



PALMETTO GBA®

MoIDX®



PALMETTO GBA®

A CELERIAN GROUP COMPANY

A CMS Medicare Administrative Contractor

# Molecular Diagnostic Program (MoIDX®)

*Coverage, Coding, and Pricing  
Standards and Requirements*

## DOCUMENT VERSION CONTROL

Version No.	Date	Purpose / Changes
1.0	08/02/2013	Original document
2.0	02/07/2014	Regular program updates
3.0	09/03/2014	Updated trademark, CPT codes, CTEP information, language for statutory excluded tests, replace CED with CDD, changed MEF from quarterly to weekly, add MoIDX tracker#
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## CHAPTER I: BACKGROUND

### 1. Background

#### 1.1. Objective

The objective of this document is to describe the process that Palmetto GBA (Palmetto GBA) uses to determine coverage, coding, and pricing for molecular diagnostic tests and other molecular pathology services administered through the Molecular Diagnostic Services (MoIDX<sup>®</sup>) Program.

#### 1.2. Current Scope of the Palmetto GBA MoIDX program

The following Medicare Jurisdictions have implemented the MoIDX program:

- JE A/B MAC, which covers California, Nevada, Hawaii and the US Pacific Territories of Guam, American Samoa and the Northern Marianas, administered by Noridian Healthcare Solutions
- JF A/B MAC, which covers Oregon, Washington, Idaho, Utah, Montana, Wyoming, Arizona, North Dakota, South Dakota, Alaska and the Aleutian Islands, administered by Noridian Healthcare Solutions
- JM A/B MAC, which covers North Carolina, South Carolina, Virginia and West Virginia, administered by Palmetto GBA
- J5 A/B MAC, which covers Iowa, Kansas, Missouri and Nebraska, administered by WPS Government Health Administrators
- J8 A/B MAC, which covers Michigan and Indiana, administered by WPS Government Health Administrators
- J15 A/B MAC, which covers Ohio and Kentucky, administered by CGS Administrators, LLC
- JJ MAC, which covers Georgia, Tennessee and Alabama, administered by Palmetto GBA

MoIDX affects diagnostic services reported with the following CPT/HCPCS codes:

The scope of the MoIDX Program is outlined in [LCD MoIDX: Molecular Diagnostic Tests \(MDT\) \(L35025\)](#), and associated Billing and Coding articles: [Billing and Coding Article MoIDX: Molecular Diagnostic Tests \(MDT\) \(A56853\)](#) and [Billing and Coding: MoIDX: Proteomics Testing \(A59636\)](#).

For questions about specific tests/assays not described above, please [Contact Us](#).

Tier 1 molecular pathology services that are not covered in the Medicare Clinical Laboratory Fee Schedule, Tier 2 codes, and NOC codes will be subject to the coverage, coding, and pricing processes outlined in the MoIDX Program. MoIDX codes published in the Medicare Clinical Laboratory Fee Schedule or in the MDFSB will be priced and covered as published.

MDTs and LDTs present challenges because the Clinical Laboratory Fee Schedule pricing methodology does not account for the unique characteristics of these tests. As such, Palmetto GBA's MoIDX Program strives to create a consistent approach to coverage and pricing decisions for MDTs and LDTs.

##### 1.2.1. MoIDX Program and AB MAC roles:

Palmetto GBA will maintain and provide MACs, which have established operating agreements with Palmetto GBA, a weekly Master Edit File (MEF). In addition to the MEF, Palmetto GBA will coordinate appropriate LCD development and provide educational articles to support the coverage decisions as necessary. This model will be used as the MoIDX Program is expanded to additional A/B MACs.

MoIDX will administer MoPath claims in the following manner:

- Per policy (see Chapter II), services within the scope of this program require a test identifier (DEX Z-Code<sup>®</sup>) and this identifier must be submitted as additional information at the time of claim submission in order to be fully adjudicated. MACs will use the DEX Z-Code as the identifier to align coverage and/or payment with the MEF.
- MACs will receive and implement weekly updates of the MoIDX MEF to adjudicate claims
- For CPT NOC codes (81479, 81599, and 87999), this additional information (Test identifier/Z-Code) is submitted in the Loop 2400 or SV101-7 (5010A1-837P) or SV202-7 (5010A1-837I) claim line detail field
- When entering the DEX Z-Code<sup>®</sup> on the SV101-7 documentation field for Part B claims please do not add additional characters and/or information on the line.
- If the Z-Code is not on file, the MAC will reject the claim
- MAC adjudicates claim
- MoIDX generates an article and/or LCD as appropriate to support decision
- MoIDX updates MEF with new information for weekly release

### 1.3. Definitions

- *Common Procedure Terminology (CPT) Code*: Level I codes in the Health Care Common Procedure Coding System (HCPCS) CPT, a uniform coding system consisting of descriptive terms and identifying codes, used to identify medical services and procedures furnished by physicians and other health care professionals. The American Medical Association (AMA) establishes CPT codes, which are used by payers under license.
- *Health Care Common Procedure Coding System (HCPCS)*: The HCPCS Code Set is one of the standard code sets used to process claims in an orderly and consistent manner. The HCPCS is divided into two principal subsystems, referred to as level I and level II of the HCPCS.
- *Health Care Common Procedure Coding System (HCPCS) Level II*: Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.
- *Laboratory developed test (LDT)*: A test developed by a laboratory for the use of its own clients. Typically LDTs are not approved or cleared by the FDA.
- *Part A/Part B Medicare Administrative Contractor (MAC)*: Private entities delegated authority to receive, review, price and pay Medicare claims for items and services, including clinical laboratory services, under Medicare Part A and Part B.
- *Molecular Diagnostic Services Program (MoIDX)*: A program designed and operated by Palmetto GBA to identify and establish coverage on existing tests, newly developed LDTs, tests using pathology NOC codes, and other molecular diagnostic tests that fall within the scope of the Molecular Diagnostic Test (MDT) LCD.

- *Molecular diagnostic test (MDT)*: A test that involves the detection or identification of nucleic acids (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolites. The test may or may not include multiple components. An MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.
- *Molecular Pathology Codes (MoPath)*: A series of CPT codes published by the AMA describing molecular diagnostic tests. MoPath codes are found in the 80000 series of CPT codes. Certain MoPath codes are subject to unique coverage, coding and pricing provisions of Palmetto GBA's MolDX program. MoPath codes are subject to gapfill pricing at the request of CMS.
- *National Limitation Amount (NLA)*: Calculated as a percentage of the median of all contractor-determined prices for services paid under the Clinical Laboratory Fee Schedule, the NLA serves as a ceiling rate, above which no MAC may pay in excess.
- *Not Otherwise Classified Codes (NOC)*: Codes used to report an item or service for which no specific code exists. Sometimes referred to as “unlisted” or “miscellaneous” codes.
- *Test Panel*: A predetermined set of medical tests composed of individual laboratory tests related by medical condition, specimen type, frequency ordered, methodology or types of components to aid in the diagnosis/treatment of disease.
- *Local Coverage Determination (LCD)*: An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Social Security Act.

#### 1.4. Coverage for Clinical Laboratory Services under Medicare

Medicare provides coverage for items or services that:

- Fall within a defined Medicare benefit category
- Are not excluded from coverage by statute, regulation, National Coverage Determination (NCD) or Local Coverage Determination (LCD)
- Are determined to be reasonable and necessary for the treatment of illness or injury

Section 1833(a)(1) of the Social Security Act establishes coverage for “medical and other health services” under Medicare Part B. Section 1861(s)(3) of the Act defines “medical and other health services” as including “diagnostic laboratory tests.”

The CMS may outline conditions and limitations in which an item or service may be covered by Medicare in a National Coverage Decision (NCD).

Section 1862(a)(1)(A) of the Act excludes from coverage any item or service which is not reasonable and necessary for the treatment of illness or injury or is a replacement for a missing or non-functioning body member. Reasonable and necessary limitations are administered through an LCD. An individual MAC may outline conditions and limitations in which an item or service may be covered by Medicare in a Local Coverage Determinations (LCDs). An LCD covers the MAC geographical jurisdiction and complies with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the item or service is reasonable and necessary).

#### Coding

Services (including clinical laboratory services) must be reported using the alpha-numeric HCPCS code (e.g., CPT code) that best describes the service. The AMA's CPT workgroup

establishes CPT codes, which are grouped into series of related codes. CPT codes in the 80000 – 89999 series describe clinical laboratory services.

Clinical laboratory services not described by a specific procedure code should be reported using a NOC (or unlisted) procedure code. Because NOC codes may potentially be used to report many different types of services, claims processing systems are not capable of automatically assigning service-specific pricing to NOC codes. As such, NOC claims require review of additional information in order to identify the service provided, determine coverage, and make a pricing determination.

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual test results provided, all MDT services must include an identifier as additional claim documentation. Test providers must apply for an identifier specific to the applicable test and submit the test assigned identifier on the claim for reimbursement. The assigned identifier will provide a crosswalk between the test's associated detail information on file and the submitted claim detail line(s) required to adjudicate each test's claim. The unique identifier limits the need to submit the required additional information about the test on each claim.

Laboratory providers who bill MDT services must obtain a test ID (as described in Chapter II).

## CHAPTER II: COVERAGE

### 2. Coverage Policy

As set forth in Palmetto GBA's "Molecular Diagnostic Tests (MDT)" LCD, Palmetto GBA provides coverage for MDTs and LDTs that are identified as covered in the LCD. Palmetto GBA may also develop and publish specific LCDs, and/or Palmetto GBA coverage articles as required. MDTs and LDTs not identified as covered in an NCD, LCD or coverage article are not covered. Coverage for items or services that are outlined in the Medicare Benefit Category may be addressed in an NCD, LCD or article. Items or services that are **not** considered a Medicare benefit may only be addressed in an article.

To obtain coverage for an established MDT or LDT, laboratories must apply for and obtain a unique test identifier. For newly developed tests or for established tests that have not been validated for clinical and analytical validity and clinical utility, labs/developers must submit a detailed dossier of clinical data to substantiate that the test meets Medicare's requirements for coverage.

#### 2.1. Unique Test Identifier

Labs must report LDTs and MDTs with the CPT and/or HCPCS code(s) that most accurately describe(s) the specific test performed. Tests that are not described by a specific code require the use of an unlisted code. Although many of the MoPath codes were assigned descriptions, these descriptions do NOT identify a specific test. Therefore, MoPath codes must be processed in the same manner as an unlisted code and require additional documentation.

For this reason, the MolDX Program requires laboratories to obtain a test-specific identifier — a DEX Z-Code® — that is unique to the laboratory's specific test (i.e., the unique test identifier establishes a link to the specific test performed). When reported in conjunction with the appropriate CPT/HCPCS code, the identifier allows payers to determine the exact test that has been performed, facilitating the process of making pricing and/or coverage determinations (subject to Palmetto GBA's analysis of the data supporting the use of the test).

Laboratories seeking coverage for the following types of tests must obtain a test ID:

- LDT or MDT reported using an unlisted code
- Test reported with a MoPath Tier 1 or MoPath Tier 2 CPT code
- FDA-approved version of an MDT test (if multiple, identical versions of the test are available, including tests that have not been approved by the FDA)
- All versions of a single test performed in multiple laboratories (to the extent that each laboratory performs the test differently)
- Modified version of an FDA-approved IVD

##### 2.1.1. Registration

To submit claims on tests reported with the CPT/HCPCS codes in 1.2 of this manual, laboratories must register and receive a test ID. To access the online MolDX registry, laboratories should follow the following steps:

- For laboratory providers that have not registered a test for a DEX Z-Code®:
  - Go to the DEX® Diagnostics Exchange: <https://app.dexzcodes.com>
  - Select **Register My Organization** and follow the prompts to register your organization, including participation in the MolDX program

- An email with a user name and a link for activating your account will be sent to you once DEX activates your account. You will choose a password when you activate your username.
- Once you've completed the registration of your organization, and activation of your account you will have access to add test information
- For laboratory providers that currently have a DEX Z-Code<sup>®</sup> assigned to a test:
  - Log into the Diagnostics Exchange using your existing username and password combination

This access enables the following functions:

- Review specific test information
- Review each DEX Z-Code<sup>®</sup>
- Request edits for tests
- Register new tests

### **2.1.2. Registration Review Timelines**

Within 2 weeks of receiving a valid submission, the applicant will receive notice of one or more of the following:

- Additional information or clarification needed
- Assigned ID
- Suspension of claims pending technical assessment (TA) submission and favorable decision

## **2.2. Technical Assessment (TA)**

MolDX only provides coverage for MDTs and LDTs that demonstrate analytical validity, clinical validity (AV/CV) and clinical utility (CU). Non-validated tests must submit a comprehensive dossier of scientific information.

Laboratories that perform FDA-approved tests with **proven utility** and only perform the test within labeling indications may be exempt from TA.

The dossiers are reviewed by unbiased subject matter experts. Once a coverage determination has been established, the results will be published to the provider community. An LCD may also be developed if the test requires administration of reasonable and necessary limitations.

Only tests assigned a Z-Code will be accepted for TA. During the review period of the TA, claims submission for the service should be suspended in order to avoid denial.

### **2.2.1. Clinical Dossier Requirements**

To determine coverage, a TA is required for molecular assays that are laboratory developed tests (LDT), employ new or novel technology, or have undefined or unproven clinical utility. During the TA period, developers should suspend claims submission for the test service. TA submissions should be submitted to [MolDX@palmettogba.com](mailto:MolDX@palmettogba.com).

During the TA process, subject matter experts (SME) and the MolDX Team determine if an assay demonstrates clinical utility (CU) and fulfills the CMS “reasonable and necessary” criteria. In order to receive favorable review results, the assay must also meet analytical and clinical validity (AV/CV) standards. In addition to these three broad categories of evidence, CMS has directed MolDX to follow the [ACCE criteria developed by the Centers for Disease Control and Prevention](#).

In order to reduce delays and unfavorable determinations, please ensure that the TA submission is complete. Please review the [Technical Assessment](#) page and complete the Technical Assessment Checklist which will guide you to the additional supporting documents required for your test. To ensure submission accuracy, reference the assigned identifier on all documents and in the subject line of email exchanges.

Possible LCD coverage determinations:

- Full coverage; and TA review initiated after LCD finalized
- Limited coverage
- Non-coverage — does not meet Medicare “reasonable and necessary” criteria

## 2.3. Excluded Tests

Medicare is a defined benefit program. In order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Although IOM 100-2, Ch. 15, Sec 10 identifies “Diagnostic X-Ray tests, laboratory tests, and other diagnostic tests;” as a benefit category; Sec. 1862 (1)(A) Statutory Exclusion “except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” must also be applied. In order to be paid under this benefit category, a diagnostic test must be ordered by a physician who is treating the beneficiary and the results used in the management of a beneficiary’s specific medical problem.

Step 1 for test assessment: Does the test fall within a Medicare benefit category?

Although many molecular diagnostic tests may provide valid and useful information, they do not meet this definition. Based on the Medicare Benefit requirements, the following test types are examples of services that may not be considered a benefit (statutory excluded) and therefore would be denied as Medicare Excluded tests:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law
- Tests that confirm a diagnosis or known information
- Tests to determine risk for developing a disease or condition
- Tests performed to measure the quality of a process
- Tests without diagnosis specific indications
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

### 2.3.1. MoIDX-Specific Exclusions from Coverage

The MoIDX Program will also deny coverage for the following tests:

- Tests that have not been reviewed and approved through the MoIDX process outlined in this document
- Tests provided with dates of service prior to the effective date of an approval

## 2.4 LCD Process

### 2.4.1 NEW LCD Requests

New LCD Requests: The New LCD Request Process is a mechanism by which interested parties within a contractor's jurisdiction can request a new LCD. The process for developing a new LCD is described below.

- **Informal Meeting (Optional)**  
Prior to submitting a formal New LCD request, Palmetto GBA encourages requestors to schedule an informal meeting review the requirements for a valid request.
- Request for a conference call may be submitted via email to [MolDX.Policy@palmettogba.com](mailto:MolDX.Policy@palmettogba.com). The request should include the following information:
  - Subject line of the email should state "Request for New Informal Meeting"
  - Several dates and times the requestor is available for a 30 minute conference call
  - Agenda for the call, including requestor participants and titles
  - Summary information (1-2 paragraphs, maximum) for the LCD request
- **New LCD Request Submission Criteria (Required)**  
A complete request must:
  - Clearly identify the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provide a rationale justifying the assignment;
  - Identify the language that the requestor wants in a new LCD;
  - Include a justification for the new LCD supported by peer-reviewed evidence. Full-text copies (not abstracts or meeting poster presentations) of published evidence from peer-reviewed literature must accompany the request. Failure to include full-text clinical literature invalidates the request;
  - Include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and
  - Include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.
  - The level of evidence required for LCD development may be found in the CMS Program Integrity Manual, Chapter 13.
- **How to Submit Request**  
New LCD requests may be sent via email to [MolDX.Policy@palmettogba.com](mailto:MolDX.Policy@palmettogba.com). The subject line of the email should state: "New LCD Request — [Name of LCD]. Or by mail to: Palmetto GBA Attn: MolDX, 17 Technology Circle, Mail Code AG-315, Columbia, SC 29203.
- **Next Steps**  
Palmetto GBA will review materials received within 60 calendar days upon receipt and

determine whether the request is complete or incomplete. If the request is incomplete, Palmetto GBA will respond, in writing, to the requestor explaining why the request was incomplete.

- If the request is complete, Palmetto GBA will follow the process outlined in the Program Integrity Manual, Chapter 13. A complete request response does not convey that a determination has been made as to whether the item or service will be covered or non-covered. It is simply an acknowledgement to the requestor of the receipt of a complete, formal request.
- If the request is complete and a new LCD is developed, Palmetto GBA will follow the process outlined in the Program Integrity Manual, Chapter 13. This involves:
  - Consultation with the requestor or subject matter experts (if necessary)
  - Contractor Advisory Committee (CAC) meeting to discuss the quality of evidence used to make a determination (if necessary)
  - Publication of a proposed LCD
  - Open Meeting to allow stakeholders the opportunity to present comments and/or concerns regarding the proposed LCDs
  - Opportunity for public comment in writing (45 days following the publication date of the proposed LCD)
  - Publication of a final LCD, including:
    - A response to public comments received
    - Notice to public of new policy at least 45 days in advance of the effective date

#### 2.4.2 LCD Reconsideration

- The Local Coverage Determination (LCD) Reconsideration process is a method by which interested parties can request a revision to an active LCD. Palmetto GBA follows the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-Only Manual 100-08), Chapter 13 process for LCD Reconsiderations. The reconsideration process is available for final, effective LCDs only. The entire LCD or any part of it is subject to reconsideration. The process for LCD Reconsideration is outlined below.
- **Informal Meeting (Optional)**  
Prior to submitting a formal LCD Reconsideration, Palmetto GBA encourages requestors to schedule an informal meeting to review the requirements for a valid request.
- Request for a conference call may be submitted via email to [MoIDX.Policy@palmettogba.com](mailto:MoIDX.Policy@palmettogba.com). The request should include the following information:
  - Subject line of the email should state: "Request for Informal Meeting — [Title/LCD ID#]"
  - Several dates and times the requestor is available for a 30 minute call
  - Agenda for the call, including requestor, participants, and titles
  - Summary information (1–2 paragraphs, maximum) for the reconsideration request
- **Reconsideration Request Submission Criteria**  
Reconsideration requests are only accepted for LCDs published in final form. Requests will not be accepted for other documents including:
  - National Coverage Determinations (NCDs)

- Coverage provisions in interpretive manuals
- Proposed LCDs
- Template LCDs, until they are adopted by the contractor and become effective
- Retired LCDs
- Individual claim determinations
- Bulletins, articles, training materials
- Any instance in which no LCD exists, i.e., requests for development of an LCD
- Palmetto GBA has the discretion to consolidate valid requests if similar requests are received. Any request for LCD reconsideration that, in the judgment of the contractor, does not meet these criteria is invalid.
- Palmetto GBA may revise or retire LCDs at its discretion.
- If modification of the final LCD would conflict with an NCD, the request will not be valid. For information about the NCD reconsideration process, reference [http://www.cms.gov/DeterminationProcess/01\\_overview.asp#regs](http://www.cms.gov/DeterminationProcess/01_overview.asp#regs). Information about requesting an NCD or an NCD revision is found under "How to Request an NCD" in the Coverage Process section.
- **A valid request must include:**
- The specific language that the requestor proposes added to or deleted from an LCD; and
- Justification for the proposed change supported by new evidence in the medical literature which will materially affect the LCD's content or basis. Electronic copies of published (i.e., not embargoed), English language, full-text articles are required. The level of evidence required for LCD reconsideration is the same as that required for new or revised LCD development (see Program Integrity Manual, Chapter 13).
- **How to Submit Request**  
LCD reconsideration requests may be submitted via email to [MoIDX.Policy@palmettogba.com](mailto:MoIDX.Policy@palmettogba.com). The subject line of the email should state: "Request for LCD Reconsideration Request — [Title/LCD ID#]."
- **Please note that this information is for Palmetto GBA LCD reconsiderations only.** Information for submitting an LCD reconsideration request for other jurisdictions may be found on their websites.
- **Next Steps**  
Palmetto GBA will review materials received within 60 calendar days upon receipt and determine whether the request is valid or invalid. If the request is invalid, Palmetto GBA will respond in writing to the requestor explaining why the request was invalid.
- A valid request response does not convey that a determination has been made as to whether the item or service will be covered or non-covered; it is simply an acknowledgement to the requestor of the receipt of a complete, valid request.
- If the request is valid, Palmetto GBA will follow the process for LCD reconsiderations detailed in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-Only Manual 100-08), Chapter 13.
- Once the submitted material is reviewed, the requestor will be contacted should the Palmetto GBA have additional questions. If there are no additional questions from Palmetto GBA, the requestor should monitor the Palmetto GBA websites and email updates for the posting of a proposed LCD, date and time for an open meeting, and a timeline for completion of the reconsideration request. This information can be found under the Medical Policies section of the Palmetto GBA website.
- **Related Information:** Medicare Program Integrity Manual, [Chapter 13](#) (PDF, 124 KB) —

Local Coverage Determinations.

## CHAPTER III: PRICING AND CODING REQUIREMENTS

### 3. Pricing and Coding Under the MoIDX Program

To determine the price for established tests, the data submitted with the MoIDX application was reviewed. Tests were categorized into “like tests” using the CPT descriptions for each gene/allele/or gene component as outlined in the CPT. The submitted CPT stacking codes, used by CPT prior to 2012 were used to standardize the process for various labs. Each stack was reviewed for accuracy and labs contacted as needed for clarification. Once the correct stack had been validated, “like tests” were collected and compared. An example of “like tests” would be tests for full gene sequence of the APC gene. Whenever possible, the simple average of the like tests was used to calculate the MoIDX price per test. As more “like tests” are added to the universe of tests, the average may be recalculated and submitted to CMS as requested.

For new MDTs and LDTs, the MoIDX Program uses the 2011 stacking codes if applicable to establish a baseline for new tests consistent with values developed for established tests. Because of the unique nature of these tests, the MoIDX Program considers a variety of factors, including but not limited to the following:

- Innovator tests, such as those performed by a single lab or offered by an in vitro diagnostic test kit manufacturer, have different cost structures because the innovator must develop the test and provide evidence of the clinical validity and utility of the test. Innovator tests include, those tests performed using kits cleared by the FDA under a de novo 510(k) application or approved by the FDA under a Pre-Market Approval application as well as proprietary laboratory tests offered by a single laboratory.
- Economic Impact — In addition to considering the resources required to develop and furnish a test, the MoIDX Program considers the value of the information provided by test in patient management decision making and in achieving improvement in health outcomes and the overall impact to all patient costs

#### 3.1. MoIDX NOC Claims Pricing

To allow for varied values for an LDT and an innovator tests, the MoIDX Program validates a lab only uses the FDA-approved for an unmodified FDA-approved test. Once validated, the MoIDX Program instructs these specified labs to use an NOC code so the payer systems can identify and correctly price the FDA-approved test.

Since the fees are based on the ID and not the CPT reported code, the MoIDX program can vary prices of “like tests.” Palmetto GBA’s MoIDX edit processes all NOC codes according to tables by specific test identifier. This system is used to process MoIDX claims submitted with NOC codes and the identifier submitted on the claim (SV101-7 or SV202-7).

### 3.2. Pricing Tests Using NOC Codes

The MoIDX Program considers the following factors to establish values reported with unlisted codes or for innovator tests:

- Laboratory charges and discounts from charges
- Allowed rates established by other payers for the same test including median or geometric mean rates on fully adjudicated claims and/or median or geometric mean rates for contracted claims
- Validated resources to furnish the test including the price of the kit, the cost of the kits and other supplies combined with clinical labor, equipment and overhead factors based on cost-per-test
- Independent health care economic information supporting the value of the test in patient management and/or improvement of health outcomes

### 3.3 Additional MoIDX Information

- All information regarding the MoIDX Program may be reviewed from the MoIDX website located at <https://palmettogba.com/palmetto/moldxv2.nsf>
- Select **Email Updates** to receive notifications of current updates to the program.