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Pave the way to innovation

Incorporate DEX Z-Codes® into genetic test management to identify tests and review quality

Why pay for a genetic test if you can't trust the results?

Variability in genetic lab-developed test (LDT) quality has been in the headlines recently, with articles citing inconsistencies in some genetic test results, including widely used prenatal test results. This has led the U.S. Food and Drug Administration (FDA) to publish a warning to patients and health care providers about the risk of false-positive results with these genetic tests, since none have been authorized, cleared or approved by the FDA.

Lack of regulatory oversight has contributed to nationwide genetic-testing billing fraud, leaving payers vulnerable to overpaying on genetic-testing claims. This vulnerability is underscored when payers don't have a scalable process to identify discrete tests, validate test legitimacy and incorporate adequate controls in test utilization and claims processing.

Genetic-testing fraud has largely impacted Medicare Administrative Contractors (MACs) that have not adopted MolDX. Z-Codes® and the DEX® Diagnostic Exchange Registry have been instrumental tools in minimizing exposure to fraudulent claims without specific policy language to MACs that adhere to MolDX.

The Precision Genetic Test Management solution from Optum and Avalon Healthcare Solutions incorporates the DEX® registry and Z-Codes and builds on these tools to support all lines of business with a comprehensive solution.

Fraud and genetic testing in the headlines

CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments

OIG Fraud Alert: COVID-19 Scams

Ocenture LLC and Carelumina LLC Settle Allegations of False Claims for Unnecessary Genetic Testing

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

FDA seeks to regulate lab-developed tests, closing the "Theranos loophole"

Recently, the FDA has recognized the need to more tightly regulate lab-developed tests. A recent article titled "FDA seeks to regulate lab-developed tests, closing the 'Theranos loophole'" cites a quote from Jeffrey Shuren, the FDA's director of the Center for Devices and Radiological Health. "Despite the important role [lab-developed tests] play in patient care, some of these tests perform poorly or don't work at all," Shuren said during a press call. "Because LDTs aren't generally coming to the FDA for review, nor are additional safeguards in place, patients cannot be assured their tests provide accurate results."

CLIA regulations are different than what is intended to be regulated by the FDA. They are centered around establishing and verifying performance specifications as they relate to analytical validity of a test.

According to CMS: "This analytical validation is limited to the specific conditions, staff, equipment and patient population of the particular laboratory, so the findings of these laboratory-specific analytical validations are not meaningful outside of the laboratory that did the analysis."

What can the lab industry learn from the drug market?

In the drug market, all non-prescription drugs (which includes over-the-counter products) and prescription medication packages in the U.S. are classified with an NDC, or National Drug Code. The NDC delineates the drug, formulation, manufacturer and package size. The NDC is the drug's unique identifier.

To obtain an NDC, the drug's manufacturer submits data to the FDA for safety and efficacy before market approval. The FDA plays a role in verifying that the drug manufacturer's claims are valid.

As drug manufacturers seek reimbursement, the NDC is a critical element in determining the drug's place on plan formularies, building utilization management strategies, and establishing rates and reimbursements. This is critical, as several NDCs are often linked to a single HCPCS, CPT or revenue code.

Without an FDA-like process in place for molecular lab developed tests, in 2011 Palmetto GBA established the MolDX program for CMS to register tests to uniquely identify the test, lab manufacturer and performing labs by assigning a unique genetic identifier referred to as a Z-Code. As the FDA does with the drug market, Palmetto GBA also requires and validates lab manufacturers' clinical evidence supporting the claims that their test does what it says.

There are over 175,000 genetic tests on the market and fewer than 500 CPT codes to describe them, including a small number of PLA codes[1,2]

1. Michel R. Eight macro trends for clinical labs in 2023. The Dark Report. Jan. 3, 2023.
2. Market Research Report. The U.S. genetic testing market. March 2021.

What are Z-Codes and how do they help?

Broad application and enforcement of test quality regulations are one challenge with LDTs. The second is genetic test identification. There have been various attempts to classify and catalog discrete genetic tests. Z-Codes are Palmetto GBA's proprietary, unique 5-character alpha-numeric codes that start with a Z for molecular diagnostic tests. The Z-Codes are used by health care payers and providers as an adjunct to CPT codes.

Labs submit their tests and supporting documentation to Palmetto GBA's DEX program for review. A Z-Code is assigned that is unique to a test and the rendering provider. Palmetto GBA will perform a technical assessment of the test to validate intended use population, determine quality and review clinical value. There is no cost to lab test developers to obtain Z-Codes.

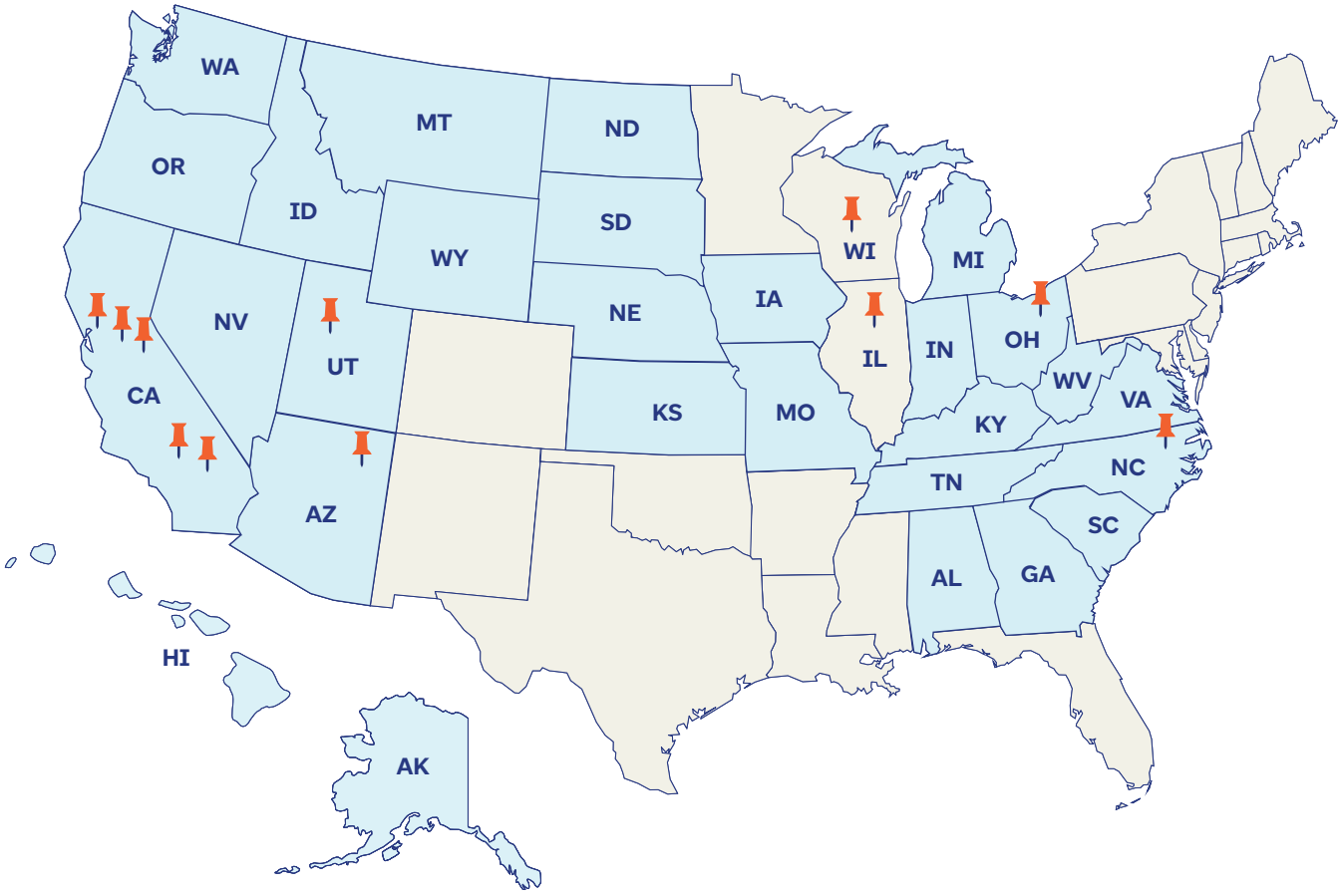
A Z-Code is not just an "administrative identifier." Z-Codes are a commitment to establishing test quality through a multifaceted process:

- A unique 5-digit identifier is assigned.
- A technical assessment vets the test to ensure it does what the test developer claims it's supposed to do.
- Tests are priced according to a fair and equitable pricing model that considers multiple variables around the test.
- All tests submitted for a review are assigned a Z-Code and tests that meet the criteria receive coverage for Medicare and a pass indicator for commercial usage.

No other genetic identifier has an established, scalable test quality component leveraged by CMS with a large national adoption rate.

Prior to the Palmetto GBA and Optum partnership, Palmetto GBA had required tests in scope for Medicare to receive a technical assessment, prioritized by complexity and spend, to determine base quality when registering for a Z-Code. Tests not covered by Medicare may have received a Z-Code with notation that a technical assessment was not performed. Some labs will need to submit technical documentation and pass a technical assessment if there is a test evaluation framework available.

The goal for labs is to reduce administrative burdens. Submitting existing data for a technical assessment once is less burdensome than submitting for a prior authorization every time a test is performed that necessitates a full medical review.



Labs across the U.S. are using Z-Codes for Medicare claim submissions

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

Labs in these states that submit Medicare claims are familiar with the process for applying for a Z-Code (to uniquely identify tests) and having Palmetto GBA perform a quality check that maps tests to an appropriate single CPT code; validates test intended use (by binding it to a set of ICD-10 terms) to create Medicare coverage rules (LCD and NCDs); and maps pricing for tests to 81479 (unlisted molecular test CPT).

Thumbtacks on the map highlight the location of the labs where health plans, across lines of business, paid the most lab dollars in one year.* This indicates most of these labs are located in MolDX states and familiar with the Z-Code process. This map highlights the correlation of where the labs are by utilization compared to what states have Z-Codes.

Key of labs and locations:

Ambry Genetics Corporation – Aliso Viejo, CA

Assurex Health Inc. – Mason, OH

Caris MPI Inc. – Phoenix, AZ

Exact Sciences Laboratories LLC – Madison, WI

Foundation Medicine Inc. – Morrisville, NC

Genomic Health Inc. – Redwood City, CA

Myriad Genetics Inc. – Salt Lake City, UT

CareDx Inc. – Brisbane, CA

Guardant Health – Palo Alto, CA

Tempus – Chicago, IL

Decipher Biosciences Inc. – San Diego, CA

* Independent study performed by Optum across various health plan data sets, annualized

How can health plans leverage Z-Codes for non-Medicare tests?

Currently, there are health plans that have mandated Z-Codes for submission on claims across multiple lines of business.

This enables health plans to:

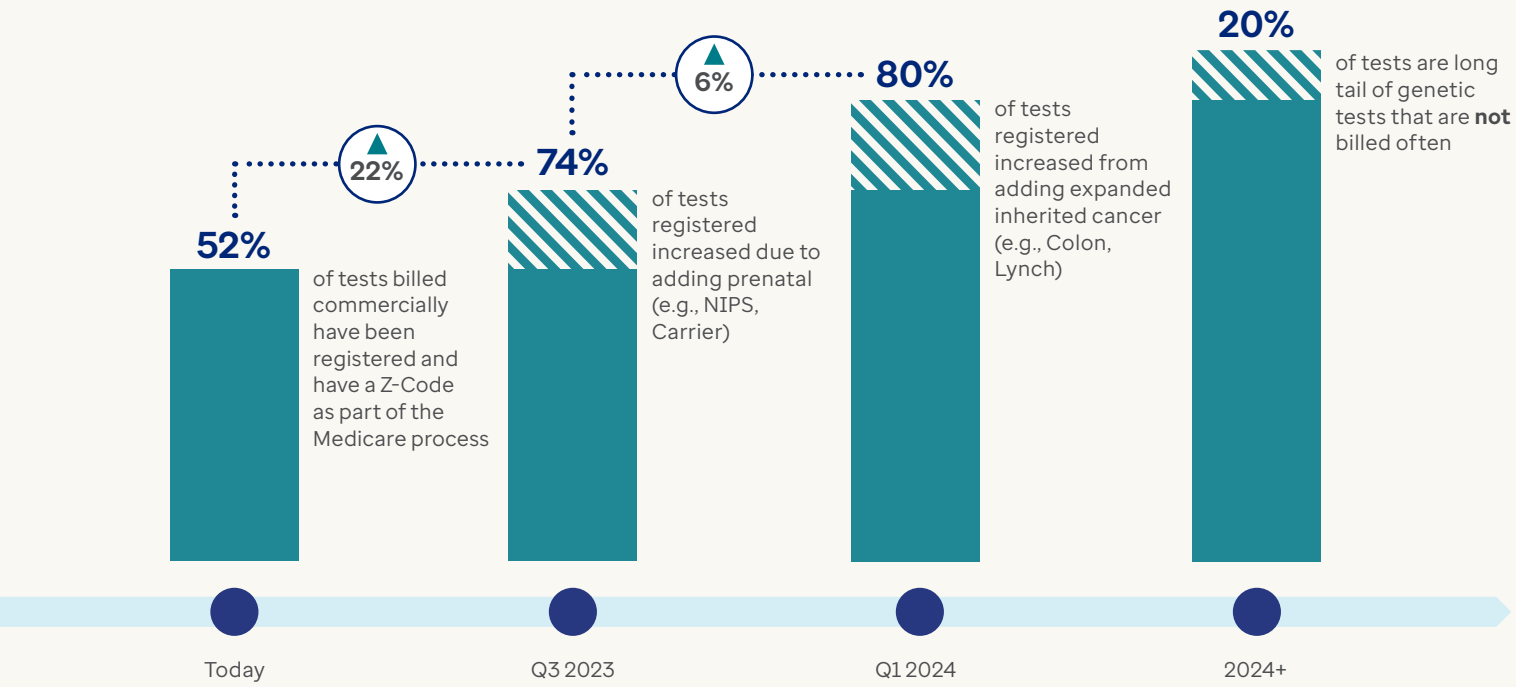
1. Increase automation in adjudication by uniquely identifying genomics tests
2. Better enforce their own reimbursement and medical policies through greater test specificity
3. Eliminate overpayment caused by unbundling
4. Minimize waste and abuse in billing
5. Reimburse a discreet amount at a specific test level, even for tests that are billed using NOC code 81479

Palmetto is expanding access to test assessment frameworks exclusively for commercial tests with feedback from Optum to establish assessments for prenatal cell-free DNA screening, prenatal carrier screening, inherited cancers and other needs specific to health plans.

The expansion of technical assessments enables health plans to:

1. Enforce test quality
2. Inform coverage decisions based on technical assessments (pass or fail)
3. Identify and report tests that contribute to effective care pathways

Adoption of Z-Codes and technical assessments



Over half the commercial tests billed have already been registered through DEX.

Why should health plans mandate Z-Codes on claim submission?

CPT codes alone lack specificity for health care payers to enforce coverage policy rules and often require manual medical record reviews to determine what test was performed, which delays payment. Z-Codes on a claim promote transparency so health care payers and members know the specific test that was given and how it should be reimbursed.

The additional specificity provided by a Z-Code also allows health plans to identify when providers may have unbundled or added unnecessary tests into a panel. If a health plan is using prior authorization for some of their genetic testing, the Z-Code will provide additional clarity from end to end in their process.

Z-Codes are not only a means to identify a specific genetic test. They reflect a process to enable test-specific quality review, which may positively impact members.

Can Z-Codes be used in prior authorization workflows?

Yes. When Z-Codes are linked to clinical policies, health care payers can offer lab providers faster approvals with a reduction in the number of requests needing medical reviews.

Lab providers know their test's Z-Code, and we encourage them to submit this code when requesting a prior authorization.

Where can health plans find Z-Codes on a lab claim?

The Z-Code identifier is entered adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:

- Line SV202-7 for 837I electronic claim
- Block 80 for the UB04 claim form

The Z-Code identifier is entered adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:

- Loop 2400 or SV101-7 for the 5010A1 837P
- Box 19 for the HCFA 1500 form

Even if health plans are not using or storing Z-Codes today, they are still getting them because the labs are submitting them.

The Precision Genetic Test Management solution from Optum and Avalon Healthcare Solutions has already linked thousands of tests to nonspecific CPT codes across clinical guidelines in a systematic way that can save health care payer clinical teams valuable time.

How do I know if Z-Codes are on claims we receive today?

Health plans can ask their contracted network labs if they are submitting them. Health plans can also review raw claim data that was submitted to them and reference the field(s) indicated above. Most health plans are surprised to see Z-Code data is being sent, even though it's not captured in their claim adjudication system.

Not all claim adjudication systems store the CPT comment/narrative field, even though CMS requires use of this field. The following adjudication systems have recently added this field:

- Cognizant, QNXT – version 6.0 R2
- HealthEdge, Healthrules – version 21.5
- DST, Amisys Advance – version 10.0
- NASCO (enhancement submitted)
- EPIC Tapestry (will add at client's request)

Optum has an exclusive partnership with Palmetto GBA to leverage their DEX® Diagnostics Exchange platform and content. This is the same platform used to administer the Medicare FFS MolDx® Program for CMS. Optum and Avalon have created a differentiated product to manage genetic test spend, combining test identification and quality, evidence-based genetic clinical guidelines, prior authorization services, payment accuracy services and a supplemental genetic wrap network. Optum is the exclusive reseller of the DEX® Diagnostics Exchange Registry content.

The Precision Genetic Test Management solution from Optum and Avalon Healthcare Solutions was developed to be compliant with the MolDX program administered by Palmetto for CMS through an exclusive partnership with Palmetto and Z-Code licensing. Our product offers a fully automated claim review for Medicare and commercial plans, allowing prior authorization processing to focus on guidelines where clinical subject matter expertise is most needed.

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