (pre- and post-service), automated provider decisions, and clinical reviews based on health plan policies.
4. Payment accuracy: Automated claim coding rules to enforce policy development and validate authorization decisions during claim adjudication.
5. Genetic network management: A curated network of genetic labs that supplements a health plan's preexisting routine lab network with vetted providers and pre-negotiated pricing.

Benefits of incorporating DEX Z-Codes



Genetic testing faces a significant challenge in the form of limited CPT codes to cover the exponentially increasing number of tests. Currently, only around 500 codes cover over 175,000 genetic tests. This shortage of codes makes it difficult for labs and health plans to monitor testing, and it may lead to fraud, waste, and abuse.

To address this issue, PGTM incorporates DEX Z-Codes into coding and billing. Z-Codes are Palmetto GBA's proprietary, unique five character alpha-numeric codes associated with certain molecular diagnostics tests as an adjunct to CPT codes that are assigned within Palmetto GBA's Diagnostics Exchange (DEX). When submitted on a claim, in addition to the CPT code, Z-Codes provide greater clarity to ensure all parties understand which test is being ordered, performed, and billed.

This unique identification creates a one-to-one relationship among the Z-Code, CPT code, test, and lab. This allows for automated policy enforcement and payment decisions at the discrete test level while restricting unbundling. It also provides test quality measures to help payers decide if tests are clinically valid.

Z-Codes are quickly becoming the standard for discrete test identification. CMS has adopted them, and commercial carriers follow suit by mandating Z-Codes to reimburse molecular diagnostic tests. The benefits of this for other health plans include little to no provider confusion or abrasion regarding DEX Z-Codes, informed and educated providers on DEX Z-Codes nationally, providers registering for a Unique Test Identifier (DEX Z-Code), and providers being accustomed to including the DEX Z-Code on claims for reimbursement.

Pairing DEX Z-Codes with quality assurance policies

Genetic testing should always adhere to evidence-based clinical guidelines. However, with the ever-increasing number of tests available, it has become challenging for healthcare providers and health plans to assess each test's clinical validity and usefulness.

To address this issue, PGTM offers a comprehensive and regularly updated library of science-based policies covering over 530 genetic CPTs. Additionally, PGTM leverages Optum's exclusive partnership with Palmetto GBA to expand on DEX® Diagnostics Exchange, the same platform that powers the CMS MolDX program.

PGTM offers a comprehensive library of science-based policies covering over 530 genetic CPTs.

To ensure that tests meet the required quality standards and are clinically valid and helpful for providers, PGTM pairs these policies with DEX Z-Codes. The program is also equipped with the necessary resources to keep up with the growth in the volume of genetic tests, enabling health plans to scale.

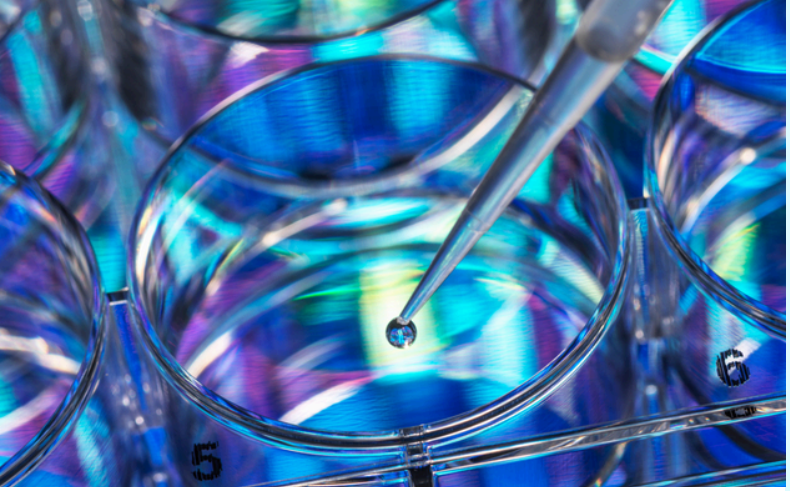
With PGTM, healthcare plans can be confident that the genetic tests they cover are valid, helpful to providers, and ultimately beneficial to patients.

Technology for policy adherence and payment integrity

The current system for coding and payment policies related to genetic testing can be inconsistent and varies depending on the test, lab, and order. Although there are fee schedules for CPT codes, there are none for individual tests, and health plans are missing out on the opportunity to negotiate rates using a test "formulary."

To eliminate inconsistencies, PGTM uses automated claim coding rules developed by Optum and Avalon and adopted by the health plan to enforce clinical guidelines and validate authorization decisions during claim adjudication. Additionally, the product includes integrated payment integrity capabilities that may help identified savings to occur post-service.

By aligning the clinical, lab network, and payment integrity teams, PGTM allows plans to move from focusing solely on cost containment to promoting affordability.



Improved network management

Avalon's Genetic Network is a carefully selected group of genetic labs that complement a health plan's existing network of routine labs. This means that health plans can continue to use their current lab relationships while outsourcing the management of genetic testing, pricing, compliance enforcement, test quality assessment, and contracting. This leads to streamlined prior authorization (PA) and an improved experience for providers when ordering tests.

Labs that join the network can benefit from an improved PA submission process and the removal of PA for certain providers/procedures. They may also experience reduced costs, administrative burdens, and a faster reimbursement timeline.

The network also offers provider education and network reporting to identify and influence behavior redirection, fraud, waste, and abuse. It can also help identify and address abusive ordering procedures, ultimately improving patient care quality.

To have an optimal genetic test benefit program, several key elements are suggested. These include:

1. Accreditation by NCQA and/or URAC in Utilization Management and compliance with state and federal regulations and statutes.
2. Coverage criteria based on the latest clinical science of genetic tests, including rapidly changing federal and state legislation and regulations.
3. An ongoing evaluation of test quality ensures members receive high-quality laboratory testing.
4. Expedited review of prior authorizations with clear expectations for laboratory providers on the covered clinical situations for genetic tests and the required documentation to support the authorization evaluation.
5. Clear expectations for laboratory providers on the coding necessary to bill genetic tests.
6. Genetic test-specific claim to authorization matching during claims adjudication.
7. Continually evaluate genetic tests, required coverage criteria, and historical lab performance to determine when a test should be managed through utilization management or claims adjudication.
8. An integrated program to prevent FWA (Fraud, Waste, and Abuse).
9. An optimized network of laboratory providers through differentiated quality, pricing, and health plan promotional activities.

Chapter 3
The benefits of improved genetic testing management

Introduction

Health plans, healthcare providers, labs, and patients all stand to benefit from improving the management of genetic tests.

Scientifically validating tests, ensuring that the right ones are ordered at the right time, making sure they're coded and reimbursed properly, and integrating the results into timely patient care are crucial to realizing the most significant possible benefit from this burgeoning technology. As all parties search for a better way, it's essential not to improve one operation at the expense of the others.

When they developed Precision Genetic Test Management (PGTM), Avalon and Optum kept everyone in mind. This program improves all processes associated with genetic testing to support better patient care. As Chapter 2 of this e-book explains, PGTM, using the Palmetto GBA® DEX® registry and Z-Codes®, provides structure, order, and quality control in a chaotic genetic testing environment.

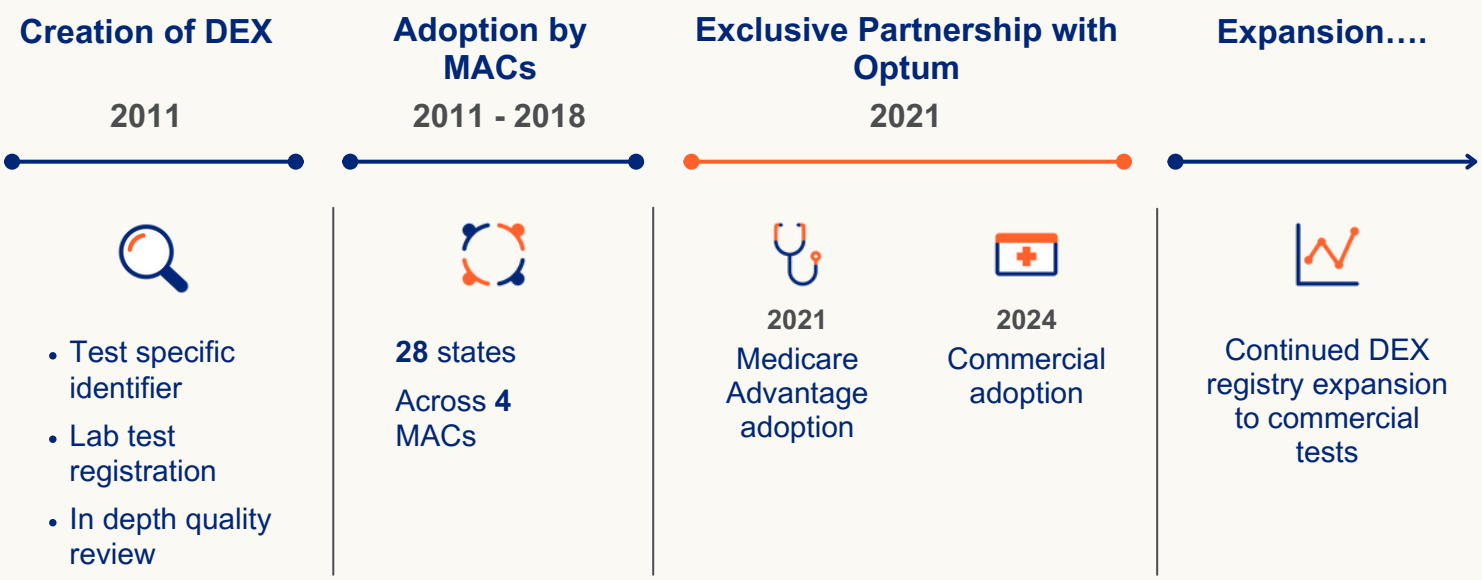
How improved genetic test management benefits health plans

Health plans typically need more resources to scientifically validate the efficacy and utility of the genetic tests for which they're billed. The number of tests is growing so fast that plans cannot keep up with their intended use, applicability, or quality. To add to the difficulties, most tests do not require regulatory approval or oversight, and they have limited ability to validate quality and clinical validity as they quickly enter the market.

PGTM uses evidence-based genetic policies validated by an independent clinical advisory board, NCQA-accredited utilization management prior authorization (PA), and automated provider decisions and clinical reviews based on health plan policies to evaluate genetic tests. Its automated claim coding rules enforce policy development and validate authorization decisions during claim adjudication to ensure payment accuracy. At the same time, the DEX Diagnostics Exchange provides access to a network of the highest-quality tests. The result is that plans can be assured that the tests for which they are paying are valid and valuable. Health plans control the adoption of guidelines as they adopt genetic policies. They will benefit from harmonizing these policies and automated claims editing, which traditionally have been separate operations.

Over seventy-five percent of commercial genetic tests have already been registered through DEX, requiring them to meet evidence-based technical performance thresholds.

Expansion of Z-Codes into the commercial market



75% of commercial test registrations complete in DEX as of Q2 2024

PGTM's unique identification process creates a one-to-one relationship between the Z-Code, CPT code, test, and lab. This allows for automated policy enforcement and payment decisions at the single test level while restricting bundling. Validating tests and carefully tracking their use limits vulnerabilities to fraud, waste, and abuse.

Plans report seeing fewer PA requests from providers. Coverage guidelines linked to Z-Codes increase auto-approvals in real-time, which improves the quality of care and increases patient and clinician satisfaction. PGTM's NCQA-accredited utilization management includes:

- Full-service PA review
- Outreach by Avalon's clinical team before the denial decision
- Low utilization management appeal rate

All the items listed above are combined to control plan costs by reducing administrative burden and increasing savings while improving care quality.

Benefits for providers and members

Like health plans, providers generally need more resources to stay abreast of the rapidly expanding number of genetic tests available or requested by patients. This can lead to a reluctance on the part of providers to order testing, overordering, and uncertainty about how to integrate results into a diagnosis or treatment plan.

Avalon offers peer-to-peer provider education through its physicians to support providers and increase efficiency. By validating the quality and utility of genetic tests, providers are better informed on which tests to order and when. With this knowledge, clinicians can proceed more confidently when treating patients.

On the administrative side, precise coding and unique identifiers for each test will result in fewer claims denials and easier adjudications, which saves providers time and reduces frustration. Using Z-Codes will help automate PA, which lessens the burden on staff and clinicians.

Patients are the ultimate beneficiaries of PGTM. They can be confident that their tests have been validated for quality and utility and that the results will be used appropriately to inform their care. And treatment will be expedited because there will be fewer PA requests. As a result, more patients will benefit from genetic testing.

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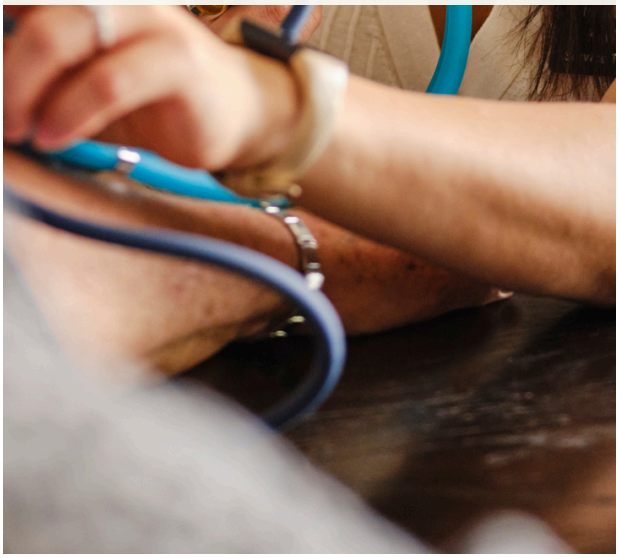
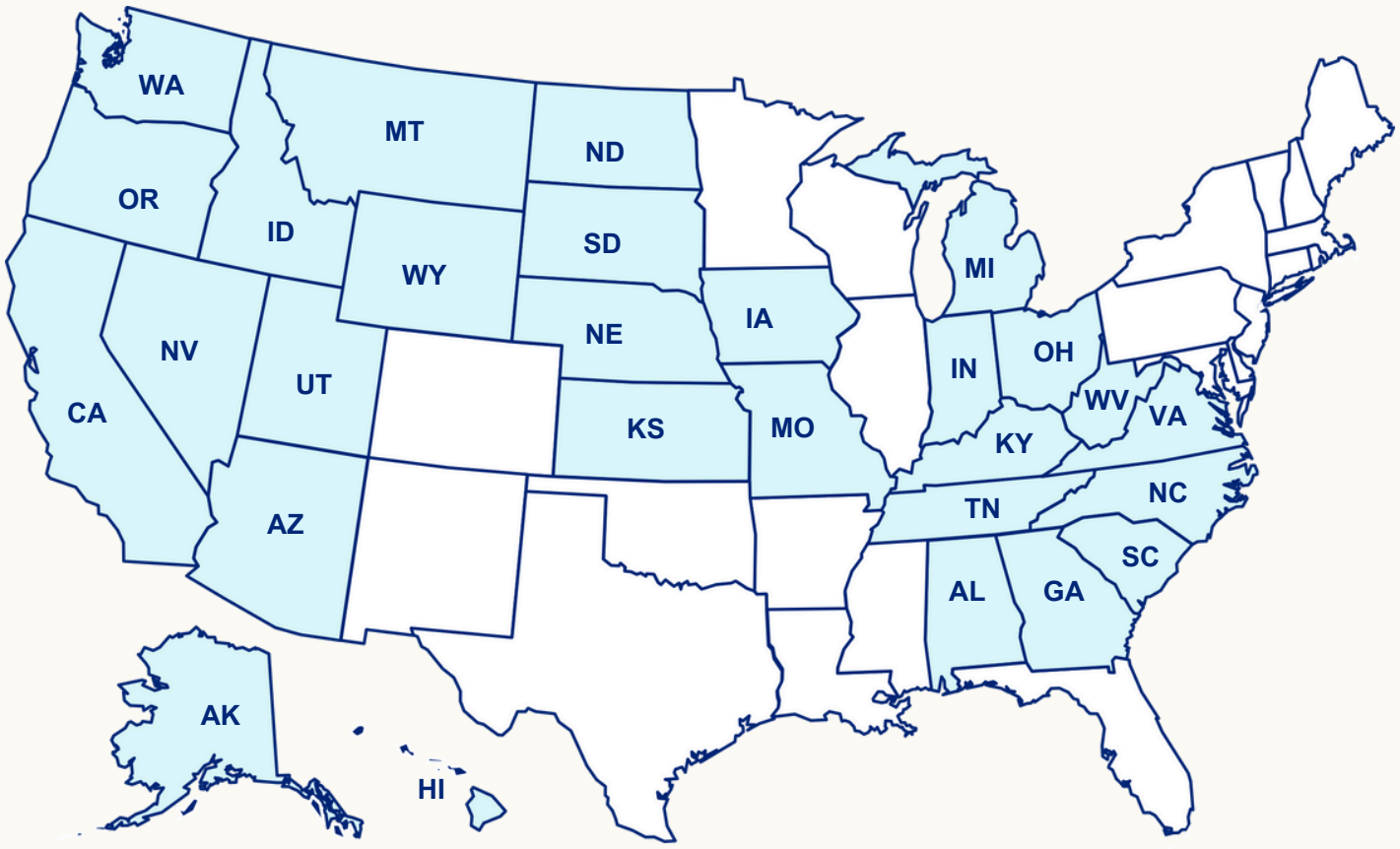


Benefits for labs

Labs are at the center of genetic testing. Providers, patients, and health plans rely on them to perform efficiently and follow best practices. However, like everyone else dealing with genetic testing, labs need help to cope with the exploding number of tests, their quality and utility, inadequate coding, reimbursement, and more.

PGTM allows labs to do their jobs more efficiently and effectively, with less abrasion and back and forth among themselves, providers, and health plans. Because top labs across the country are familiar with Z-Codes due to their use by CMS, it will be easy for them to adapt to using them for health plans.

States Participating in the Medicare MolDX Program



Source. https://www.palmettogba.com/palmetto/providers.nsf/att/MolDX_General_FAQs.pdf/$FILE/MolDX_General_FAQs.pdf

Areas of the map highlighted in blue show states participating in the Medicare MolDX program that Palmetto GBA administers on behalf of CMS.

Ultimately, the new clarity and structure provided by PGTM lead to greater satisfaction among lab staff and shorter wait times for results for patients and providers.

Conclusion

Genetic testing is advancing rapidly, demanding that healthcare systems quickly adopt new policies and procedures to maximize benefits while minimizing misuse and controlling costs. Precision Genetic Testing Management (PGTM) offers a comprehensive solution, incorporating DEX Z-Codes, a national network of genetic labs, evidence-based testing policies, and payment safeguards to better manage and control genetic testing. PGTM enhances care quality, provides precise policy coverage, reduces administrative burdens, minimizes provider and member abrasion, and prevents fraud, waste, and abuse, ultimately lowering medical expenses and increasing savings.

Genetic testing is currently in a chaotic phase that is typical of new technologies. Health plans, providers, labs, and patients are eager to optimize its use, but this requires improved management systems. PGTM introduces much-needed structure and predictability, building on the existing system with precision tracking, stricter enforcement, and science-based policies. This approach saves money while enabling genetic testing to achieve its full potential, resulting in better patient care.

To learn more about how the Precision Genetic Test Management solution from Optum and Avalon can help you better manage your genetic test program, please visit www.avalonhcs.com **or contact us at** avalon-info@avalonhcs.com.

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