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MolDX and Z-identifier Codes: Why, How, and the Future

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Problems with Molecular Tests

(why we exist)

- Understanding molecular tests require knowledge and experience most clinicians (and CMDs) may lack
- Lack of well-defined billing codes makes claims processing difficult; many are not sufficient to understand what was done
- Lack of standardization in testing makes it difficult to know if any given test is both reasonable and necessary (or has medical necessity)

Examples

Examples from a claim:

- CPT 81408: Which gene was tested and for what purpose?
- CPT 81445: Does this panel contain all the genetic information needed to render a decision on therapeutic intervention for this patient? Has the lab demonstrated validity for this LDT?
- One lab bills 87632 for a specific ICD-10 code, and another bills 87798 x 10 for the same ICD-10 code. What was done?

Acronym key (1):
CMS: Medicare

Introduction: What is MolDX?

MolDX is leveraged by the Centers for Medicare and Medicaid Services (CMS) to utilize expertise in the molecular diagnostics space to create PAYOR CONTROLS in the space, including:

- Identify relevant molecular tests and create administrative processes for dealing with those tests
- Determine coverage policies for molecular tests (with SMEs deciding on evidence and what is “proven”; currently 5 molecular pathologists/geneticists on staff)
- Determine reimbursement for tests (when needed) and “edits”
- Deployed in 28 states across 7 jurisdictions and 4 MACs (contractors)
- Not only a problem for Medicare…

MolDX Process Requirements

MolDX policy for coverage and claims processing described in Molecular Diagnostic Tests Policy (LCD L35025):

- Requirement for Z-identifier to describe the test
  - **Allows AUTOMATED adjudication of claims**
- Requirement for a Technical Assessment (TA) of the test
  - **Ensures reasonable and necessary compliance (meets AV, CV, CU requirements)**

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Acronym key (13):
CMS: Medicare
MAC: CMS admin contractor
NCD: national policy
LCD: Local policy
CAG: CMS policy makers
CMDs: MAC medical director
CFR: code of regulations
PIM: program manual
TA: Technical assessment
CAC: Contractor Advisory Committee
AV: analytical validity
CV: clinical validity
CU: clinical utility

The TA process

TA includes assessment of a tests':

1. Analytical validity (AV)
2. Clinical Validity (CV)
3. Clinical Utility (CU)

AV: How well does the test detect the mutation/compound it is seeking to detect? *Analytical and Clinical validations*

CV: How well does the analyte/variant relate to the presence/risk of disease?

CU: How clinically useful is this test? Can it change management to improve patient outcomes?

DEX registry

- The DEX registry is a free to use platform and database for providers to register their tests with Palmetto GBA. This is required for MolDX providers and now for some commercial payors.
- Providers register their entity and submit their test services. Upon review, a Z-code for the service is created and a TA performed. For Medicare, the results coverage decisions are made public as well as pricing (if needed)
- The registry maintains all relevant information about the services rendered and can be used by payors to automate claims processing by incorporating its contents.
- Type of information stored: test name, provider, methodology used, analytes measured, intended use, appropriate CPT and ICD-10 codes, price, etc.

Shared data set and automation

Palmetto GBA has created processes, procedures and controls that result in the automation of adjudication of molecular claims by determining *a priori*:

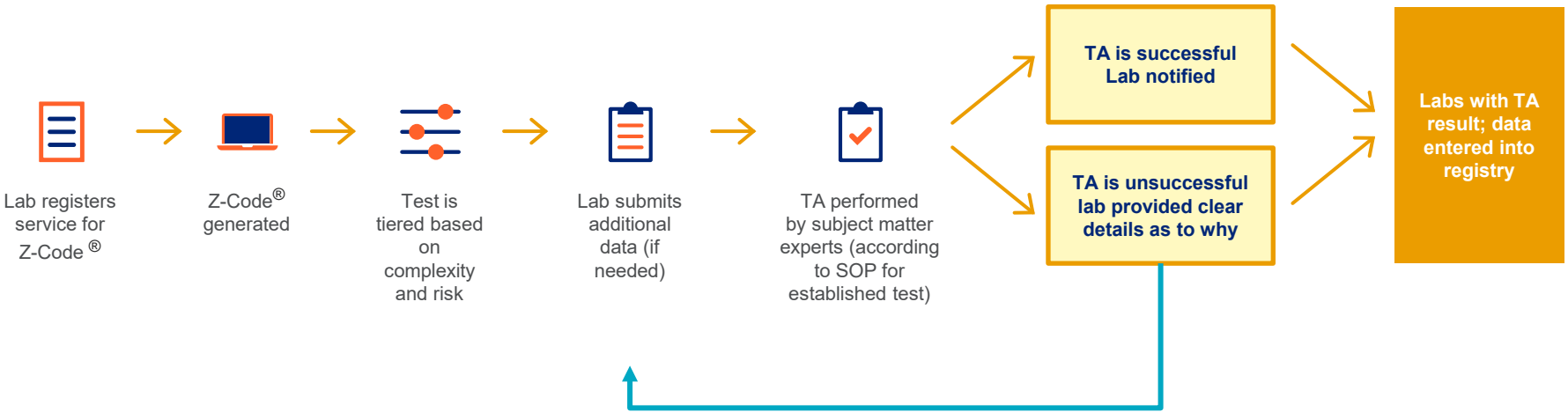
- If the ***specific test*** is the appropriate test for the patient
- If the ***specific test*** does what it says it does
- If the ***specific test*** is of sufficient quality
- If the ***specific test*** has demonstrated clinical value
- If the ***specific test*** is billed appropriately

These payer controls are already in use by the MolDx program for CMS and for MA programs.

OF NOTE: commercial services are NOT MolDX; they are part of our DEX services

Palmetto GBA test evaluation

- **Test registration and review (performed once for each test submission)**



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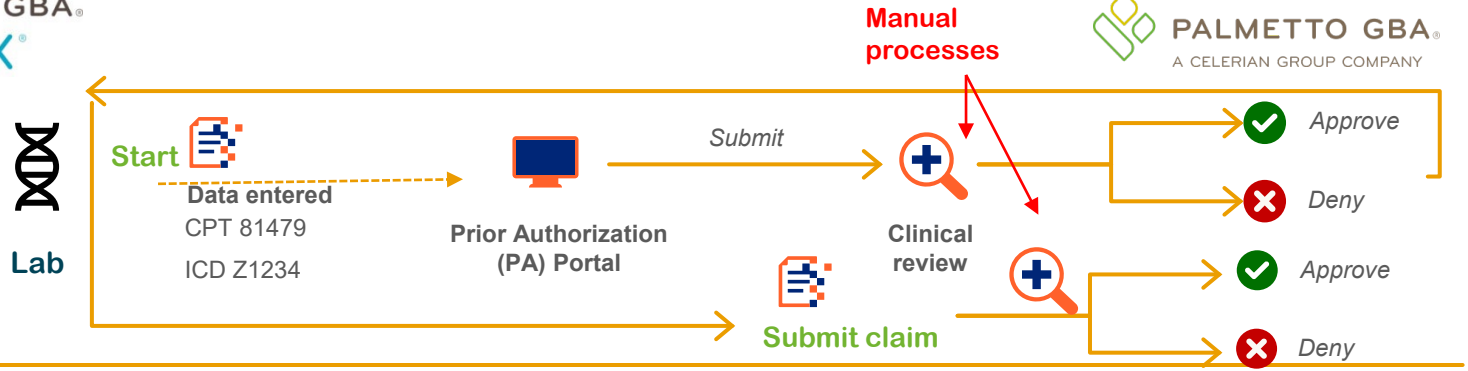
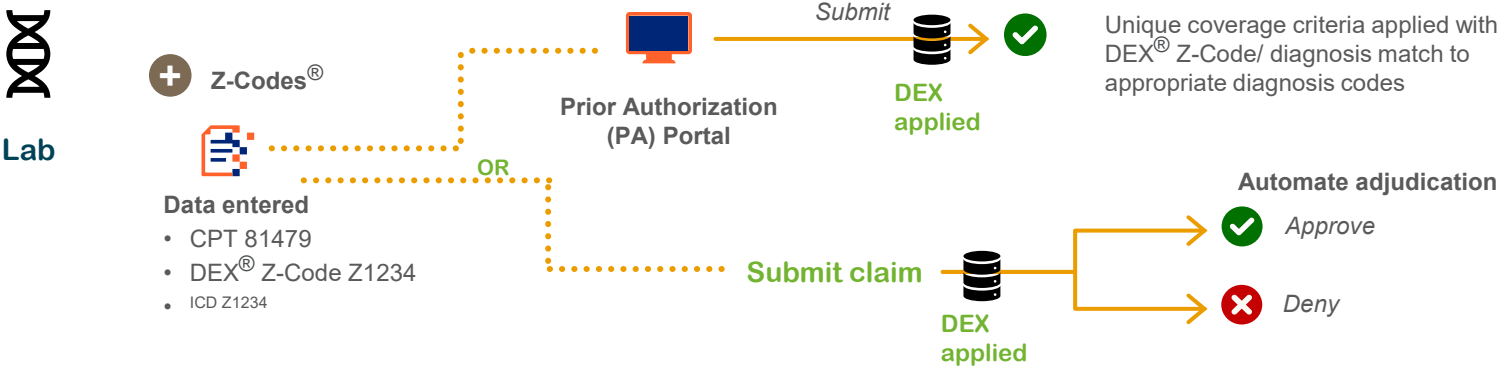
Before



How commercial payors can use our system moving forward

After



Adding a Z-Code® reduces abrasion, increases reproducibility of pre-authorization and claims processing, reduces unnecessary delays by automating processes. There will also be less discrepancies between payors are they are relying on the same data for adjudication.

Palmetto GBA Content and Processes For Commercial Use

- **Palmetto GBA registry content and services was licensed to Optum in 2021 to bring these controls into the commercial market**
- **Commercial plans started rolling out use of our services in late 2021 for Medicare Advantage plans**
- **Commercial plans are now starting to leverage our solutions for commercial business for NON-Medicare services; we expect many payors to use this system**

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Thank you!

Questions?

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