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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 (M00106)*

DOCUMENT VERSION CONTROL

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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 (MolDX[®]) Program.

1.2. Current Scope of the Palmetto GBA MolDX program

The following Medicare Jurisdictions have implemented the MolDX 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

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

Code Category/Description	2018 MolDX Code Range
Tier 1	81105-81112, 81120-81121, 81161-81383
Tier 2	81400-81408
Genomic Sequencing Procedures	81410-81471
Molecular Multianalyte Assays (MAAA)	81490-81595
MAAA Admin. Codes	MAAA codes for molecular tests only
Immunology	86152-86153
PLA	PLA codes for molecular tests only
Cytology	88120-88121
The following NOC codes are in scope for molecular tests only	81479, 81599, 84999, 85999, 86849, 87999

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 MolDX Program. MolDX 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.

*As a group, all CPT PLA codes for molecular tests are inclusive in MoIDX and are not listed individually.

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 AB MACs (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™) 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, 84999, 85999, 86849, and 87999), this additional information (Test identifier/Z-Code) is submitted in the SV101-7 (5010A1-837P) or SV202-7 (5010A1-837I) claim line detail field.
- For CPT non-NOC codes, Labs may either use the SV101-7 or SV202-7 (preferred) or the NTE field to submit this required information.
- If the identifier is not on file, MAC forwards claim information to MoIDX for review and determination.
 - MoIDX processes for coverage, correct coding, and price (see section 3)
 - MoIDX submits information to MAC for adjudication
 - 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 MoIDX 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.

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 describes 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 MoIDX 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 Tier 1 or 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 MoIDX 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 MoIDX program

- An email with a user name and a link for activating your account will be sent to you once McKesson 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™ 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™
- Request edits for tests
- Register new tests

2.1.2. Registration Review Timelines

Within 30 days 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)

MoIDX only provides coverage for MDTs and LDTs that demonstrate analytical validity, clinical validity (AVCV), 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 test ID 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 MoIDX@palmettogba.com.

During the TA process, subject matter experts (SME) and the MoIDX 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 MoIDX to follow the ACCE criteria developed by the Centers for Disease Control and Prevention. Reference (M00096)

In order to reduce delays and unfavorable determinations, please ensure that the TA submission is complete. The table below lists all required elements.. To ensure submission accuracy, reference the assigned identifier on all documents and in the subject line of email exchanges.

Executive Summary	Other	A concise summary with description of assay, intended patient population(s), and intended purpose
Technical Assessment (TA) Summary Form (M00116)	Other	Complete this form if assay is performed by all platforms except NGS.
Analytical Performance Specifications for Comprehensive	Other	Complete this form, in addition to M00116, if assay is performed using NGS technology
Clinical Utility Studies	Clinical Utility	All CU articles must be submitted as completed and published work. Abstracts and non-published studies are not accepted.
Analytical Performance Specifications for Quality Tumor-only Somatic Variant Detection Using Circulating Tumor DNA (M00135)	Other	Complete this form, in addition to M00116, if testing circulating tumor DNA (ctDNA)
Clinical Validity Studies	Clinical Validity	Submit all relevant data supporting CV.
Analytic Validity Materials	Analytical Validity	Submit all relevant AV data
Economic Value Studies	Economic Value	Submit relevant economic impact studies

Possible LCD coverage determinations:

- Full coverage; and pricing review initiated after LCD drafted
- 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. Excluded Test Reconsiderations

This section applies to a specific gene that may include different tests from multiple labs. To reconsider a decision on a specific laboratory test, please follow the Technical Assessment Process covered in 2.2.

Although the Program Integrity Manual (PIM Chapter 13.11.E.2) does NOT allow reconsideration requests for NCDs, coverage provisions in interpretive manuals, draft, template or retired LCDs, individual claims, bulletins, articles, training material, and any instance in which an LCD doesn't exist, Palmetto GBA will continue to accept and consider requests on excluded genetic tests. The following reconsideration requirements have been modeled from the LCD reconsideration PIM language and will be used in support of this excluded service reconsideration process:

1. Requests shall be submitted in writing with all attachments (email or hardcopy), and shall identify the language the requestor wants added to or deleted from the Excluded Test determination. Requests shall include a justification supported by new evidence, which may materially affect the determination or basis. Copies of published evidence shall be included. The level of evidence required for SE reconsideration is the same as that required for new/revised LCD development. (PIM Chapter 13 Section 13.7.1)
 - Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
 - General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts. Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.
2. Any reconsideration request for an Excluded test determination that, in the judgment of the contractor, does not meet these criteria is invalid
3. Contractor will have the discretion to consolidate valid requests if similar requests are received

2.3.2. Excluded Test Reconsideration Process

- Submit a valid Excluded Test Reconsideration request by one of the following methods:
 - **Email** (Preferred): MolDX@palmettogba.com
 - **Regular mail:**
Palmetto GBA, Attn: MolDX

17 Technology Circle, Mail Code AG-315
Columbia, SC 29203

- Within 30 days of the request receipt date, Palmetto GBA will determine whether the request is valid or invalid
 - If invalid, Palmetto GBA will notify requestor of the reason for the invalid determination
 - If valid, Palmetto GBA will make one of the following decisions within 90 days of a valid request receipt date:
 - Continue to exclude coverage
 - Allow coverage and retire article, if applicable
 - Allow limited coverage through the LCD process

2.3.3. MolDX-Specific Exclusions from Coverage

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

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

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 <http://www.PalmettoGBA.com/PalmettoGBA/MoIDX.nsf/DocsCatHome/MoIdx>
- Select “Email Updates” to receive notifications of current updates to the program