### Molecular Test Update

### Some Labs Report Faster Pay For Molecular, Genetic Tests

## Medicare's MolDx Program and use of Z-codes can speed coverage/reimbursement decisions

URING RECENT MONTHS, some labs are reporting improvement in how their claims for certain molecular and genetic tests are being reimbursed. This is progress from the financial crises experienced during 2013 for many labs performing molecular and genetic tests.

Disruption in these payments was one of the clinical lab industry's biggest stories during 2013. There was a major upheaval in coverage and payment guidelines associated with molecular and genetic tests because both government and private payers were not prepared to deal with the implementation of 114 new CPT codes for specific molecular assays and genetic tests.

#### **▶**No Claims Paid In Early 2013

In fact, during the first four months of 2013, few labs reported getting any payment from Medicare for lab test claims involving the new molecular CPT codes. It was not until May of 2013 that some labs began to see a flow of regular payments for some of these molecular test claims. (See TDR, May 28, 2013.)

There was a bigger aspect to this story than simply the introduction of new CPT codes for molecular and genetic tests. It was the Molecular Diagnostic Services Program (MolDX), a pilot program developed and administered by **Palmetto GBA**, a Medicare Administrative Contractor, with the approval of CMS.

MolDX was implemented only in the JE (formerly J1) region of California, Nevada, Hawaii, and the Pacific Territories (now administered by **Noridian Administrative Services**) and then expanded into the J11 region of South Carolina, North Carolina, Virginia, and West Virginia (currently administered by Palmetto GBA). It is not yet a national program.

When a lab has a molecular or genetic test that it would like to submit to Palmetto for coverage and reimbursement decisions, it needs to follow the requirements of the MolDx program. This includes registering the molecular or genetic test with MolDx. One method to accomplish this is to obtain a unique Z-code identifier for that assay from the McKesson Diagnostics Exchange, then submit the necessary documentation concerning this lab test to the Medicare program.

MolDx officials can then use the Z-code number and supporting documentation for that unique molecular or genetic test to answer this question: should the test be covered by Medicare as reasonable and necessary? All affirmative coverages are published on the Palmetto website as LCD updates. From that point, the lab can submit the claim with the Z-ID and an appropriate CPT charge code. Covered Z-IDs are paid promptly.

To update this important story, THE DARK REPORT contacted a number of lab companies that perform proprietary molecular or genetic tests to learn about their experience at getting paid for these tests. In some cases, it seems that the MolDx program and use of the Z-code system has played a role in improving

how quickly some health plans pay for genetic and molecular tests.

One clinical lab director who asked not to be named explained that the Zcodes have improved payment processing of claims for his lab's unique molecular test. This was particularly true for claims submitted to Palmetto GBA. "At our lab, the McKesson Z-code system has played a critical role in helping us obtain payment via the MolDx program," noted the lab director. "Throughout 2013, our lab went unpaid because of the changes Palmetto put in place for the Medicare coverage determination and reimbursement process for advanced molecular tests.

"For our lab, Z-codes resolved a significant problem that Palmetto officials have openly discussed—namely the need to identify specific laboratories and assays so that Palmetto could adjudicate claims appropriately for advanced molecular tests that lacked distinct codes when the molecular stacking codes were eliminated," continued the lab director. "Under the MolDx program, Z-codes allowed Palmetto to price and reimburse for our unique advanced molecular test. Otherwise, we would need to bill with a miscellaneous and unspecific molecular pathology code.

#### **▶**Payment For Lab Claims

"As most lab managers know, use of miscellaneous molecular pathology codes on a claim makes it more difficult to get paid for that advanced molecular test," he noted. "When a lab files claims that way, payers default to asking for medical documentation, which delays payment even when the test is covered under medical policy.

"With the Z-codes, our lab's claims for covered services have been adjudicated and paid quickly and consistently," added the lab director. "That said, we are also learning that having a Z-code does not guarantee payment. No coding system can do that.

"But our experience is that, by giving payers the information they need to understand what test they're paying for and the

# **Dissatisfaction Remains About Coverage Decisions**

HATEVER POSITIVE PROGRESS some labs report in getting claims paid for their advanced molecular and genetic tests, there remain plenty of lab executives who are dissatisfied with how government and private payers are making coverage and payment decisions for these tests.

Critics within the lab industry point out that there are potential conflicts in the way federal laws, including the recently-enacted Protecting Access to Medicare Act, require government health officials to collect data needed to make coverage and reimbursement determinations and then how that data are used to establish appropriate guidance and payment for these molecular and genetic tests.

One example is the uncertainty about the specific roles of CPT codes and the MolDx test registry (which incorporates Z-codes) in the overall processes CMS and the Medicare Administrative Contractors use. These and related issues will be the subject of ongoing dispute between labs and government and private payers.

medical necessity for those tests, our lab is experiencing faster processing speeds for those claims," he said.

According to this lab director, one major health insurer in the Northeast currently uses the Z-code registry in an effective way. "What we have seen is that our use of the Z-codes with this payer enables more timely resolution of claims for those specific molecular assays," he explained. "That is because the payer's reviewers can make a more rapid determination of the medical necessity. It also means that we are asked for medical necessity documentation less frequently. That's because now, when they get our lab's molecular test claims, they know the clinical purpose for those tests."

—Joseph Burns