

## Case Study - Payer (Government)

Palmetto GBA

### Client

Headquartered in Columbia, S.C., Palmetto GBA (Palmetto) is a Medicare Administrative Contractor (MAC) for the Centers for Medicare & Medicaid Services (CMS), and is the administrator for the MolDX program, with six jurisdictions encompassing 25 states.

### Challenge

Escalating molecular diagnostic test volume and proper reimbursement for same, along with the inability to identify specific tests submitted on claims, which led to difficulty in applying Medicare coverage properly.

### Solutions

DEX™ Diagnostics Exchange  
DEX Z-Code™ Identifiers

### Results

- \$16 million per month in cost savings from unnecessary tests
- More than 1,500 tests mapped to the same NOC code now uniquely identified with a DEX Z-Code
- More precise claims information, resulting in timely and more accurate payment for labs

## Palmetto GBA Expands Innovative Program to Ensure Appropriate Molecular Diagnostic Test Coverage with the DEX Diagnostics Exchange

Palmetto had been seeing a steady increase in the spend on molecular diagnostic (MDx) tests, but the existing coding system for billing MDx tests left the company unable to discern which tests it was paying for and whether they met the Centers for Medicare & Medicaid Services' (CMS) coverage policies.

“We had perceived risk and vulnerability in this particular space,” said Palmetto’s Vice President of Operations Mike Barlow. “Our first and foremost objectives were to know what we were paying for, and to ensure that we could accurately apply Medicare coverage.”

### Shedding Light on MDx Claims: the MolDX Program

The Palmetto MolDX program was developed to uniquely identify — and improve coverage and reimbursement for — molecular diagnostic tests. Palmetto launched the MolDX program to bring transparency to an increasingly important part of its business in terms of the reimbursement dollars that molecular diagnostic claims represent, and the clinical promise of the tests behind those claims. First piloted in 2011 in one jurisdiction — encompassing California, Nevada, and Hawaii — it has since expanded to six jurisdictions encompassing 25 states.

Palmetto’s MolDX program is designed to help determine which molecular diagnostic tests are ultimately improving clinical care, according to Barlow. “The objective of accumulating this data and performing the analysis is that we want this information to benefit both beneficiaries and providers,” he said. “We ultimately want providers to be able to determine exactly what test they should be ordering, and we want the most promising tests — the innovative ones that can improve clinical care — to be available to the Medicare beneficiary population.”

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– Dr. Elaine Jeter, Medical Director,  
Palmetto GBA

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Palmetto turned to the DEX™ Diagnostics Exchange to be the technology engine for the test registration and technical assessment components as part of its MolDX program, which has been successful in enabling tests to be appropriately identified and billed. “The world of molecular diagnostics has been growing rapidly, and we needed visibility into what was going on,” said Barlow. “Our MolDX program has provided the clarity we didn’t have before. Expectations are more easily communicated, and from a stakeholder standpoint, everything is much more transparent. We’re now an integrated part of the process among the major stakeholders.”

### The DEX Diagnostics Exchange Informs Clinical and Coverage Decisions

The technology engine of the MolDX program — DEX Diagnostics Exchange — is an open, online test registry and workflow solution for information and evidence about MDx tests. Labs register each MDx test with the DEX Diagnostics Exchange, and then that test is assigned a unique, five-digit alphanumeric identifier, a DEX Z-Code™.

“All the lab has to do is register,” said Dr. Elaine Jeter, Palmetto’s medical director. “The fact that DEX can generate a test-specific code, and we can have it to a laboratory to be using it in as little as two weeks, has been extremely helpful.”

Through the DEX Diagnostics Exchange, the lab agrees to share its test data with its payers. At that point, the lab adds the DEX Z-Code as additional information to the claim line. The payer uses this information to analyze the code pairing and adjudicate the claim, and can measure results at the test level.

Providers and payers can use the DEX information submitted by labs to understand and evaluate each test. This process enables labs to provide visibility and specificity about their tests. The shared test resource then helps inform clinical and coverage decisions made by payers.

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Palmetto’s MolDX program has continued to grow, and requires every laboratory in its jurisdictions to obtain and use the DEX unique identifiers to pinpoint the exact test for which they are billing. To date, the program’s registrations include about 6,500 unique tests from more than 550 registered labs, extending to networks of more than 1,000 participating laboratories. More than 1,500 of these tests are mapped to the same NOC code (81479) that, without DEX Z-Codes, could not be differentiated on a claim without manual research and processing.

“DEX registration provides assay specificity — one Z-code per test, per provider,” Barlow said. “We can manage test panels that offer analyte groupings as a unit of one rather than permitting the unbundling of these panels into individual CPT codes. Adjudication requires all three elements — DEX Z-code, CPT® code and NPI to apply coverage and payment.”

### Saving Money Immediately

The return on investment for the MolDX program and DEX was almost instantaneous, according to Barlow. “DEX paid back in the first month of operation,” he said. The program works in tandem to enable both labs and Palmetto to meet Medicare reimbursement policies. First, it enables new and current laboratories to have a way to uniquely identify their tests, so that they can be billed properly. Secondly, it enables Palmetto to accurately process claims by identifying the specific MDx test and applying Medicare coverage accurately, ensuring appropriate reimbursements. This has resulted in significant savings by reducing extraneous payments. Because of the transparency into molecular diagnostic tests, Palmetto was no longer paying for some services that were not a Medicare benefit. And those savings have been significant.

“Now, through proper coding and identification, we’ve been able to identify savings within the Medicare program’s claims processing,” Barlow noted. “We’ve identified potential cost-avoidance savings, claims that Medicare would have paid if the program hadn’t been in place. After five years with DEX, it’s a substantial amount of money — well over \$16 million a month for the 25 states where the program is operating today.”

But Barlow said he wasn’t entirely surprised by those numbers.

“We knew that if you had a program in which you had clear identification as to the tests that were being performed, and you had a rigorous review of those tests before they became eligible for Medicare coverage, that you would in fact steer the program down a clear path

of coverage,” he added. “And by default, that would create savings for the program overall, because you know what you’re paying for, and you don’t pay for what’s not reasonable and necessary, and you don’t pay for something that’s statutorily excluded from the Medicare program. We now can make that clear distinction.”

The DEX Z-Code assigned to each test in the MolDX program allows the labs to report precise information on claims and avoid billing for tests that are not covered by Medicare, which saves time for the lab and helps speed payment. It also affords the laboratories the opportunity to educate their providers about tests that are not covered, thus reducing the number of non-reimbursable tests performed. The unique identifiers also facilitate claims submission and reimbursement for new technology, an area that hindered payment due to the new science and lack of test specificity.

### **Partnering to Educate the Industry**

As Palmetto anticipated for the MolDX startup, labs incorrectly perceived the program as a method to cut reimbursement, and, according to Barlow, they needed educational support to understand the program’s goals and purpose. It was a tough paradigm shift for many in the industry. “The labs would say, ‘I’m following the coding system, billing you for four DNA extractions and amplification,’ ” said Barlow. “We had to explain to them that we weren’t changing the coding system, but that we simply wanted to know what those four DNA extractions were for, so we could use that information to properly adjudicate the claim based on Medicare policies for coverage.”

Barlow added that the challenge that remains with these tests — specifically with the newer technologies being developed — is that, in many cases, the technology is years ahead of the clinical application. Historically, providing evidence of clinical utility has not been an area of focus for the labs. However, Palmetto has worked with the industry to change the dynamic. It has worked with test developers, in some cases, to support coverage concurrent with data development. “It’s not just the fact that with DEX we now have a process to review tests, but that the labs understand that process and they understand the expectation of the evidence that they need to submit,” said Barlow.

“Not every gene and not every piece of information is actionable,” Jeter added. “If you want good personalized medicine, we’re actually supporting it by advancing the kinds of tests that do provide that data and do allow and promote that growth and knowledge. And our ability to do that is dependent on the DEX Z-Codes.”

### **Priorities and Process Give Palmetto a Clearer Focus**

Jeter noted that, “DEX helps Palmetto follow the growth of specialty labs, new assays and/or methodologies coming to market, identify aberrant coding practices and identify molecular assays for which there is no clinical utility.” She said that, “Reviewing the test registrations in DEX helps us stay tuned in to what is happening in the lab industry, so we’re able to get out in front of patterns.”

Hence, part of the process today is that if someone sees something in DEX, or some new technology or a new test, it triggers an action for MolDX to reach out and get more information about that test or to do the tech assessment.

“With McKesson as a partner, we have launched an industry-impactful program that brings transparency to this emerging technology and identifies the role of molecular diagnostics,” Barlow said “Molecular diagnostics directly impacts overall health care, but we need clarity, so these tests can do what they are supposed to do — improve the quality of care.”